THE FISCAL YEAR 2017 HHS BUDGET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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WEDNESDAY, FEBRUARY 24, 2016

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

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Barton, Guthrie, Whitfield, Shimkus, Murphy, Burgess, Blackburn, McMorris Rodgers, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Upton (ex officio), Engel, Capps, Schakowsky, Butterfield, Castor, Sarbanes, Matsui, Schrader, Kennedy, Cardenas, and Pallone (ex officio).

Staff present: Gary Andres, Staff Director; Mike Bloomquist, Deputy Staff Director; Leighton Brown, Press Assistant; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Jerry Couri, Senior Environmental Policy Advisor; Jessica Donlon, Counsel, Oversight and Investigations; Paul Edattel, Chief Counsel, Health; David McCarthy, Chief Counsel, Environment and the Economy; Carly McWilliams, Professional Staff, Health; Katie Novaria, Professional Staff, Health; Tim Pataki, Member Services Director; James Paluskiewicz, Professional Staff, Health; Graham Pittman, Legislative Clerk, Health; Mark Ratner, Policy Advisor to the Chairman; Michelle Rosenberg, GAO Detailee, Health; Chris Santini, Policy Coordinator, Oversight and Investigations; Chris Sarley, Policy Coordinator, Environment and the Economy; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Advisor, Health; Josh Trent, Deputy Chief Counsel, Health; Christine Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Professional Staff Member; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Una Lee, Minority Chief Oversight Counsel; Rachel Pryor, Minority Health Policy Advisor; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Matt Schumacher, Minority Press Assistant; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Health Policy Advisor; and Arielle Woronoff, Minority Health Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS [presiding]. The subcommittee will come to order.

This is a pretty busy day. A lot of members will be here today. I will have to run a tight gavel, so everyone can get an opportunity to speak today.

The Chair will recognize himself for an opening statement.

Today the Health Subcommittee will examine the President's budget for fiscal year 2017 for the Department of Health and Human Services. We are grateful the Secretary has agreed to appear before this subcommittee. Certainly there are a number of issues in the budget and at HHS that members will be interested in discussing.

I appreciate the strong bipartisan record this committee has in working with Secretary Burwell, especially our work to solve the Medicare physician payment issue last year. Our committee has passed more bipartisan bills into law than any other committee in Congress, and we appreciate Secretary Burwell's partnership to help make that possible.

However, as I reviewed the budget, I have to say I am disappointed. This budget does not balance. Ever. The CBO warned that under current law the deficit will balloon from $616 billion this year to $1.4 trillion by 2026. Medicare is on course to be insolvent and unworkable in the year 2026. Federal debt will soar from $14 trillion this year to about $24 trillion by 2026.

Economists warn us that our runaway federal health spending will eventually lead to an economic crisis, and drastic and disruptive cuts, higher taxes that harm workers and families, or some combination of all of these outcomes. I believe Congress and the administration have a moral responsibility and duty to solve the problems before they fail the millions of people who depend on them.

Unfortunately, our long-term spending challenges have been worsened by changes to federal programs in recent years. Specifically, ObamaCare is over $2 trillion in new entitlement spending. Yesterday's Washington Post highlighted a new report from the HHS Office of Inspector General which examined HHS's mismanagement of Healthcare.Gov. As the report makes clear, there was more that failed beyond just a Web site.

The OIG concluded, "We found that HHS and CMS made many missteps throughout development and implementation that led to the poor launch. Most critical was the absence of clear leadership, which caused delays in decisionmaking, lack of clarity in project tasks, and the inability of CMS to recognize the magnitude of problems as the project deteriorated...CMS's organizational structure and culture also hampered progress."

Today a new report out from the GAO has new findings regarding mismanagement of the federal marketplace. The auditors find CMS is, quote "passive" in their approach to fraud prevention and has failed to resolve major inconsistencies in applications in 2014 and 2015. Because of re-enrollments and CMS's poor oversight, these problems are largely still ongoing.

Time and time again, HHS seems to be ignoring or flouting the law. For example, one issue I continue to be concerned about is the matter of illegal actions taken by the California Health Department with respect to their unilateral action requiring all health plans to cover abortions. This is in direct violation of federal law under the Weldon amendment and a direct assault on conscience rights.

As you know, individuals have been harmed since August 22nd, 2014 and filed complaints with the HHS Office of Civil Rights. And I have pleaded with you, Madam Secretary, give this matter your immediate attention and redress. To my knowledge, no action or redress has been taken by your agency. So, we hope and expect to receive real answers today.

Madam Secretary, thank you for being here. We look forward to your testimony.

I yield the remainder of my time to Mr. Burgess.

[The prepared statement of Mr. Pitts follows:]

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Madam Secretary, thank you for being here and we look forward to your testimony.

Mr. BURGESS. Thank you, Mr. Chairman.

Secretary, welcome and thank you for coming to our subcommittee.

Look, the President and I are never going to agree on the Affordable Care Act, but I do remain committed to making real improvements to healthcare right now for the American people. Unfortunately, the administration has persistently refused to acknowledge the failures within the Affordable Care Act, making it near impossible for Congress to reduce harm to people going forward.

The chairman already outlined the statements in the Office of Inspector General's report that recently became public. I hope that the agency will share with us the lessons learned from this exercise. Clearly, there will be other administrations; there will be other people in charge of the agency in the future.

The lessons learned from the failures at healthcare.gov I think are important. I would like for you to share with us what the total cost of the Web site was. The published figure of $830 million I believe is way too low. I would like for you to share with us what the actual cost was. Were you able to recoup any of the costs from the product that was not delivered and was anybody paid a performance bonus for actually supplying a flawed product to the American people?

I think these are questions that ongoing will need to be answered. We need to know what lessons your agency has learned from this process.

Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now, standing in for Ranking Member Green is Representative Castor of Florida. The Chair recognizes her for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Well, thank you, Mr. Chairman.

Good morning, Madam Secretary.

You and the administration have crafted a budget that works for American families. It strengthens Medicare, extends the life of the Hospital Trust Fund, Medicare Part A, for 15 years. It makes vital investments in cancer research, Alzheimer's research, and in the NIH, and keeps those fabulous researchers across the country on the job, finding the treatments and cures of the future.

I want to thank you for answering the call for help from communities and families across the country with more robust resources for mental healthcare and for the heroin prescription drug opioid epidemic. And you have done this at the same time while the overall budget reduces deficits by $2.9 trillion over the next 10 years,

and that is on top of the $4 to $5 trillion deficit reduction that we have achieved together since 2010.

I would like to encourage you during your testimony to discuss the progress of states that are taking care of their citizens through the expansion of health services under Medicaid. This is smart fiscal policy, and the majority of states have realized that. But it is difficult to reconcile that we have the majority of states that have done it and, then, some states that have not, including my home State of Florida, because that puts my citizens at a disadvantage. So, I want to thank you for offering hope to those citizens in those states that have yet to expand Medicaid.

Back to mental health, this is directly related to our ability to serve our neighbors with mental health services because the most important reform we can bring to communities for mental health would be expansion of Medicaid in those states.

But on your watch, for the first time ever, more than 90 percent of Americans have health coverage, including 1.7 million in Florida this year on healthcare.gov. The Medicare Advantage premium has declined since the ACA became law. In Florida, $1.3 trillion is being put back into the pockets of my neighbors through closing the donut hole under the ACA. And the growth in premiums for employee-sponsored health insurance has slowed down.

But we have more work to do. We will look forward to hearing your testimony.

At this time, I yield a minute to my good friend Mr. Kennedy of Massachusetts.

Mr. KENNEDY. Thank you, Congresswoman, for yielding.

Madam Secretary, thank you for coming. Thank you. It is wonderful to see you again.

Under your leadership, the Department of Health and Human Services confronts some of our nation's most stubborn and systemic challenges head-on. With the reforms to Medicaid outlined in the President's budget, we can enroll millions of vulnerable Americans who remain uninsured and risk losing a lifetime of savings due to a hospital bill.

Expanding access to Medicaid is especially critical because the program's beneficiaries are twice as likely to face mental illness than the general population. But we can't limit our response to those enrolled in Medicaid. With an increase of $115 million for the mental health programs under SAMHSA, investments in community early intervention programs, and an end to the 190-day lifetime limit on inpatient psychiatric facilities, we can ensure millions of Americans receive the treatment they need and deserve.

In the midst of an opiate epidemic that has had a devastating impact on the communities represented by everyone on this dais today, your request for a billion dollars to increase access and treatment should be quickly considered and approved by Congress.

I also want to thank you and recognize your commitment to community health centers where the budget makes a sizeable investment, and also thank you and your staff for continuing to speak with our governor as we work on Medicaid waiver negotiations and our hospital system.

I am looking forward to hearing you talk more about these projects in some detail and ask you to just let us know how we can be a partner in your work ahead.

Thank you, and I yield back.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the chairman of the committee, Mr. Upton, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

Secretary Burwell, welcome back to the committee. Although we do have policy differences, I appreciate the professionalism that you have brought to the job from day one. It is most appreciated. I know that you were in Michigan last week regarding the tragic Flint water crisis. I appreciated the call last Friday when you were leaving and I thank you for your attention and look forward to closely working together to ensure that we make it up to the residents of Flint for the many unacceptable failures that have occurred at all levels. And I really appreciate that.

We have also enjoyed our partnership in 21st Century Cures. You and your team have been terrific during this 2-year effort, working closely and providing valuable insight, technical assistance, and guidance, as we developed a bill that achieved 344 votes in the House. The momentum is building as the Senate now has taken real and bipartisan steps forward through their parallel innovation project. With a little more hard work and bipartisan cooperation, we are going to be able to get this done for patients across the country looking for hope for safer cures.

And we are excited with President Obama tasking Vice President Biden to lead a moonshot effort to cure cancer. I know that you are part of that leadership team. Surely, we will bring a jolt of energy for this very important project, the goals of which are consistent with the bill passed by the House last summer. It is important to remember that time is a very precious resource, especially for countless patients across the country who can't wait for another task force. The clock is ticking. They need action and they need cures now.

It is my belief, shared by Chairman Alexander, that the way for policy to be enacted through 21st Century Cures and the Senate's innovation project is by working together. We have done the hard, time-consuming work of listening, soliciting ideas, listening some more. Legwork is done and, as I mentioned, 344 votes in the House. The policies have been pressure-tested. We look forward to combining our efforts and the Vice President's best ideas into one unified bill to improve our healthcare innovation ecosystem. We have got a great opportunity that we know that we have to deliver.

This hearing also gives us an opportunity to discuss the important work of putting our fiscal house in order. As astounding $1 trillion now flows through HHS. We have significant concerns that our budgetary path is on a dangerous trajectory towards disaster. Under this President's budget, the national debt will more than double than when the President took office. The projections cannot be ignored, especially as health and entitlement spending will be

the main factor in driving additional debt on top of future generations. We can and must do better.

And I yield the balance of time to Mrs. Blackburn.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Secretary Burwell, welcome back to the committee. Although we do have our policy differences, the professionalism that you have brought to the job is appreciated. I know you were in Michigan last week regarding the tragic Flint water crisis. I thank you for your attention and look forward to closely working together to ensure we make it up to the residents of Flint for the many unacceptable failures that have occurred at all levels.

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Mrs. BLACKBURN. Thank you, Mr. Chairman.

Madam Secretary, we do thank you for being here.

There are a couple of things that I will want to hit and hear from you, as you talk today. First of all, I think HHS needs to look at a regulatory model that is going to enable innovators. Many of those innovators and healthcare informatics are in Tennessee. What they find many times is lack of certainty and clarity. So, let's discuss that. Also, transparency as we work with these innovators. They are looking at these new delivery systems.

Also, I know you are working on RAC reforms. We will want to discuss that, the RAC audit process, and look at whether or not a shot clock would be helpful in that.

I appreciate your being here to give us insight into what the trends are with your budget and what your expectations are for reducing the size of that budget with your outlays.

And so, thank you for being here, and I yield back.

Mr. PITTS. The Chair thanks the gentlelady.

I now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

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

Mr. PALLONE. Thank you, Mr. Chairman.

Thank you, Secretary Burwell, for joining us this morning.

Today we are meeting to discuss the President's fiscal year 2017 Health and Human Services budget proposal. As is often said, budgets are about priorities, and I am pleased to see that the President's proposed budget aligns quite well with what should be the top priority of this committee. That is ensuring access to high-quality, affordable healthcare for all Americans.

First and foremost, the budget recognizes the simple truth the Affordable Care Act is achieving its goals. As a result of the ACA, 18 million Americans have gained access to both high-quality health insurance and the peace of mind that comes with maintaining coverage. Of course, more could be done, which is why I am pleased the President proposed additional incentives for the remaining states that have yet to expand Medicaid.

Medicaid expansion has been life-changing for the millions of Americans that have been able to access health coverage through Medicaid, many for the first time in their lives. In the 19 states that have yet to expand Medicaid, more than 4 million people could gain coverage. States could realize major savings in other parts of their budgets, and over $4 billion in uncompensated care costs could be avoided. Democrats have already introduced legislation to put the President's proposal into action, and Congress should act swiftly to enact that bill into law.

Beyond building upon known successes, the budget also directs funding into known areas of need. To put it simply, our nation's biomedical research budget is simply inadequate. As a committee, we have already recognized and acted upon this fact when we passed the bipartisan 21st Century Cures Act. In that same spirit, I applaud the proposed $755 million allocated for NIH and FDA through the Vice President's National Cancer Moonshot Initiative. Over 1.6 million Americans will be diagnosed with cancer this year, and it is our responsibility to ensure that all Americans have the best shot at a cure.

Finally, the President's budget recognizes the devastating effects of the heroin and opioid abuse crisis. Sadly, my home State of New Jersey is not immune from this epidemic. In fact, if every one of our New Jersey residents addicted to heroin or prescription opioids lived in the same city, it would hold a population larger than that of New Jersey's largest city.

That is why I have introduced a comprehensive bill, H.R. 4396, The Heroin and Prescription Drug Abuse Prevention and Reduction Act, to address heroin and prescription drug abuse. I would like to thank you for your strong leadership on this issue, Madam Secretary, and I urge the committee to act quickly to put a halt to this public health emergency.

Finally, just as a side note, Secretary Burwell, I know I will not have enough time to discuss this issue today, but I would like to have a followup conversation with you about the Indian Health Service. Specifically, I would like to address concerns that have been raised about the quality of care provided by hospitals in the

Great Plains area as well as to get an update on the continued implementation of the Indian Health Care Improvement Act, which, of course, was included in the ACA.

But I have 2 minutes left. I would like split that between Representative Matsui and Representative DeGette, and yield one minute now to Representative Matsui.

Ms. MATSUI. Thank you so much.

Secretary Burwell, welcome.

This budget definitely is something that makes critical investments in the long-term health and well-being of America's families, from supporting the expansion of Medicaid of millions of low-income Americans, investing in medical research, to bolstering the behavioral health workforce, so that patients with mental illnesses have someplace to turn. I am especially pleased with the incentives you put in for community behavioral health centers.

The Affordable Care Act has improved millions of Americans' lives. Thanks to the ACA, nearly 18 million previously uninsured Americans no longer have to worry that they are one illness away from financial ruin.

I am very pleased that this HHS's budget makes critical investments to ensure the continued success of the Affordable Care Act, and this budget is intertwined in the fabric of our healthcare system. It is time that we move forward with implementing all aspects of it.

Thank you very much, and I yield to my colleague.

Mr. PALLONE. Ms. DeGette.

Ms. DEGETTE. Thank you very much for yielding, Mr. Pallone.

I just want to underscore something that both Chairman Upton and you talked about, and that is the importance of the 21st Century Cures Act, which passed this committee unanimously. To make the investments that we talk about in that bill effective, we need to provide leaders at the NIH the ability to make decisions with some kind of freedom from the back-and-forth budgeting and appropriations process. After all, it is that process that, coupled with damaging cuts from the sequestration, set our medical efforts back a long way.

And that is why mandatory funding is created and the 21st Century Cures Act Innovation Fund is so important. For too long, budgetary pressures have kept promising research projects from being carried out. With the stability of the Innovation Fund, researchers could submit proposals that would not otherwise be guaranteed the funding needed to complete the science. That was the approach that the House overwhelmingly supported and that is the approach that we are trying to work on in the other body.

So, as much as you can do, Madam Secretary, that really helps us out in our efforts. Thank you very much.

And I thank you, Mr. Chairman, for the comity in allowing me to sit in on this subcommittee.

Mr. PITTS. The Chair thanks the gentlelady.

That concludes the opening statements. As usual, all members' written opening statements will be made a part of the record.

We will now go to our panel. I am happy to welcome the Honorable Sylvia Mathews Burwell, Secretary of the Department of Health and Human Services, as our witness today.

Thank you for coming. We have your testimony. The written testimony will be made part of the record. But you will be given 5 minutes to summarize.

So, at this point, the Chair recognizes Secretary Burwell, 5 minutes for her summary.

STATEMENT OF HONORABLE SYLVIA MATHEWS BURWELL, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary BURWELL. Thank you. Chairman Pitts, Chairman Upton, Ranking Member Pallone, and Representative Castor, Members of the Committee, I want to thank you all for the opportunity to come and discuss the President's budget here today.

As many of you all know, I believe that all of us actually share common interests and that we can find common ground. In the last legislative session, as was mentioned, this committee embraced that spirit of bipartisan leadership when it took the historic steps to pass the Medicare Access and CHIP Reauthorization Act of 2015. And thank you very much for this leadership on this issue.

The budget before you today is my final budget and the final budget of this administration. It makes critical investments to protect the health and well-being of the American people. It helps ensure that we can do our job to keep people safe and healthy, accelerate our progress in scientific research and medical innovation, and expands and strengthens our healthcare system. And it helps us continue to be responsible stewards of the taxpayers' dollars.

For HHS, the budget proposed is $82.8 billion in discretionary budget authority, and our request recognizes the constraints in our budget environment and includes targeted reforms to Medicare, Medicaid, and other programs. Over the next 10 years, these reforms to Medicare would result in net savings of $419 billion in Medicare.

This budget invests in the safety and health of all Americans. Let me start with an issue we have been working on here at home and abroad. As we work to stop the spread of Zika, the administration is requesting $1.9 billion in emergency funding, including $1.5 billion for HHS to enhance our ongoing efforts, both domestically and internationally. We appreciate the Congress' consideration of this important request as we implement the essential strategies to prevent, detect, and respond to this virus.

I know the rise in opioid misuse and abuse and overdose has affected many of those in your districts. Every day in America 78 people die opioid-related deaths. And that is why this budget proposes significant funding, over $1 billion, to combat the opioid epidemic.

Today too many of our nation's children and adults with diagnosable mental health disorders don't receive the treatment that they need. So, this budget proposes $780 million in new mandatory and discretionary resources over the next two years. This request will ensure that the behavioral healthcare system works for everyone. It will help expand behavioral health services and workforce capacity, so that more people can have access to care. And it will help individuals with serious mental illness get engaged and get the care that they need.

While we invest in the safety and health of Americans today, we must also relentlessly push forward the frontiers of science and medicine, and I know this committee is deeply involved and engaged in that issue.

This budget invests in the Vice President's Cancer Initiative. It is a vital investment for our future. Each 1 percent drop in cancer death rates saves our economy approximately $500 billion, not to mention the comfort and security it can bring to so many families.

Today we are entering a new era of medical science with the proposed increases of $107 million in the Precision Medicine Initiative and the $45 million additional for the administration's BRAIN Initiative.

But, for Americans to benefit from these breakthroughs in medical science, we need to ensure that Americans have access to affordable, quality care. The Affordable Care Act has helped us make historic progress, and today more than 90 percent of Americans have health coverage, the first time in our nation's history.

This budget seeks to build on that progress by improving the quality of care that patients receive, spending our dollars more wisely and putting an engaged and empowered consumer at the center of care. By advancing and improving the way we pay doctors, coordinate care, and use health data and information, we are building a better, smarter, and healthier healthcare system.

Finally, I just want to thank the employees of HHS. In the past year, they helped us with the Ebola outbreak in West Africa. They have advanced the frontiers of medical science. They have helped millions of Americans enroll in health coverage, and they have done the quiet day-to-day work that makes our country stronger. I am honored to be a part of the team. As members of this committee I hope know, I am personally committed to working closely with you and your staff to find common ground, so we can deliver for the American people.

With that, I look forward to your questions. Thank you.

[The prepared statement of Secretary Burwell follows:]

Statement by
Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
on
The President's Fiscal Year 2017 Budget
before
Committee on Energy and Commerce Health Subcommittee

U.S. House of Representatives
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Chairman Upton, Ranking Member Pallone, Chairman Pitts, Ranking Member Green, and Members of the Committee, thank you for the opportunity to discuss the President's FY 2017 Budget for the Department of Health and Human Services (HHS). Last legislative session, this Committee took historic steps to pass the bipartisan Medicare Access and CHIP Reauthorization Act of 2015. We thank you for your leadership on that important issue and look forward to working with you on implementation in the year ahead.

The Department has made historic strides towards ensuring that all Americans have access to the building blocks of healthy and productive lives—a priority that I know we share. Thanks to the Affordable Care Act, we have helped millions of Americans find quality, affordable insurance, and slowed the growth in health care costs for families and taxpayers. At the same time, we have worked to improve the quality of coverage—with more protections and benefits, like wellness visits and some cancer screenings now offered at no extra cost—no matter where you get your insurance. Alongside this work, we have responded to a number of national and global health challenges. In coordination with our partners across the federal government, we led a response to the Ebola outbreak in West Africa and prepared our infrastructure here at home, and have helped to unite global health leaders to prevent and respond to future outbreaks. We continue

these efforts to protect the public health in our work responding to the lead crisis in Flint, Michigan and implementing essential strategies to prevent, detect, and respond to the spread of Zika. We convened state leaders in our fight against prescription drug abuse as part of a nationwide three-pronged strategy to drive progress. And we advanced the frontier of medicine through cutting-edge research in genomics and technology. Through all these efforts, we have worked to ensure the responsible stewardship of taxpayer dollars by taking steps to further strengthen program integrity, saving money for the taxpayer and making sure our programs deliver in the best possible way for those we serve.

The President's FY 2017 Budget for HHS builds on this progress through critical investments in health care, science and innovation, and human services. The Budget proposes $82.8 billion in discretionary budget authority, and additional mandatory funding to further support specific initiatives in the discretionary budget. This includes investments in critical priorities that I know we share—cancer research, opioids abuse prevention and treatment, and behavioral health efforts. The Budget recognizes our continued commitment to balancing priorities within a constrained budget environment through legislative proposals that, taken together, would save on net an estimated $242 billion over 10 years.

Building upon the Successes of the Affordable Care Act

The FY 2017 Budget advances access, affordability, and quality in our nation's health care system—goals that we share with Congress and this Committee. Through targeted investments, the Budget expands access to care, particularly for rural and underserved populations,

strengthens services for American Indians and Alaska Natives, and supports primary and preventive care.

Expanding Access to Health Insurance Coverage. The Affordable Care Act is expanding access to care for millions of Americans who would otherwise be uninsured, improving quality of care for people no matter how they get their insurance, while slowing the growth in healthcare costs nationwide. To encourage more states to expand Medicaid, the Budget would give any state that chooses to expand Medicaid eligibility three years of full federal support, no matter when the state expands. The Budget also funds the Children's Health Insurance Program through FY 2019 to ensure comprehensive and affordable coverage for beneficiaries as well as budget stability for states. We look forward to working with Congress to extend this program for the millions of children who depend upon it.

Investing in Health Centers. For 50 years, health centers have delivered comprehensive, high-quality, cost-effective primary health care to patients regardless of their ability to pay. Today, more than 1,300 health centers operate over 9,000 sites and provide health care services to 1 in 14 people in the United States, including to nearly 1.2 million patients at 448 service delivery sites in Texas and 600,000 patients at 248 service delivery sites in Michigan. Health centers also play a role in reducing the use of costlier care through emergency departments and hospitals. The Budget invests $5.1 billion in health centers, including $3.75 billion in mandatory resources, to serve over 27 million patients across the country in FY 2017.

Bolstering the Nation's Health Care Workforce. The Budget includes investments of nearly $14 billion over ten years in our Nation's health care workforce to improve access to healthcare services, particularly in rural and other underserved communities. This includes support for over 10,150 National Health Service Corps clinicians serving the primary care, mental health and dental needs of more than 10.7 million patients in areas with limited access to care. The request includes additional funding to place providers in rural areas and other underserved communities in order to expand access to treatment for prescription opioid and heroin abuse and to improve access to crucial mental and behavioral health services. We know this is a priority for many of you on this Committee.

Strengthening Health Outcomes in Indian Country. The FY 2017 Budget continues the Administration's commitment to support and strengthen services in Indian Country. The Budget funds the Indian Health Service (IHS) at $6.6 billion, an increase of $402 million over FY 2016, to bolster programs that serve over 2 million American Indians and Alaska Natives at over 650 health care facilities across the United States. The Budget includes $67 million in new investments in the critical area of behavioral health to address high rates of mental illness, substance abuse, and suicide in tribal communities. The Budget also fully funds contract support costs, which provides critical overhead funding to tribes who operate facilities under self-determination and self-governance agreements.

Strengthening Health Programs in the Territories. The Budget removes the cap on funding to Medicaid programs in the U.S. territories to better align territory Medicaid programs with those of States and expands eligibility to 100 percent of the Federal poverty level in territories

currently below this level. This proposal would gradually increase the share of Medicaid costs covered by the federal government as territories modernize their Medicaid programs—providing critical healthcare funding to Puerto Rico and helping to mitigate the effects of its fiscal crisis.

Healthcare Delivery System Reform

At HHS, we are focused on moving towards a health care system that delivers better quality of care, spends dollars in a smarter way, and keeps people healthy. The Budget advances the Department's work in three critical areas: improving the way providers are paid, finding better ways to deliver care, and creating better access to health care information for providers and patients.

Improving the Way Providers Are Paid. Rather than paying for the quantity of tests and screenings that providers order—a common practice—the Department is moving toward paying for the quality of care given. For patients, this can lead to more frequent communication with their care provider and fewer unnecessary trips back to the hospital. The Budget includes proposals to establish competitive bidding for Medicare Advantage payments and introduce value-based purchasing for certain Medicare providers. The Budget also encourages participation in alternative payment models through a number of proposals, including creating a bonus payment for hospitals that collaborate with certain alternative payment models. The Department has already committed to moving Medicare fee-for-service payments to 30% in alternative payment models by the end of 2016, and 50% by 2018. We believe that we are on track to meet our goal, and look forward to working with Congress to build on this progress.

Improving Care Delivery. To drive progress in the way care is provided, HHS is focused on improving the coordination and integration of health care, engaging patients more fully in decision-making, and improving the health of patients—with an emphasis on prevention and wellness. As part of that, we are focused on improving access to care by investing in and supporting telehealth, especially for rural areas. The Budget proposes to expand the ability of Medicare Advantage plans to deliver services via telehealth, and to enable rural health clinics and federally qualified health centers to qualify as originating telehealth sites under Medicare.

Improving Access to Information. In an effort to promote transparency on price, cost, and billing for consumers, the Budget supports the standardization of billing documents and elimination of surprise out-of-network charges for privately insured patients receiving care at an in-network facility. The Budget also provides continued investments to achieve secure, seamless data interoperability in order to better serve individuals, providers, and payers, including a funding increase and new authorities for the Office of the National Coordinator for Health Information Technology.

Building Evidence to Drive Systemic Improvement. Reforming the delivery system requires an evidence base of effective practices. The Budget proposes an increase of $24 million for health services research at the Agency for Healthcare Research and Quality (AHRQ) to advance and improve the performance of the healthcare system. For example, AHRQ data show that 87,000 fewer patients died in hospitals due to patient harms from 2010 to 2014—saving nearly $20 billion. While we are encouraged by this progress, substantial challenges remain to build a

health system that meaningfully involves patients in decision making, and consistently uses high quality evidence to provide safe and high quality care for all.

Reducing the Cost of Prescription Drugs in Medicaid and Medicare. Nationally, prescription drug spending growth has accelerated to its highest rate since 2002 and is projected to drive overall healthcare cost growth. New therapies and cures change lives, but too many Americans struggle to afford the medications they need. The Department is focused on improving patient access to affordable prescription drugs, developing innovative purchasing strategies, and incorporating delivery system reform concepts like value- and outcome-based models into drug purchasing arrangements. The Budget includes a number of proposals, including Medicare Part D negotiation, aimed at improving access to necessary treatments and increasing the value that Americans are getting from their medications, while continuing to encourage important and lifesaving innovations.

Improving Healthcare for Dual Eligible Beneficiaries. As members of this Committee are aware, people enrolled in both Medicaid and Medicare have complex and often costly health care needs. The Budget includes legislative proposals to improve access for dual-eligible beneficiaries, while decreasing overlap and inefficiencies that currently exist between the two payers.

Keeping People Healthy and Safe

The President's Budget builds on the Department's strategy to address prescription drug abuse, invests in crucial behavioral health services, and strengthens our nation's public health infrastructure.

Preventing Prescription Drug Abuse. Prescription drug abuse impacts the lives of millions of people across the country—with 78 Americans dying in opioid-related deaths every single day. The Budget proposes significant new discretionary and mandatory funding totaling nearly $1.1 billion to build on investments funded by Congress in FY 2016 and to execute on the Department's three-pronged evidence-based approach to combat the opioids crisis:

- ***Expanding the Use of Medication-Assisted Treatment.*** The new two-year, $1 billion mandatory funding investment will help ensure that every American who wants to get treatment for an opioid addiction will be able to. These funding levels will enable individuals with opioid use disorder to get treatment in FY 2017 and FY 2018 by reducing costs, engaging patients, and expanding access to treatment.
- ***Improving Prescribing Practices.*** The Budget invests in programs that support improved prescribing practices, including by supporting improved uptake of CDC's upcoming prescribing guidelines for providers. The Budget also proposes to require states to track high prescribers and utilizers of prescription drugs in Medicaid—saving $770 million over 10 years—and bolsters other critical efforts to support providers with the tools they need.
- ***Expanding the Development and Use of Naloxone.*** To best prepare communities and first responders, the Budget includes a total of $22 million for programs that support the

use of naloxone – a life-saving drug. Among other critical programs, the Budget invests in the Rural Opioid Overdose Reversal Grant program to target rural areas hit hardest by opioid abuse.

Expanding Access to Mental and Other Behavioral Health Care. Despite the expanded behavioral health coverage for millions of Americans by the Affordable Care Act, less than half of children and adults with diagnosable mental health disorders receive the treatment they need. To address this gap, the Budget proposes a total of $999 million, including a new two-year $500 million investment in mental health care, to help engage individuals with serious mental illness in care, improve access to care by increasing service capacity through certified community behavioral health clinics, boost the behavioral health workforce, and ensure that behavioral health care systems work for everyone. A portion of the two-year, $500 million mandatory initiative will allow six additional states to participate in the Certified Community Behavioral Health Clinic Demonstration—established by section 223 of the Protecting Access to Medicare Act of 2014 under this Committee's leadership.

Combating Antibiotics Resistant Bacteria. The emergence of antibiotic-resistant bacteria continues to be a significant public health concern. The FY 2017 Budget includes $877 million to continue expanding the nation's ability to protect patients and communities by implementing interventions that reduce the emergence and spread of antibiotic-resistant pathogens. This funding will also support ongoing ground-breaking research to aid the development of new drugs and diagnostic products, building the nation's treatment options for these dangerous pathogens.

Investing in Domestic and International Preparedness. The Department leads critical efforts to strengthen our public health infrastructure here at home and bolster the nation's preparedness against chemical, biological, nuclear and radiological attacks. The Budget invests $915 million, an increase of $2 million, for domestic and international public health infrastructure, including funding to expand implementation of the Global Health Security Agenda (GHSA) to strengthen capacity in Phase 2 countries to address public health emergencies. Over the next five years, the United States will work with more than 30 partner countries—representing over four billion people—to help them prevent, detect, and effectively respond to infectious disease threats. I am pleased to share that work with many of these countries has already begun. We appreciate the funding provided by Congress last year for this crucial priority.

As we work aggressively to combat the spread of Zika, the Administration is requesting more than $1.8 billion in emergency funding, including $1.48 billion for HHS, to enhance our ongoing efforts both domestically and internationally. The requested resources will build on our ongoing preparedness efforts and will support essential strategies to combat this virus, such as rapidly expanding mosquito control programs; accelerating vaccine research and diagnostic development; enabling the testing and procurement of vaccines and diagnostics; educating health care providers, pregnant women and their partners; improving epidemiology and expanding laboratory and diagnostic testing capacity; improving health services and supports for low-income pregnant women, and enhancing the ability of Zika-affected countries to better combat mosquitoes and control transmission. We appreciate the Congress's consideration of this important request.

Serving Refugees and Unaccompanied Children. In light of a global displacement crisis, the Administration has committed to expanding the Refugee Admissions Program in FY 2016 and FY 2017. All refugees are subject to the highest level of security checks of any category of traveler to the United States. At HHS, the Administration for Children and Families' role is to link newly-arrived humanitarian populations, including refugees, asylees, Cuban entrants, and special immigrant visa-holders, to key resources necessary to becoming self-sufficient, integrated members of American society. The Budget provides initial financial and medical assistance for an estimated 213,000 entrants, including, 100,000 refugees, consistent with the Administration's commitment to admitting at least 100,000 refugees in FY 2017.

In addition to serving the populations discussed above, HHS is also legally required to provide care and custody to all unaccompanied children apprehended by immigration authorities until they are released to appropriate sponsors to care for them while their immigration cases are processed. Based upon the increase in unaccompanied children apprehended at the Southwest border this fall, ACF has taken prudent steps to add temporary capacity so that we are adequately prepared. To ensure that HHS can provide appropriate care for unaccompanied children in FY 2017, the Budget includes the same amount of total base resources available in FY 2016, as well as a contingency fund that would trigger additional resources only if the caseload exceeds levels that could be supported with available funding.

Leading the World in Science and Innovation

The FY 2017 Budget builds on the historic gains the Department has made in medical and scientific research and lays the ground work for scientific and technological breakthroughs for

the 21st century. Thanks to biomedical research, including NIH investments, cardiovascular death rates in the United States have fallen by more than 70% in the last 60 years. Cancer death rates are now falling 1-2% per year; each 1% drop saves approximately $500 billion. Breakthroughs in HIV therapies enable people in their 20's to live a full life span. The FY 2017 Budget includes $33.1 billion for the NIH, an increase of $825 million, to build on the funding provided by this Congress in order to advance our shared commitment to support research that promotes economic growth and job creation, and advances public health.

Launching the Cancer Moonshot. Investments in research have led to significant developments in the prevention, screening, and treatment of cancer. To support the Vice President's Cancer Moonshot, the Budget includes a multi-year $755 million initiative that accelerates the nation's fight against cancer by expanding access to clinical trials, pursuing new vaccine technology, and funding exceptional opportunities in cancer research. These investments will drive scientific advances that aim to understand the causes of cancer, discover new prevention strategies, improve early detection and diagnosis, and develop effective treatments.

Advancing Precision Medicine. Recent breakthroughs in genomics, computing, and molecular medicine have ushered in a new era where more treatments are based on the genetic characteristics of each patient. The Budget increases funding for the Precision Medicine Initiative by $107 million to a total of $309 million to support critical new studies on therapies, and to continue to scale a cohort study to gather data on the interplay of environmental exposures, physical parameters, and genetic information.

Investing in the BRAIN Initiative. Despite the advances in neuroscience in recent years, the underlying causes of most neurological and psychiatric conditions remain largely unknown due to the vast complexity of the human brain. To further revolutionize our understanding, the Budget provides an increase of $45 million, for a total of $195 million within NIH, for the BRAIN Initiative. This research has the potential to discover underlying pathologies in a vast array of brain disorders and provide new avenues to treat, cure, and even prevent common conditions, such as Alzheimer's disease, autism, depression, schizophrenia, and addiction.

Building Blocks for Success at Every Stage of Life

The Budget request supports the Department's efforts to serve Americans at every stage of life, including by promoting the safety and well-being of our nation's children, and helping older Americans live as independently as possible.

Investing in Child Care and Early Learning. Research has shown the significant positive impact that early learning programs can have on a child's development and lifelong well-being. The Budget proposes strategic investments to make affordable, quality child care available to every low- and moderate-income family with young children; to build on investments to expand access to high quality early learning programs including both Head Start and the newly authorized Preschool Development Grant program; and to invest in voluntary, evidence-based home visiting programs that have long-lasting, positive impacts on child development.

Supporting Child Welfare. The Department plays a critical role in supporting child welfare, particularly among vulnerable populations. The Budget includes $1.8 billion over 10 years to ensure that child welfare professionals have the right training and skills—proven to be linked to better outcomes for children across a range of measures. The Budget also includes a package of investments designed to do more to prevent the need for foster care and assist children and families so that children can either be reunited with their biological parents or placed in a permanent home.

Modernizing the Approach for Addressing Poverty. Finally, the Budget seeks to strengthen the nation's safety net to meet our 21st century poverty challenges. A total of 15.5 million children lived in poverty in 2014, a staggering number that translates into lost opportunity, productivity, quality of life, and lifespan. Twenty years after creating the Temporary Assistance for Needy Families (TANF) program, funds are proposed to reform and strengthen this critical program that serves approximately 3 million children per month. The Budget increases funding for TANF to help offset some of the erosion to the block grant, while laying out the basic principles for reform—including moving towards a stronger accountability framework for states coupled with increased flexibility, ensuring better targeting of TANF funds, and creating a renewed focus on reducing child poverty. We look forward to working with lawmakers to strengthen the program's effectiveness in accomplishing its goals.

Supporting Older Adults. As members of this Committee are aware, the population age 65 and over is projected to more than double to 98 million in 2060. In FY 2017, HHS continues to make investments to address the needs of older Americans, many of whom require some level of

assistance to live independently and remain in their homes and communities for as long as possible. The Budget continues to propose reforms that help to protect older Americans from identity theft, to support access to counseling, respite, and nutrition services that will allow states to provide approximately 205 million meals to over 2 million older Americans nationwide. The Budget also continues the Department's commitment to support effective Alzheimer's disease research, education, and outreach, as well as patient, family, and caregiver services.

Making the Department Stronger

One of my top priorities as Secretary is to position the Department to most effectively fulfill its core mission by investing in key management priorities, including program integrity and cybersecurity. I appreciate the Committee's interest in these critical issues.

Strengthening Program Integrity. The Budget continues to make cutting fraud, waste, and abuse a top Administration priority by requesting $199 million in new program integrity investments in FY 17. The Budget fully funds the Health Care Fraud and Abuse Control (HCFAC) discretionary cap adjustment. In FY 14 alone the HCFAC program returned over $3.3 billion to the Federal government and private citizens. The Budget includes proposals that will expand and strengthen the tools available to CMS and states to combat fraud, waste, and abuse, including in state Medicaid programs. In total, proposed program integrity investments and authorities in the Budget will yield an estimated $25.7 billion in scorable and non-scorable savings to Medicare and Medicaid over ten years.

Focusing on Stewardship. To improve the efficiency of the Medicare appeals system and reduce the backlog of appeals awaiting adjudication at the Office of Medicare Hearings and Appeals (OMHA), HHS has developed a comprehensive strategy that involves additional funding, administrative actions, and legislative proposals. The Budget includes resources at all levels of appeal to increase adjudication capacity and advances new strategies to alleviate the current backlog. The Budget also includes a package of legislative proposals that provide new authority and additional funding to address the backlog.

Conclusion

Members of the Committee, thank you for the opportunity to testify today and for your continued leadership on these important issues. I am grateful to have you as partners as we make the investments critical for today while laying a stronger foundation for tomorrow. I want to conclude by thanking the men and women of our Department, who work tirelessly every day to deliver impact for those we serve—the American people. I welcome your questions.

Mr. PITTS. Thank you, Madam Secretary.

I will begin the questioning and recognize myself for 5 minutes for that purpose.

Secretary Burwell, on February 12th, the administration announced that they would be using billions of taxpayer dollars to make payments to insurance companies under the ObamaCare Reinsurance Program. There is a quote on the screen there from the ACA. It says, "Notwithstanding the preceding sentence, $2 billion for 2014, $2 billion for 2015, $1 billion for 2016 shall be deposited into the General Fund of the Treasury of the United States and may not be used for the Reinsurance Program."

So, the announcement that the administration made represents an illegal wealth transfer from hard-working taxpayers to insurance, and this law is very clear, $5 billion of reinsurance fees must be returned to the taxpayers. As you can see, Section 1341 of the ACA states that this $5 billion "shall be deposited" into the Treasury. And if that wasn't clear enough, the law further states on down that these billions of taxpayer dollars "may not be used for the Reinsurance Program." It seems clear. Yet, CMS to date has diverted $3.5 billion from the Treasury to health insurance companies, effectively bailing out insurance companies with taxpayer dollars.

So, my question to you, Madam Secretary, is this: has any HHS official or any other administration official looked at the legality of these payments? Is there any legal memorandum or other analysis regarding the legality of these payments to insurers, and will you produce any such memorandum for the committee, if so?

Secretary BURWELL. So, the Reinsurance Program is part of three different programs that are about making sure that we have downward pressure on costs for individuals in the health insurance system. That is downward pressure on premiums.

This particular program is a limited program for 3 years, and that is all. Of the three programs, one extends, which is the Risk Adjustment Program. This one, the Reinsurance Program, does not.

The Reinsurance Program, as I said, was put in place so that two things would happen for people entering the new market. In a new marketplace where they didn't know, you didn't want people not coming in and offering competition for downward price pressure because they feared that they would get people who are expensive.

And then, in addition to that, it puts downward pressure, so that when you do get people that are expensive, you know in these first years, as you are understanding your book of business and doing your analysis to be able price correctly, that you have that opportunity.

So, in making any decisions about these issues, we believe we do have the statutory authority with regard to this issue. In making the decisions—and this gets to a point that I think Ms. Blackburn raised in her opening comments—the issues of making sure we are clear about lessons learned. One of the most important lessons, customer at the center. The consumer or the citizen is what we have tried to put at the center, whether that is in the decisions of how we have done the technology or how we make decisions about ensuring that those dollars actually went to the place where they

would most help the consumer with regard to downward price pressure.

It is our belief we have that authority. If it would be helpful, we can have staff come and brief in terms of why we believe we have those authorities.

Mr. PITTS. Do you have a legal memorandum to that effect?

Secretary BURWELL. With regard to the question of a legal memorandum, this is an issue, actually, we put out our guidance for public comment. We put out the guidance that articulated that we would do this.

Mr. PITTS. OK.

Secretary BURWELL. When we put out that guidance, we actually opened up for public comment specifically.

Mr. PITTS. All right.

Secretary BURWELL. And we can go through what public comments that we received with regard to that.

Mr. PITTS. We have a legal memorandum. I will ask staff to deliver it. Before you should be a memo from the Congressional Research Service on this very issue. On page 8, highlighted, before you, the memo states that your action to divert funds from the Treasury "in conclusion, would appear to conflict with the plain reading of the law."

So, my question is, CRS has concluded that your action to divert billions to insurance companies appears to be unlawful. Did your Department receive any pressure from insurance companies to divert billions from taxpayers to pay off insurers? Did former CMS Administrator Marilyn Tavenner, now representing the insurance industry at AHIP, or other insurance company executives or officials ever pressure you or other Department officials on the reinsurance issue?

Secretary BURWELL. Mr. Pitts, I would be happy to take a look. I have not seen this document that was just handed to me. We will be happy to take a look——

Mr. PITTS. Page 8.

Secretary BURWELL [continuing]. At that document and get back.

We do believe we have the authorities. As I said, I think I have given you the context and the approach we take to making these decisions. Since I have come to HHS, it is one of the key things. One of the key things that I started out with, with the whole team, is consumer at the center. As we make decisions, what we try to do is make those decisions by putting that customer and their needs, whether that is, as I said, in Web site decisions, in trying to make it easier to use, or with regard to matters like this in terms of where those funds go, so that we create that downward pressure as much as possible within statute to put downward pressure on premiums, instead of upward pressure on premiums.

Mr. PITTS. The Chair thanks the gentlelady.

Ms. CASTOR. Mr. Chairman, before you finish, can you identify the source of that slide? Because, as we know, in other congressional hearings in the past there has been a little funny business on where those slides come from.

Mr. PITTS. That is a direct quote from the Affordable Care Act, from the statute. That is from the statute.

My time has expired. The Chair now recognizes the gentlelady, Ms. Castor——

Ms. CASTOR. Did you have a statutory cite on that? Because it didn't appear to be a statutory——

Mr. PITTS. Yes, I cited it. It is Section 1341.

The Chair now recognizes the lady from Florida for 5 minutes for her questions.

Ms. CASTOR. Great. Thank you very much.

Madam Secretary, I would like to ask you to give us an update on Medicaid expansion across the country.

But, before you do that, I want everyone to be aware that a new bill was just dropped last night by Mr. Green, The Incentivizing Medicaid Expansion Act. It already has 15 cosponsors, including myself, Mr. Tonko, Mr. Butterfield, Ms. DeGette, Ms. Matsui, Mr. Pallone, Mr. Kennedy, Mr. Lujan, and others. It mirrors the very smart provision in the budget that provides a new incentive to the states that have not expanded Medicaid. Because, as I said in my opening, it simply is completely unfair that some citizens have the ability to seek Medicare care under the Medicaid expansion in some states and, because of politics in others, they don't.

So, we know what the Supreme Court said. It is not mandatory, but it is very important that we continue the incentive because it is smart fiscal policy. I know in my State we would save a lot of money, we would create jobs, and we would take care of our neighbors if the cadre that is control of the State government right now would listen to the people and expand Medicaid.

But give us an update on how it is going and what the source of your incentive under the budget was for those states.

Secretary BURWELL. We know right now 30 states plus the District of Columbia have done the expansions. The information that we are now receiving in terms of those expansion states, whether that is the benefit to individuals, which we are seeing many more people doing adherence in terms of those who have medical conditions going, taking their medication, and those sorts of things, because of the expansion.

So, the benefit to the individual is both a health benefit as well as a financial benefit. But we also know that the benefit to states is something that we are seeing, and that conversation is going on all over the country, whether that is in Kansas or the legislature in Maine, in terms of proposals to go forward to try to have Medicaid expansion.

A big part of it is the benefit. We know that in the State of Kentucky the estimates are that there will be 40,000 more jobs by 2021 and $30 billion to the State in terms of money that will flow into the State.

I think those benefits are already starting to be seen in states where what we are seeing in terms of rural hospital closures, an issue that I think many of us are concerned about, is that more of those closures are occurring in non-expansion states.

The other part of this I think is the issue of uncompensated care. The estimates are, since the beginning of the Medicaid expansion and the coverage expansion that has resulted in the 90-percent coverage, that we estimate that there have been about $7.8 billion in a reduction in uncompensated care. Those reductions are not

spread evenly; 68 percent of that is in states that have expanded. So, both about the individual in terms of their financial and health well-being, but also in terms of the economics both of the state and the community.

We believe this proposal is a proposal that supports governors' desires. I spent a lot of time just last weekend, spend time all weekend, Friday, Saturday, Sunday, and Monday, with the governors that were here from the National Governors Association. These are important conversations that we are having with them about the economic needs in their state.

Ms. CASTOR. Well, over 50 years ago, when the Congress first adopted Medicaid to provide that lifeline for children and our older neighbors, all states didn't jump in right at first, but eventually, over time, didn't they all join the Medicaid world?

Secretary BURWELL. They do, and I think because of the benefits this will provide and a number of issues we will talk about, behavioral health is one I am sure we will spend time on in this committee. We know that that Medicaid expansion will make a difference in terms of these behavioral health issues as well.

Ms. CASTOR. Thanks.

And one other issue, there is a lot of bipartisan interest in Congress to address graduate medical education. If we can fix the doc fix, I know we can make progress on graduate medical education. We know we have a looming doctor shortage. We know that, since 1997, there has been a cap and it has been static where residency slots exist across the country.

But I think there is this newfound momentum, bipartisan, in the Congress to do some creative things, but we will need your help. Most folks don't know that residency positions are paid for by Medicare. I think we can stretch that Medicare dollar by creating innovative partnerships with health providers and hospitals across the country. There is legislation to do so. Sean Cavanaugh came over and talked about it. He said this could be an area to take that Medicare dollar, expand it, and provide the doctors we need in the areas we need in the future.

So, can you commit to doing that during your remaining time?

Secretary BURWELL. I hope you see our GME policy for children's GME. It responds to many of the concerns that were expressed to us last year in terms of the proposal we have now. So, we look forward to working on these issues.

Mr. PITTS. The gentlelady's time expired, and the Chair now recognizes the chairman of the full committee, Mr. Upton, 5 minutes for questions.

Mr. UPTON. Again, thank you for being with us this morning.

I really want to focus on two things: Cures and Flint. Let me ask you first about cures. When we get about halfway through the time, I hope not to be rude, but I want to make sure that we cover both.

We have worked so closely on this. Again, I thank your staff for the technical assistance, particularly on precision medicine, which we included in the bill, which, as Ms. DeGette said, passed the committee 51-to-nothing.

I know that you are a part of the Vice President's Task Force under the Executive order for the National Cancer Moonshot. You have had at least one meeting, maybe a couple.

Mr. Pallone and myself and Ms. DeGette, as well as the Senators, have been working with the Vice President's Office. We are hoping to sit down next week formally to see exactly where we are.

But what are some of the ideas, in addition to what we have in Cures, that you think that we might be able to incorporate? Our idea, of course, is to take the House-passed bill already. The Senate has begun the markup stage in the last 2 weeks, and they are looking at doing a series of bills which are all bipartisan at this point, intend to be so, Mr. Alexander and Ms. Murray, and then, to look at injecting the Cancer Initiative as part of that process, go to conference, and accept all the goods parts, which is, in essence, the whole thing now.

But what additional ideas are you all thinking about as part of that initiative as we begin to move forward?

Secretary BURWELL. First, thank you for your leadership and the leadership of other members of this committee in the 21st Century Cures space, the PMI space, and now, this space as well.

We are excited about working in that space. A couple of the things that I would be specific about in terms of places where I think we can build on the work that you all were already doing in your bill are some of the key areas we want to do investments in. Some of those have to do with immunology in terms of advancing that science, where we know that people's own immune systems are some of the best ways that we can advance the ability to treat cancer, as well as it is good overlap with some of the proposals that we are thinking about in the cancer space related to genetics. That overlaps very directly with your PMI work.

I would also mention—and I am sure you will have the conversation with the Vice President, and I always welcome it, too—as we think about making sure that FDA, I think you know we have suggested that FDA actually have a particular expertise and develop a part of FDA that is cancer- and oncology-focused. I think we think that is an important addition to our work.

And so, those are some of the specifics of what we do. We also look forward to your ideas about how we can expand access to trials. That is something I think we want to have those conversations with you about and, as you reflected, before we get to the end of the process, have those conversations earlier.

Mr. UPTON. Well, that is great, and we look forward to meeting with the new FDA Director. I don't know if he was formally confirmed yesterday. I think he has been confirmed, but he has not been sworn in yet.

Secretary BURWELL. He will, hopefully, be today at noon or 1 o'clock.

Mr. UPTON. We look forward to that.

Let me just switch now to Flint. Again, your office has been most helpful. Dr. Laurie has had very good reviews. We have dispatched to Michigan over the last number of weeks. Our Michigan delegation, on a bipartisan basis, is meeting with her today. I know that you were there last week.

I talked to our governor earlier this week specifically about this, and I know that he has got a number of waiver requests that are in. CHIP expansion for pregnant women and children up to the age of 21, increased Medicaid eligibility for lead-abatement activities, a number of things.

Can you tell me where you all think you are in terms of the requests that Michigan has put forward?

Secretary BURWELL. As I articulated with the governor and when I was in Flint, I think we will be able to approve an expansion of Medicaid that will be for pregnant women and children. That will be a major expansion. It will also include something that is pretty important, which is comprehensive targeted approaches to individual management. So that when we understand that a child has had a certain level of exposure, that we make sure that they receive the comprehensive services that they do. That is another part of the waiver conversation. So, my expectation is that we will be able to do most of what is in that waiver and that we will get that done quickly.

Mr. UPTON. Knowing that you were there last week, the water is still unsafe to drink, is that correct?

Secretary BURWELL. With regard to the water, at this point people should either use the bottled water or filters. But, once you have a filter that is appropriately installed and you do the directions in terms of the changing and the cleaning of your filter that you need to do, that water should be safe. If you want it tested, though, call 211. Anyone should just call 211 to make sure, if that is what you want for comfort. If you are a pregnant woman or if you are a child under 6, we recommend, out of an abundance of caution, use the bottles. But, otherwise, filters applied, and those filters are being tested. EPA continues to test regularly.

Mr. UPTON. Thank you. Yield back.

Mr. PITTS. The chairman yields back. I now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Secretary Burwell, in your testimony you noted that part of the goal of the budget is to build upon the successes of the Affordable Care Act, and the latest round of open enrollment just recently ended. Can you tell us more about how this open enrollment has gone, including how many people signed up for health insurance, how many were eligible for tax credits to make insurance more affordable?

Secretary BURWELL. With regard to this open enrollment, 12.7 million Americans enrolled in this open enrollment. There are some other things that I think are important about the open enrollment that get to some of the broader issues that I am sure we are going to discuss.

We know that, of those folks, there were 4 million new people that came in. Of the 4 million new, 60 percent of them signed up for coverage for January 1st. Why is that important? It says it is a product that they want and they want to start at the beginning of the year. It is also important because, from an insurance company or an issuer's perspective, you want them in for the full year in terms of downward pressure, again, on price.

The other thing that happened in this open enrollment, in addition to that 12.7, is when you look at the people that were in before—so, I talked about the new, but the other folks—70 percent of the folks who had been enrolled last year and came back and are re-enrolled actually took some action. They came in, updated their information, or they shopped. This is an engaged, empowered, educated consumer making choices.

If I asked in a setting where there is employer-based coverage, those numbers generally don't even ever get above 10 percent in terms of the number of people who engage in a re-enrollment process. So, it is an engaged consumer. It is a consumer that is seeking that produce. And so, those are some of the highlights of what we have seen in this year's open enrollment.

Mr. PALLONE. OK. Thanks.

I know that the gentlelady from Florida mentioned Medicaid expansion and the President has proposed these additional incentives for states to expand Medicaid. Could you describe the benefits that Medicaid expansion, that the states are experiencing and why it is so important that the remaining 19 states join them in moving forward?

Secretary BURWELL. So, as I mentioned, it is the advantage and the benefit to the individual. I am sure you all meet folks every day who it makes a difference in terms of their ability to get the health coverage they need, whether that is the preventative services they need to prevent other things or when they have something going wrong, their ability to treat those. And so, that is the individual.

But the economic benefits of this and the other benefits we have seen, that the number of people in the country now who are struggling with making their healthcare payments has gone down as a nation. We have seen The New England Journal of Medicine most recently put out a study saying that the changes through Medicaid expansion are affecting payer mix for hospitals and making a difference to them on the ground.

And so, it is both about the individual, the communities, and the state, as we think about those benefits.

Mr. PALLONE. Then, lastly, I wanted to ask about the proposals in the President's budget to address the opioid abuse and overdose crisis. The President's 2017 budget requests a billion in new mandatory funding over two years to expand access to treatment for prescription drugs and heroin use. Can you just walk us through this funding request? Why is this investment necessary? Why is our current treatment capacity insufficient? Why is it important that the billion dollars be provided in the form of mandatory funding over the two years, and how is this going to be allocated?

Secretary BURWELL. With regard to the money that we have asked for, it is money to support an evidence-based strategy that we have talked about, and let me just hit those points because that is where the money will go.

The first area is in the area of prescribing. We know that part of what has contributed to the issue of the opioid epidemic is overprescribing. And so, it is money to support the efforts of new guidelines that will come out from CDC and making sure that those guidelines are actually used, learned, and applied.

The second area is in the area of medication-assisted treatment. This is the space where the vast majority of this money goes. It goes to that and it will go to communities and states. This is money that will not be used at HHS, but will go to communities and states.

This is part of what we know. Behavioral health is something that has been a local issue for so many years. It is paid for mainly at the state and local level. And so, making sure that communities can have the access.

Right now, I was told 2 weeks ago that in 85 percent of the counties, rural counties, in this country that their ability to have behavioral health providers and access is quite limited. And so, that money, and that is the vast majority of the money in the budget.

The last area is in the area of Naloxone or Narcan. That is, sadly, we know that in our communities people are overdosing. And so, to prevent them from dying, you apply Naloxone or Narcan. There will be money to go to the communities to get that access to that drug. So, in the last-case scenario where we have someone who has overdosed, we can at least have first responders and community members that can save lives.

Mr. PALLONE. Thank you so much.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the Chair emeritus, Mr. Barton, 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman.

Before I ask my questions, I want to file a mild complaint. The Secretary called me on my cell phone the other day and was very charming and disarming. It makes it very difficult to ask her tough questions when she is so polite and receptive to my input. So, we may want to consider adopting a rule that Cabinet Secretaries, at least of the opposition party of the majority, cannot do that.

[Laughter.]

So, I just want to put that on the record.

Mr. PITTS. We will take it under advisement.

Mr. BARTON. All right.

Madam Secretary, it is always a delight to have you come before the committee and answer questions that are usually not at all related to the budget which you are supposed to be prepared to answer. I have got a difficult question and an easy question. Which do you want first?

Secretary BURWELL. Difficult.

Mr. BARTON. The difficult question? I am surprised at that.

Secretary BURWELL. I think you know me.

Mr. BARTON. There are many of us that are very concerned about the issue of harvesting and selling what you could either call body baby parts or you can call it fetal tissue, whichever term you choose to use. I am very concerned about that, not opposed to family planning, not opposed to funding women's health issues at all.

My staff has done some research and found out that the last time the issue of fetal tissue research was studied was during the Reagan administration. There was a special commission appointed by the President that did a study. That is over 30 years ago. There have been tremendous changes in medical practice and medical research since that time.

The NIH is not currently funding such research internally, but externally they have supported about $76 million in such areas of research outside the NIH.

Would you support a new commission to take a look at this issue, so that, regardless of which side you are on or the politics, we could at least know what the facts are?

Secretary BURWELL. With regard to the issue, I agree with you that this is an issue of great emotion and focus on different sides of the issue, and I respect that there are differing opinions on the issue.

With regard to the question of the use of this tissue as part of our research that we do, I think in terms of the basics of the question of the value of that research, we continue to see—and whether it is the fact that the measles vaccine, the mumps vaccine, hepatitis A are all products that have derived and come out of this research, to the fact that some of this research has helped us move in terms of the research that was done for the Ebola vaccine. And so, for us, the question of the research, when done appropriately and in accordance with the laws and the statutes, and no valuable consideration, are things we take extremely seriously.

Mr. BARTON. But would you support a new commission to review the issue?

Secretary BURWELL. We would welcome the opportunity to have the conversation. I think the question is to understand which issue. Because I think at its heart is the question of the value of this research and the question, I think, in terms of the guidelines that are put in, which are very strict, are there issues or problems with that? So, we would welcome the opportunity to understand more fully what you think are the issues around this that we would——

Mr. BARTON. Well, the gentlelady next to me on my right, Mrs. Blackburn, is heading up a select committee that I believe is going to be looking into this.

Secretary BURWELL. And I think we have responded, both the Department and NIH, as an operating division, to your request, Ms. Blackburn.

Mr. BARTON. Well, here is my easier question: the majority of this committee has sponsored a piece of legislation that we called the ACE Kids Act. It would change federal policy to create a medical home for families that have special needs children. It would allow there to be an anchor hospital that would, then, create a network. So that, if you had a child who was a special needs disadvantaged child with multiple medical conditions, they could come into the network and there would be a single home. We have a majority of the committee and we have almost a majority of the House of Representatives as cosponsors.

Has your office taken a look at that legislation and, if so, what is your position on it?

Secretary BURWELL. We welcome the leadership that you and others have provided in this area of complex cases. We are continuing to work right now with our administrative authorities to work with states in order to get the kind of care and service that you are talking about for parents and their children. And so, we want to continue to work on that. We have a proposal in our budget that extends that. Because one of the things is, when some of

the states do this, it carries over not for just children, but for larger populations. Sometimes that is why states are hesitating.

So, we look forward to working in terms of, as I said, we have a proposal in our budget, would like to have the conversation about—I am not sure if your legislation includes that part of it or not.

Mr. BARTON. OK.

Secretary BURWELL. But I think we are with you on the objective of helping families with this complex care.

Mr. BARTON. Thank you. Thank you.

And I thank the chairman for his discretion.

Mr. PITTS. The Chair thanks the gentleman, and now recognizes the gentlelady from California, Mrs. Capps, for 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

And thank you, Secretary Burwell, for your testimony today.

The President's budget proposal this year includes many important investments in our nation's healthcare delivery system, workforce, and prevention programs. HHS programs touch each one of us in some way, whether as a Medicare beneficiary, someone needs a tobacco cessation program, or perhaps being cared for by a healthcare provider trained with federal funding. I recognize that balancing the many competing proprieties in this space is a challenge and appreciate your efforts on this.

Today I would like to highlight two different programs that very much deserve your strong support and ask a question about each of them. Specifically, I would like to highlight the importance of the federal investment in the training and retention of the nursing workforce. Title VIII provides critical federal grants for nursing schools and organizations to advance their educational programs to promote diversity in the field, repay loans for nursing students who work in facilities with critical shortages, and train geriatric nurses.

Our nation faces a significant challenge of caring for a growing patient population with limited resources. Title VIII nursing workforce programs, programs that have been around since 1964, are a key component to this effort because they train highly-skilled healthcare workers who can serve in hospitals, research labs, and communities.

Will you discuss briefly what this budget request does to support the development of a highly-qualified healthcare workforce important today and known as the Title VIII programs, and ways that it can be continued?

Secretary BURWELL. So, over $200 million in investment, and those are split, basically, in two different pieces. The first is actually education, as you mentioned, in terms of educating and training, in terms of that supporting the provider community. The second part is actually with loan forgiveness programs that help us have those trained professionals go to the places where we have shortages and needs. Those are the two main ways.

But, throughout the budget and throughout the proposals that are before you now, there are a number of things that I think are supportive of the nursing community because we believe they are part of getting us to a system where we have better quality care in a more affordable way. And so, having nurses and other health

practitioners operate at the top of their license, and steps that we are taking. For instance, in our budget we actually propose with regard to buprenorphine, which is an important medication-assisted treatment for opioids, we are proposing that it is considered by the Congress to expand those that can prescribe, if they meet certain conditions. So, we are supporting it in terms of our funding, but also in terms of how we think about the role of the nurse in a system that can improve quality and reduce cost.

Mrs. CAPPS. Thank you, Madam Secretary.

And this is why I joined with my House Nursing Caucus Co-Chair to author bipartisan legislation to reauthorize Title VIII, The Nursing Workforce Development Programs, with my colleague, Mr. Joyce from Ohio.

Another key priority for the administration and for many of us personally is making an impact on cancer treatment care and prevention. As you know, cancer continues to be one of the leading causes of death globally. With the number of new cancer cases expected to rise to 22 million within the next two decades, it is a huge number.

As one of the Co-Chairs of the Cancer Caucus, I commend the administration for launching the National Cancer Moonshot Initiative. If we are going to win the war on cancer, we must take a comprehensive approach to this fight, as this initiative proposes to do.

Only 5 percent of cancer patients in the United States participate in a clinical trial, and most do not have access to their own data. I believe participation in clinical trials is so essential to finding new treatments and, ultimately, a cure for cancer or cures for cancer.

Increasing data-sharing is also critical, as it can help to advance a better understanding of the disease and how best to treat it. Increasing participation in clinical trials and ensuring these trials include a diverse range of participants, including of women of all backgrounds, ages, and risk levels, is something I have long advocated for.

Secretary, how will you, through the National Cancer Moonshot Initiative, help to increase access to clinical trials in the area of cancer?

Secretary BURWELL. With regard to the issue of trials, as I mentioned in responding to Mr. Upton, that is one of the issues that is a priority.

In terms of things that we can do right now, and should do right now and are doing right now, this ties into the issues around electronic health records and precision medicine. Those are separate but related issues, as is the cancer part of this, which is making sure that patients and consumers can get access to their data.

This, I think, also relates to the issue that we were talking about with regard to 21st Century Cures on this side. But on the Senate side, I think Mr. Alexander and Ms. Murray are thinking of including things that would prevent data-blocking. Data-blocking is when the providers of software to electronic health records, so a provider of software to a hospital, does things, and sometimes they might be about cost, but sometimes they may be about making things really hard for the consumer to get that data information.

And so, these are steps that I think we can take right now and are working on. I will actually be speaking at a conference of all the technology people as soon as this Monday with regard to getting commitments from the private sector to work against this data-blocking. Hopefully, we can get there, but I think it is important that, certainly, your colleagues on the other side are considering legislation which we are having conversations with them about. This would come together in the 21st Century Cures version, the House and the Senate coming together when you all come together in a conference.

Mrs. CAPPS. Thank you very much. I yield back.

Mr. PITTS. The Chair thanks the gentlelady.

I now recognize the Vice Chair of the subcommittee, the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Madam Secretary, for being here today. I really appreciate it and echo what my colleague said, willingness to work together.

One of the big concerns I have had—I was in state government before in Kentucky—and since I have been here, it is the growth of Medicaid. We are looking at how we deal with the growth of Medicaid, how we cover the vulnerable, but we have to do it in a way that is sustainable for our budgets.

I know you worked in the Clinton administration. I have a Congressional Record, a letter, so I can show the documentation. But it was Senator Murray and it was a letter that she sent to President Clinton, and I will quote what she said on the floor of the Senate.

This letter is partisan in that it is signed by all Democrats, which would include the Vice President. At the time he was in the Senate. But it is my feeling that, as Americans, every Member of the Senate should have an opportunity to endorse the position described in the document.

And I will just read the opening of the letter. It says, "We are writing to express our strong support for the Medicaid per-capita cap structure in your 7-year budget."

So, as we are looking at all options and dealing with Medicaid—Medicaid is now about three times what it was in 1995, three times the size. Would you support a per-capita cap structure or Congress adopting that structure?

Secretary BURWELL. As we think about the issue of healthcare cost, which I think everyone agrees is what is driving our deficit over the long-term, I think one of the things is separating out two issues. One is per-capita costs, which is related to the issue you are talking about, and, also, the overarching cost. As we, as a nation, move to have more people covered and we have a baby-boom through Medicare, we are going to have to focus on those issues as we think about it.

With regard to the question of caps and how that works, I think the question—and we are also seeing this right now in Puerto Rico in Zika, which basically has a blocked approach to Medicaid, a blocked approach——

Mr. GUTHRIE. Right, yes.

Secretary BURWELL [continuing]. That right now we are having a very difficult time. That is part of why we will need the supple-

mental money. That is part of why we have a proposal in our budget on Puerto Rico.

And so, the concerns that we have around those issues are, one, that what happens is pressure gets put on the state or the beneficiary in ways that you end up with reductions in quality of care. Those are suggestions and ideas—I am sorry I am not familiar with the letter that you are——

Mr. GUTHRIE. But it was just that concept. I think that was in President Clinton's budget proposals twice, I think, in the 1990s. And so, I was just showing that it had bipartisan support. Even the Vice President signed onto it in the Senate at the time.

If that is the direction we need to go for that, is that something you would support?

I do want to get to Kentucky.

Secretary BURWELL. OK.

Mr. GUTHRIE. I don't want to be rude, though. I actually don't want to be rude.

Secretary BURWELL. Go ahead. Go ahead. We will come back if we have to.

Mr. GUTHRIE. But you did meet with our governor. As you said, you met with the governors last week, and I understand from people I have talked to and him—I haven't talked to him, but people with him—that it was very productive and they really appreciated the time.

One of the concerns, though, as we move forward, because I know you quoted that a lot of money is going to flow to Kentucky through their Medicaid expansion, but also a proposal right now is like 9-percent cut in universities for 2 years. It is 18 percent over 2 years to universities and other levels of government, just because it is not just Medicaid, but Medicaid is a big part of it. Part of it is public pensions, but Medicaid. And so, they are looking at ways to innovate, as you know, because you met with them. Like I said, I appreciate that.

But there was a Vikki Wachino responding to some questions from the committee on Medicaid, the head of Medicaid at CMS. She wrote, "In some cases where new approaches are being tested, such as Healthy Indiana Plan 2.0, approved earlier in 2015, it is also important to evaluate the impact of new approaches being tested in 1115 demonstrations before approving similar policies."

Can you give examples where you had to have evaluations before you could move forward on the others? Because I know I don't think CMS does it for stuff like delivery system reform programs, premium assistance, managed long-term care service and supports, and managed care. So, is there a criteria saying you can't move forward on a similar plan until we evaluate that?

Secretary BURWELL. With regard to CMMI, the Centers for Medicaid and Medicare Innovation, you all actually gave us pretty high standards with regard to evaluation, and standards that, actually, I think it is good because I think we should meet the high standards before we take a demonstration and expand it.

So, in that part of the work that we do, yes, we have seen that, similarly in the Medicare work and the delivery system reform work. I think what we want to do is make sure, when there are

things that are new and untested, that before we expand to other states that we know and understand.

I think it is important to reflect that——

Mr. GUTHRIE. But this is CMS, not CMMI. It is CMS.

Secretary BURWELL. CMMI is part, is the Center for Medicare and Medicaid Innovation, is what was created and is part of CMS in terms of how we are doing that. And so, there is that Center. There is the Medicaid Center. We work to align as much as possible.

But I think to get to the core of the issue that I think you are raising, every state comes in with a different history and a different desire and need. Those are conversations that I think most governors will tell you on both sides that I welcome to have the conversation and that is what we will do.

Mr. GUTHRIE. I understand that, but also in that quote was that innovations that work in some states may not work in other states. That is some of the question. So, if something doesn't work in one state, it still could work in another state.

But we appreciate your openness, and I know I am out of time. But we really need to make it work and we need to be innovative to make our Medicaid system work. So, I appreciate the opportunity.

Secretary BURWELL. I think we want to make sure those folks stay covered and it is done in ways that improve quality and do downward pressure on cost as much as possible. So, we are agreeing.

Mr. PITTS. The Chair thanks the gentleman.

Did you want to submit your letter for the record? Did you want to submit the letter for the record?

Mr. GUTHRIE. Well, it is in The Congressional Record for the 1995 Senate, but I submit that for the record.

Mr. PITTS. All right. Without objection, so ordered.

[The information was unavailable at the time of printing.]

Mr. PITTS. The Chair now recognizes the gentleman from Oregon, Dr. Schrader, 5 minutes for questions.

Mr. SCHRADER. Thank you.

Thanks for being here, Madam Secretary.

Secretary BURWELL. Thank you.

Mr. SCHRADER. I always enjoy it.

Is it accurate to say that the total discretionary budget authority for your Department, HHS, is actually $658 million less than it was in 2016 for 2017? And even accounting for rescissions, it is $441 million less than in 2016?

Secretary BURWELL. That is correct.

Mr. SCHRADER. I appreciate it. There are very few agencies that come in, realizing we are in tough economic times, that are willing to take a little hit in the budget arena and make sure things balance, and it is not at the risk of patients, which I also appreciate. We are getting better healthcare out there, as you have testified.

I also want to appreciate the fact that the administration is committing to 85 percent of Medicare payments being tied, frankly, to positive health outcomes by the end of 2016. I think that is the future. We are having great success on the CCO level in Oregon——

Secretary BURWELL. Yes.

Mr. SCHRADER [continuing]. And our Medicaid expansion project. We are actually getting more for less. The patients love it. The healthcare providers are very excited. We are getting great outcomes in terms of reduced hospital stays, less ER visits, more primary care attention.

I had the mental healthcare providers in the other day, also part of the CCO expansion. So, it is not just your physical health; they are starting to get at the stuff that Congressman Murphy and many of us are trying to get at, to incorporate mental health into the holistic approach to folks. I think it is very, very, very exciting.

I guess I would be interested in your update on the next generation of ACOs in the Medicare area, where we are going with the outcome-based care that we are talking about.

Secretary BURWELL. So, in terms of this idea of getting an educated, empowered, and engaged consumer at the center of care, and we often call that delivery system reform, there are three basic tools that we are working against.

One is payment reform, so that we are paying for that value versus volume. And you talked about that in terms of the statistics. This year we, hopefully, will meet the goal we set out that 30 percent of Medicare payments will be in value, not volume by the end of 2016.

The second area of focus is changing the way we actually deliver care. This gets to some of the innovation projects that we are working on and measuring. One of those, for example, in terms of where we are seeing real progress, not to the point where it meets the standard of evaluation yet, that we would expand. But we are seeing that in terms of long-term care for people in the homes and making sure that we are doing certain types of care in the home, we see a reduction in hospital visits for those in the home and we see a 3,000 per Medicare beneficiary savings.

Now we need to make sure that that can hold, but that is some of the progress that we are seeing in that space and changing the way delivery—keep people in their homes; give them the education they need; give them the tools they need to get the care they need, so they can stay at home, not be in hospitals.

The third area is data and information. We talked a little bit about that with Ms. Capps.

Mr. SCHRADER. Right. Well, I appreciate all that. I think the ACOs, Medicare Advantage is another way to get value-based to folks, and particularly in the home care settings.

I have worked with Mr. Lance and Ms. McMorris Rodgers on several on several innovative programs that I hope the administration will look favorably on in terms of improving that healthcare delivery, getting it to the consumer, a nice bipartisan issue, regardless of your view of the ACA, in particular.

I am hoping that HHS will continue to work with this committee and other Members on improving the innovation opportunities through Medicare Advantage and wonder if there are other things you are doing to improve things for beneficiaries in the Medicare Advantage Program. It is working really, really well out west in Oregon.

Secretary BURWELL. With regard to the ACOs, that is a place where we have had measurable results, but we have seen the

measure had to be that you do not reduce quality, but you have savings. If you can increase quality, that is even better.

Mr. SCHRADER. Yes.

Secretary BURWELL. And we have seen that and the savings, $300–400 million in terms of that. And now, we have a new generation of ACOs, the Accountable Care Organizations.

With regard to Medicare Advantage, the issue, one of the things I would highlight that we are working on right now is one of the challenges in Medicare Advantage is the question of people with socioeconomic difficulties and the star ratings, and how those ratings perhaps might disadvantage those who have a population who have a number of chronic conditions.

And so, we have taken steps to weight——

Mr. SCHRADER. Good.

Secretary BURWELL [continuing]. And include things for that socioeconomic. We are spending time to understand more fully. We want to make sure we analytically base what are the differences in changes people should have in payment if they are serving a more difficult population.

Mr. SCHRADER. Great.

Secretary BURWELL. But, in the interim, as we are finding more solutions, those are changes we are making.

Mr. SCHRADER. Very cool.

The last comment I guess I would make is I had insurance agents in my office just the other day working really hard to get people enrolled. When they have their circumstance change, they need special enrollment opportunity. They are having a little trouble accessing the Web site compared to during the open enrollment periods. So, if you could just reach out to them a little bit and work with them to help them help people make those changes, so that we save money, people get the healthcare they need, and they are not subject to penalties later on, I would appreciate that.

Secretary BURWELL. Absolutely. We would like to reach out and find out, so we can reach out directly.

Mr. SCHRADER. Thank you.

Secretary BURWELL. We will do that.

Mr. SCHRADER. I yield back Mr. Chair.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. WHITFIELD. Thank you, Mr. Chairman.

And, Madam Secretary, thanks very much for being with us today. We all appreciate the phone call.

There are three issues I want to talk about. First of all, alternative payment models for oncology.

Secretary BURWELL. Yes.

Mr. WHITFIELD. CMS has already developed a model, the Oncology Care Model, under the Center for Medicare and Medicaid Innovation. From conversations that I have had with oncologists and others, they find the sign-up process to be overly-complicated. They say that they are being encouraged to sever relationships with certain hospitals, and that many of them are not being informed on whether or not their application is being accepted.

Now, as you also know, Cathy McMorris Rodgers and Steve Israel introduced a bill called The Cancer Care Payment Reform Act, which we had the legislative hearing on in September of last year. That is an alternative model that the oncologists very much support. They are the ones providing this care.

And so, the impression that we are getting is that you all are determined that you are going to move forward on your model. I simply would ask, would you work with the providers to see about developing a model that is acceptable to everyone?

Secretary BURWELL. Absolutely. We would like to and we would like to follow up with your staff directly in terms of talking to some of the providers that you have talked to, so we can get their input directly.

Mr. WHITFIELD. OK. Well, we appreciate that. Thank you very much.

Secretary BURWELL. Yes.

Mr. WHITFIELD. Now, on another matter, over a year ago, this committee and the Ways and Means Committee staff, which started working with HHS regarding a program with the Affordable Care Act that was authorized called the Basic Health Program. It was never funded. There was never an appropriation for that. There was a permanent appropriation for an Affordable Care Act program called the Premium Tax Credit. The administration has been taking money from that program, last year $1.3 billion, to fund the Basic Health Program.

As I said, Ways and Means has been contacting you all on a regular basis about this. Energy and Commerce has been contacting you on a regular basis about this, asking for documents about how this is being funded without a direct appropriation. After a year of asking for these documents, Ways and Means still has not received them and the Energy and Commerce Committee has still not received them.

Will you all work with us to provide this information that the staffs are asking for?

Secretary BURWELL. I think we are and continue to work. We have been responsive in terms of letters. We have been responsive, actually, on the Ways and Means side. A briefing was asked for. We provided——

Mr. WHITFIELD. OK. Well, let me just say this: I mean, I appreciate that, but I am not there. I am not negotiating. I am not even discussing it. But the staffs on both Ways and Means and on our committee tell us that what has been provided is very meager, that it is not the documents that they are requesting.

Secretary BURWELL. Well, I think we want to continue to work, and we will.

Mr. WHITFIELD. OK.

Secretary BURWELL. I think we are trying to work cooperatively with all of the issues of oversight which we think are important.

In this particular case, in terms of the authorities, we believe the authorities exist. The authorities are for the same amount; they are the same types of money.

Mr. WHITFIELD. So, you all feel like you don't need a direct appropriation, that you have other authority to do it?

Secretary BURWELL. We believe that the authority——

Mr. WHITFIELD. And that is what we want, the document, I guess, that provides that authority, at least your interpretation.

But you said that you will continue to work with our committee on it. We would appreciate that.

Secretary BURWELL. We will. We will.

Mr. WHITFIELD. One other thing I just want to bring up briefly, because I was involved in it, is the sunscreen legislation. As you know, skin cancer is the most common form of cancer in the U.S. Skin cancer is more prevalent than breast cancer, prostate cancer, lung cancer, and colon cancer combined.

And so, these ingredients that have been on file at the FDA for approval since 2002, over 14 years, and many of these ingredients are being used in Asia, Europe, South America, around the world, and yet, we passed a bill specifically to encourage a process that is more applicable to this. And even since then, there has been no movement 14 months later.

I know that Johnny Isakson, Senator Isakson, asked about it. I am asking about it. So, I hope that you all will tell us, do we need to do something? Is there anything that we can do to facilitate this?

Secretary BURWELL. We would like to follow up because I think maybe you can help us. Our concern is it goes on the new products that are coming on. First, in Europe it is a cosmetic. We actually believe, because it is going on your children 24/7, that we need to make sure that what is going through, is it absorbable in the children's skin? It is for everyone, but, of course, we are focused on children. And are those chemicals going to do something negative?

Mr. WHITFIELD. Yes, yes.

Secretary BURWELL. And so, I think if we have a conversation, there may be a way that you can be helpful——

Mr. WHITFIELD. OK.

Secretary BURWELL [continuing]. In helping us get the information we need.

Mr. WHITFIELD. No, we would love to do that because we definitely want to protect these children. But, also, when you have something pending for 14 years or 15 years, people are beginning to wonder a little bit.

Secretary BURWELL. We would look forward to that.

Mr. WHITFIELD. Thank you very much, and I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Massachusetts, Mr. Kennedy, 5 minutes for questions.

Mr. KENNEDY. Thank you, Mr. Chairman.

Madam Secretary, thank you again for making an appearance today.

I would like to commend the President's budget for including critical reforms to mental health and Medicaid, such as ending the 190-day lifetime limit on psychiatric inpatient care for Medicare beneficiaries and for expanding the electronic health record incentive program for including behavioral health providers. It is a big step forward.

I also support the President's proposal to reinstate the primary care bump, which, according to one study, resulted in an increase of appointment availability by 7.7 percent.

Do you think it is fair to say, Madam Secretary, that this proposal could also expand the program so that mental health and behavioral health providers in Medicaid could benefit from the bump as well?

Secretary BURWELL. Yes, we think that it is a continuum, and there are a number of different proposals, as you articulated, that are focused on getting us to a different level with regard to access to behavioral health and integration, as Mr. Schrader mentioned, in terms of integration of behavioral health.

Mr. KENNEDY. So, would you agree that adequate reimbursement levels are a critical piece to expanding the workforce to ensure that Medicaid patients have access to timely care?

Secretary BURWELL. We do. I think you know our proposal on primary care that we have in our budget is about making sure we do some of that. In addition, the proposal we have on behavioral health is actually focused specifically on some provider issues in terms of getting more providers, so we have that access.

Mr. KENNEDY. The President's budget I believe, Madam Secretary, also proposes lifting the federal exclusion that currently prevents some children from getting Medicaid coverage of early and periodic screening diagnosis and treatment services and limits terms. That means kids on Medicaid can't get both mental health care and physical care while they are patients at certain facilities known as IMDs.

Madam Secretary, can you tell us a little bit more about the importance of ensuring that all children, regardless of the setting, have access to comprehensive health?

Secretary BURWELL. We think it is important, which is why we have the proposal. I think it is an issue that I'm sure we may discuss, also, with Mr. Murphy, in terms of making sure that these kids have that access.

What happens, and if you visit facilities, when you are a parent and you are told, "Oh, here is a prescription. You have to go at a different time and a different place or it won't be paid for in the same way," that is prohibitive in terms of having a child get the services that they need as they need them. A warm handoff. So, whether it is in the facility itself and the payment mechanisms really make a difference to how children are receiving this kind of care. Our proposal is aimed at trying to help that along.

Mr. KENNEDY. Thank you.

I want to touch base a little bit on what Ms. Capps was getting at as well with regard to data. There are 14.1 million Americans in 31 states that have enrolled in Medicaid as a result of the Affordable Care Act, and an additional 4 million could gain coverage if the remaining states expand their Medicaid programs. These numbers represent, obviously, far more than just facts and figures. They are about prenatal appointments, cancer screenings, and lifesaving preventive care.

Perhaps most noteworthy, Medicaid expansion means that millions of Americans now access mental and behavioral healthcare. Medicaid is the largest payer of mental health services in the United States and it has the greatest potential to reform a broken system. In order to make the necessary reforms and to bolster the program more effectively, we need to first know how CMS reim-

burses doctors and at what levels. However, when I talk to doctors and patients and I ask how much Medicaid reimburses for their services, no one is able to point to exact figures, given the nature of those reimbursement mechanisms across states.

So, Madam Secretary, I would love your help in working with me on solutions to try to improve CMS's data collection for each state, so that we can ensure that we know at least how those payments stack up against private insurance.

Secretary BURWELL. We want to work on that issue. One of the things is because Medicaid is a state-run program. We are very dependent on the states in terms of their analytics, their data, and their systems.

Having said that, we look forward to, because we want to know and understand that information. Transparency of data and information is something I think we think is a very important thing across the healthcare system. Whether that is the dashboard that we put up in the December timeframe on payments in drugs, so that people can actually know which drugs have had the largest increase in cost, creating that transparency for the consumer and providers in terms of putting up on a Web site who are the largest recipients of Medicare payments. And so, this is a whole space that we believe is going to improve quality and reduce price.

Mr. KENNEDY. Thank you.

If I can, I have got about 30 seconds left. You touched based in your written testimony, and as well I think with Mr. Schrader and a couple of other times, about the transition off of fee-for-service basis in Medicare. I was hoping that you could just provide a little bit more detail on the learning and action, how that is going and what you see going forward, and if there are ways we can be helpful, in 20 seconds or so.

Secretary BURWELL. Important, thousands have joined. It is a means by which the government in its changes in payment tries to align with the private sector. So, we move together. We learn from each other. We get better results, and we prevent unintended consequences. And we are seeing that start to happen.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Thank you.

Welcome, Madam Secretary.

I am going to run through a lot of statistics, but it is an important issue because, as we are trying to deal with mental health reform legislation, one of the key issues is having more psychiatric beds because of the IMD exclusion. We used to have 500,000 psych beds in this country in the 1950s, and now we have less than 40,000. We need 100,000 because people in an acute phase of a psychotic break need a place to go besides being given a five-point tiedown in an emergency room or being sent to a jail cell or being discharged back in the streets, where they have a high risk for suicide, victimization, et cetera.

I want to do a couple of things. The consequence of non-treatment of serious mental illness, according to NIMH even back in 2010, was pretty staggering. They said that 40 percent of schizophrenics and about 51 percent of people with bipolar illness are un-

treated and a large part of the homeless, about 200,000 or so, living in abysmal conditions, have high risk for other medical problems, and 28 percent of them get their food out of the garbage. So, high risk for a wide range of things.

Out of those who are incarcerated, the seriously mentally ill make up 16 percent of the present population, about almost 50 percent of the overall prison population of mental illness, and high risk for other things. But I want to go through some of these things, too.

People with delusions and hallucinations, the longer that they go without treatment, the worse it gets. The longer a person waits for treatment for a psychotic episode, the longer it takes to get their illness under control. For bipolar disorders, the sooner a person gets on lithium or other treatments, the better their treatment goes.

But what happens here is you have a wide range of people with serious mental illness with Medicaid, with SSI and SSD recipients. The cost of untreated mental illness is pretty amazing. The direct cost that I see here for treatment of a serious mental illness, about $55 billion; indirect cost, about $70 billion. But, when you have added cost for emergency room care, private medical care, these costs go up considerably.

The cost of untreated diabetes in America is about $245 billion. That is $176 billion is direct medical costs. The reason that is important is many people with serious mental illness have very high risk for diabetes.

Similar high numbers are also there for cardiovascular disease, for pulmonary disease, for infectious disease, all of which have a higher mortality and morbidity rate for the mentally ill. And you probably know that studies have said the mentally ill tend to die 25 to 10 years sooner, not because of suicide, but because of other medical complications.

So, it comes down to this point: when we have asked the CBO to score the issue of what would happen if we looked at more hospital beds, they, quite frankly, admitted they couldn't do that and they simply took a number and the number of hospital days, psychiatric hospital days in America, and said, "Well, if we pay for them all, it is going to cost somewhere between $40 and $60 billion in 10 years. We have no idea how to do this."

We really need your help, and I actually think this would be significant savings for Medicaid and Medicare if we get this right. If we already know that people with serious mental illness are overusing emergency rooms versus caring for themselves, if we know that they have a higher incidence of those chronic illnesses I mentioned before, and we know that if they are not treated, it gets worse, it makes a lot of sense and dollars if we have hospital beds for them when they have this acute illness, stabilize them, make sure they have outpatient care then, instead of doing what we have been doing. And that is, we have traded those beds in the asylums for prison cells, for blankets on a subway grate, for the emergency room gurney, and the county morgue.

So, as we are going through this, I wonder if you have done any analysis here and can maybe talk about some direction that you are guiding CMS, because we need solid numbers of what it is costs

to not treat and what it costs to treat. I wonder if you could comment on that.

Secretary BURWELL. So, our estimation is that, by 2020, actually, just the treatment cost for behavioral health and substance abuse will be $280 billion. And so, that doesn't include even a number of the other things that you have talked about in terms of what this does as a nation. We agree, and as part of our behavioral health proposal, the idea of getting those people into care, our estimates are some of those people with severe issues don't get into care for 3 years.

Mr. MURPHY. Three years?

Secretary BURWELL. And that is about access. Yes. And so, making sure that we have the ability for access when it is severe or even before it is severe is an important part of the proposal.

With regard to our IMD proposal that Mr. Kennedy raised, I think that there are ways that we could be helpful in having conversations about how we solve those economics and how that was scored in terms of what we did. We would be happy to do that.

The other thing that I just think is an important part, sort of putting on my old OMB hat, so that we get to the place where we can understand how we spend money and what savings we get, and that sort of thing, is actually some of the money that we have asked for in this behavioral health money is about going ahead and doing the evidence-based work, evaluation.

I know many times people don't want to fund evaluation, but it is essential for the kinds of statistics that we need to show what you are talking about. But, in the meantime, we can work on our——

Mr. MURPHY. Thank you. Let's do this, because I believe we can save a lot of money. This committee really needs this because, I will tell you, there is bipartisan support that we have got to fix this problem to help Americans.

Thank you very much. I yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now I recognize the gentlelady from California, Ms. Matsui, 5 minutes for questions.

Ms. MATSUI. Thank you, Mr. Chairman.

Thank you, again, for being here, Secretary Burwell. I am glad you are here to highlight the ways that HHS plans to continue and expand critical investments in health and well-being of the American people.

The first step toward reforming our nation's healthcare system has been to improve access to healthcare by ensuring that everyone can obtain affordable healthcare coverage. We know that the Affordable Care Act has made great strides in that goal, and we must continue forward. We must also continue to be forward-looking and take the next steps in healthcare reform. We need to continue to make strikes toward ensuring that everyone has access to the right care at the right time at the right price.

I believe that there is great potential in the power of technology to help us achieve our goals of healthcare delivery system reform. Electronic health records can improve providers' ability to coordinate care, and technology such as face-to-face video between providers and patients and technology that allows providers to re-

motely monitor patients' chronic conditions can increase access to needed care, improve patients' outcomes, and reduce cost.

I was very pleased that this year's budget expands the ability of Medicare Advantage plans to deliver services via telehealth and enables rural health clinics and Federally Qualified Health Centers to qualify as originating telehealth sites under Medicare.

Secretary Burwell, I am pleased with this progress, but I think there is still much more we can do. Can you talk a little bit about the inclusion of telehealth in the budget and any other proposals that HHS is currently considering in this space?

Secretary BURWELL. So, I think we think that telemedicine and telehealth is an important part of getting access. We have talked about access. Certainly, in rural communities and other communities this is going to be an important tool.

We have taken two, as you articulated, very specific steps in our budget, because we thing Medicare Advantage should pay and because part of the reason that the field is not developing as much is because people don't get paid. So, if you don't pay for the ability to do these services—that is part of the Medicare Advantage.

The other part is finding the facilities that will meet qualifications, so you do it in an appropriate and safe way. And that is the proposal that you mentioned, and it is related to HRSA and our Federally Qualified Health Centers. We know that these health centers are serving literally millions and millions of Americans across the country, and most people actually have some in their district. And so, that idea that you can use them as a base.

The other thing that we are working on right now is—and it gets to Mr. Pallone raised in his earlier comments the issues of IHS, Indian Health Service. Right now, we are suffering from a very serious problem on our reservations in terms of youth suicide. In order to get providers in places like Pine Ridge, it is very, very difficult. And so, we are using our ability to actually use telemedicine as a means by which we can quickly get providers. Because when you have these suicides, making sure those children have the support they need, other children, is a very, very difficult thing to do quickly——

Ms. MATSUI. Yes.

Secretary BURWELL [continuing]. Because we can't get the providers to go.

And so, while we are working on permanent solutions, these may become the permanent solutions because they are stable. Providers come and go, but the telemedicine providers we think will be in a place where they are going to provide more care for a longer term.

Ms. MATSUI. Thank you very much, and I look forward to continue to work with you on these issues.

To ensure that Americans have the ability to access the right care at the right time, we must work hard to achieve that goal for the whole person, which includes access to mental health care. One of the goals of the delivery system reform is increased care coordination and behavioral health integration. We must ensure that people have access to a full spectrum of mental health services and that those services are integrated into medical care and coordinated across different providers.

I believe that the Excellence in Mental Health Demonstration Project, which I coauthored with my colleague, Congressman Lance, has the potential to reform our nation's mental health system by improving access to community-based care, and by integrating and coordinating that care across different provider types.

Secretary Burwell, thank you for including in the budget an expansion of this demonstration project to six more states. The more we can test out this model, the better chance we have of finding out what works, so we can expand it to those who so desperately need a better system of mental healthcare.

Would you like to comment further on HHS's work on this project and its potential?

Secretary BURWELL. Yes. We think it is a very important part of our work in terms of getting this integration and getting it quickly and doing it in a way that we can both get integrated care and, also, move towards where people are paying for value, not volume, in terms of getting the right payment to providers.

I think you know that, with your help and support, we have beat the statutory deadlines with regard to the implementation. And then, we have added to that by the proposal in the budget which we hope will be viewed favorably.

Ms. MATSUI. Yes. Thank you very much.

Mr. PITTS. The Chair thanks the gentlelady.

Now I recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Secretary Burwell, thank you, and thanks for reaching out.

We gave you a heads-up to talk about this CMS Web site thing. Of course, when you put something up, that means time, effort, and energy was placed to prepare for this to actually happen. Of course, it was up, it was down.

So, the basic question is, does CMS intend to go forward with this experiment?

Secretary BURWELL. In terms of the——

Mr. SHIMKUS. The Part D drug payment model.

Secretary BURWELL. So, with regard to this issue, I think as you appropriately reflect, this was something that came out ahead. With regard to the issue of high-cost drugs, which is what this issue is about in terms of the potential effort, what we have tried to do—and this is to the point of getting input in December—we had a meeting that had both those from the pharmaceutical industry and other stakeholders to come and talk about what can we do that maintains——

Mr. SHIMKUS. No, that is different than having a proposed rule. So, what you did was, what CMS did by shooting this publicly is raise a lot of red flags. Is there going to be a rule? When is there going to be a rule? When are you going to notify Congress? And so, that is why the questions.

Secretary BURWELL. The questions, in terms of speaking to the specifics of the rule, in this particular place because things are market-sensitive, I have to be careful in terms of it.

Mr. SHIMKUS. The market, that is why putting it up on the Web site, the market sensitivity to that, too, is just as bad.

Secretary BURWELL. That was an error. It was an error, and I think we have very clearly said it was an error.

Mr. SHIMKUS. But it was a premonition of future things to come.

Secretary BURWELL. In terms of specifically speaking to what and when we will do regulations, I want to be careful about that because of the market sensitivity. But what I think is fair to say is, with regard to this issue, we will speak to it more in the future.

The issue at hand is, in Medicare Part B, in terms of how the payments are done, they are done in ways where you, as a provider, are incentivized by a percentage. That incentive is, if you are going to be paid a percentage of the cost of something, then what we are doing is we are encouraging you to prescribe the larger-cost item. And that is the substance of the issue at hand and why we are focused on it.

With regard to the specifics, we hope to have more soon on that issue.

Mr. SHIMKUS. OK. Let me move to this issue on margins. The NIH states that the use of this is not appropriate means for controlling prices. So, the question is, why haven't you all responded in this process involved in the most recent petitions in this space and provide a sense of the agency's current thinking on margins?

Secretary BURWELL. We plan to respond to that. I think you are referring to the letter that I received from a number of Members in terms of the most recent questions, and we will respond to that letter.

Mr. SHIMKUS. Because, then the followup is just, obviously, the R&D and the risk and return. We need some clarity on this process.

Secretary BURWELL. Yes, and I think it gets to the bigger issue, which is what I was starting. It is the question of how we, as a nation—the high-cost drugs and the issue of drugs, when we look at Medicare expense and what we saw, the increases in 2014 came from mainly high-cost drugs. There were some changes in other things, but in terms of that, and what percentage of our Medicare budget will be paid to drugs continues to grow. And so, what we need to do is find approaches and strategies that balance both innovation—because we want that R&D to get the best things—but create some downward pressure. Because I think whether it is people in Medicare or individuals who actually pay for their drugs in employer-based care, everyone is seeing the difficulty in both specialty drugs, but in also some cases non-specialty drugs.

Mr. SHIMKUS. And my last thing, let me talk about Medicaid for a second. Under current law, illegal immigrants are not supposed to get Medicaid. However, reasonable opportunity period exists. So, the debate that is going on in America is, why is there a reasonable opportunity period for illegal immigrants when there may not be—in fact, there is not—for citizens who don't have this "reasonable opportunity period" to prove that they qualify, either through long-term care or because of their finances? And should that not be afforded to citizens the same as it is being afforded to illegal immigrants right now?

Secretary BURWELL. In terms of the affording it to immigrants, are you referring to within Medicaid immigrants aren't eligible?

Mr. SHIMKUS. That is correct, but, obviously, some are getting. There is a period of time in the law that requires—there is a reasonable opportunity period. So, there may be coverage for them to, then, either prove, yes, they are legal or not. So, then, the question is, why it is not afforded to legal citizens based upon finances and long-term care?

Secretary BURWELL. I think in Medicaid it is applied both to any——

Mr. SHIMKUS. Can you just check on that for me?

Secretary BURWELL. I will check on that.

Mr. SHIMKUS. I appreciate it. Thank you.

Secretary BURWELL. Because it may be the marketplace. It may be the distinction. Let us come back and find out because Medicaid is saying that it may be the marketplace. So, let's come back, if that is the question.

Mr. PITTS. All right. The gentleman's time has expired.

The Chair now recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Secretary. I want to join in the congratulations to you on the Affordable Care Act. While all of us acknowledge that there are some problems, we have made such tremendous strides, and it would be wonderful if we could sit down and just fix the things that we could fix, make it even better.

I had a whole bunch of questions to ask you. But, since July when abortion opponents released manufactured and highly-edited videos, my colleagues on the other side of the aisle have been on a mission to undermine women's rights. And apparently, today isn't any different.

But facts matter and not a single claim made by the other side has been supported by a single shred of evidence. On the contrary, three congressional committees found no wrongdoing in their investigations of Planned Parenthood. The chairman of one of the committees investigating Planned Parenthood, Congressman Jason Chaffetz, went so far as to say, "Was there any wrongdoing? I didn't find any," when asked about his investigation.

I would like to submit into the record, Mr. Chairman, a news article that includes this quote.

Mr. PITTS. Without objection, so ordered.so ordered.

[The information was unavailable at the time of printing.]

Ms. SCHAKOWSKY. Moreover, every state that has concluded their investigations into Planned Parenthood has come up empty-handed. In fact, a Texas grand jury ended up indicting two persons associated with the Center for Medical Progress, including its leader, David Daleiden, after their investigation uncovered illegal activity conducted by those individuals, not by Planned Parenthood.

I would like to submit into the record another article detailing that indictment.

Mr. PITTS. Without objection, so ordered.

[The information was unavailable at the time of printing.]

Ms. SCHAKOWSKY. Finally, just this week, The Washington Post editorial board published an article calling the so-called investigation, what I believe it is, a witch hunt. Not only do they point out that every state and federal entity that has investigated Planned Parenthood has found nothing, but the article also mentions the

troubling document requests and subpoenas issued by the chairman of the Select Panel to Attack Women's Health—that is what we call it—where I serve as the ranking member. I would like to submit that article into the record as well.

Mr. PITTS. Without objection, so ordered.

[The information was unavailable at the time of printing.]

Ms. SCHAKOWSKY. The relentless targeting of Planned Parenthood, the attack on women's health rights, and the disregard for facts have to stop. Here is what I want to ask you about this: research using fetal tissue conducted by reputable universities across the country has greatly contributed to our understanding and treatment of many diseases. I know you mentioned some of this before, but can you describe the importance of fetal tissue research and the advances that have been made possible because of it?

Secretary BURWELL. So, a number of the advances, as I mentioned, hepatitis A, mumps, measles vaccines, in terms of that. We also know that the research that is ongoing actually helps with issues around Down's, macular degeneration. Most recently, we have seen it contribute to our ability to work on getting an Ebola vaccine.

And so, this research is an important part of the research in advancing science. As I articulated before, we take very seriously the constraints and rules around the research at HHS and following those.

Ms. SCHAKOWSKY. So, there are definitely laws in place and regulations in place that make sure that this is done. Well, could you describe anything about the ethics of this?

Secretary BURWELL. Two of the things that I think are probably the most important is no valuable consideration. In terms of that, that has to do with the question of payment. And then, the second issue is consent. That is another issue that many states have laws about in terms of what people do. I think those are probably the two most important that people on both sides of this conversation have focused on.

Ms. SCHAKOWSKY. So, you can verify that there is no ability to make a profit on the sale of fetal tissue?

Secretary BURWELL. We have turned these documents over—they have been requested of the NIH—in terms of the attestations that our grantees have with regard to fulfilling the state and federal laws, both, in terms of saying that none of those things have occurred. That occurs when the grant is given as well as at the point of renewal of grants.

Ms. SCHAKOWSKY. Thank you.

I also wondered, in the brief time I have remaining, if you could just say what impact has Planned Parenthood had on access to reproductive health services and what it means for both men and women if those health centers were to be closed.

Secretary BURWELL. I think it is both reproductive health services, but I actually think it is important to recognize that it is broader service as well. So, about 3 million women receive services across the country every year, it is estimated. Those services are issues, also, of wellness and cancer screenings and others. So, reproductive health is one element, but it is broader in terms of the basic healthcare that women are receiving from this organization.

Ms. SCHAKOWSKY. Thank you so much. I yield back.

Mr. PITTS. The Chair thanks the gentlelady.

I recognize the gentleman, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

Madam Secretary, I apologize that I wasn't available to take your call the day you called. I appreciated you leaving the message. I knew we would have had a chance to talk today.

At the outset, let me just say I have got so much stuff that I need to cover, and I recognize we won't get through it all. So, I will submit some of this for your written attention.

Furthermore, because of the bill that repealed the sustainable growth rate formula last year, and now the payment reform that is going on in CMS—and Dr. Conway has been very good about coming in and talking to me—but I really think the ongoing dialog between HHS and the committee and Members of Congress, I mean, this will live on after this administration concludes and the next administration starts. It is so important that we get it right because this could form the basis, the nidus for what payment reform really looks like, not just in Medicare, but with other payers as well.

It is critical we get it right because the whole purpose in doing the Medicare SGR repeal was we had too many doctors that were legally practicing medicine. SGR pulled the joy out of the practice. I think we are on the right foot now with getting this fixed, but it does have to be done correctly.

But a couple of things I do want to cover with you. Somebody already referenced part of the Affordable Care Act, Section 1311(h), the part that deals with providers. It says—let me just read it, so I get it correct—that "Under the quality improvement," which is Section (h) of 1311, "beginning on January 1st, 2015, a qualified health plan may contract with (a) a hospital," and it goes through the parameters; "(b) a healthcare provider, only if such provider implements such mechanisms to improve healthcare quality as the Secretary by regulation may require."

Now can you understand why this makes many of the people that I interact with on a daily basis, the nation's physicians, can you understand why that makes them nervous? Have you begun to promulgate those regulations? Are those going to be new rules that we can anticipate? What is happening under Section 1311(h)?

Secretary BURWELL. Is it under 1332?

Mr. BURGESS. No, it is 1311.

Secretary BURWELL. So, I will have to come back on 1311.

Mr. BURGESS. OK.

Secretary BURWELL. We have done guidance under 1332. And I'm sorry, 1311(h) is not one that is front-burner, but we will come back. I apologize. Maybe I will know it by another name——

Mr. BURGESS. OK.

Secretary BURWELL [continuing]. But I am not connecting. So, we will come back on that. For 1332, we have issued guidance on. That is the one I think that many people are raising on both sides, a lot of conversations about that one.

Mr. BURGESS. Last summer you addressed the National Governors Association, I believe. I heard it on C–SPAN while I was driving around in my district through the miracle of satellite radio.

Governor Fallin from Oklahoma asked you some questions because of the problem she has in Oklahoma with prescription drug difficulties. She talked about a prescription drug monitoring program that she has developed in Oklahoma, but, apparently, Medicaid recipients fall outside of that. I think her question to you was can something be done to mandate the same prescription drug monitoring requirements that she has under her state through the federal part of the Medicaid program.

Secretary BURWELL. So, I will have to go back. But I think with regard to the mandatory using of a PDMP, a prescription drug monitoring program, it is occurring at the state level. All but one state has it in place. But it is done on a state-by-state basis in terms of having the physicians use it.

What we are trying to do—and I just met with the governors on opioids, and the governors produced a really good document that I would recommend for folks to look at in terms of their recommendations around this. Many of the states I think are trying to advance that. What we are trying to do is share best practices. I called two times, have called 50 states together, so that we can get the right procedures that are happening in some states applied to the others. If there are things we can do, we welcome the opportunity to do them. I think it is a state issue, but we will doubleback on that.

Mr. BURGESS. But her specific request to you was she needed help in the Medicaid program because somehow it fell outside what she had available to her as a governor under State law.

I will just say, speaking as a provider, we want to do the right thing. We want to be able to provide our patients who are in pain, we want to be able to provide them pain relief. At the same time, we want to participate in whatever diversionary prevention programs are out there. So, this is extremely important to providers, I will just tell you, having been on both sides of that issue.

Let me, in the brief time I have left, the issue of the unaccompanied minors, of course, Texas, the Lower Rio Grande Valley sector, I have been down there several times. I met with DHS. I met with your people, with ACF and ORR. I will tell you I am disturbed.

I am also on the Helsinki Commission. We had a hearing last fall on the Helsinki Commission where we heard from two victims of child trafficking. Both of these women were trafficked through family members, by family members, had come into the country illegally. Granted, OK, they broke the law. But they had very compelling testimony of why was no one looking out for us. They were delivered to a family, which subsequently, then, put them into a sex trafficking situation, and there was no respite, no help for these individuals.

We have had so many people in the last 2 years, so many unaccompanied minors come across. They produce a telephone number from goodness knows where. This is an uncle. This is a brother.

Look. Many, many years ago, I went through a child adoption process. I know how intrusive and exhaustive that was. We are just sending these people off to a telephone number that they happened to produce out of their back pocket when they are picked up out

of the river. And we wonder why now there are problems that are surfacing.

Again, I ask for your help in interacting with your agency, ACF and the Office of Refugee Relocation. We have got to do a better job. Yes, I get the security side and we have got to do a better job on the border. But, if we also have a role for HHS with dealing with people who end up in the country, we have got to do a better job there. So, I do welcome the opportunity to talk to you and the agency more about that in the future.

Secretary BURWELL. Thank you. We take it very seriously. We want those children to be safe. We have made a number of changes. We have ideas from PSI on the Senate side. We will be working to implement those. But, if there are other things we can do—we have put in an 800 number. The background checks have been expanded. There are a number of things that we are doing, followup calls, and that sort of thing. If there are other things that you see, having been through that same process you described, making sure you do everything you can to have children with safe people is something we think is extremely important.

Mr. PITTS. The gentleman's time has expired.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. PITTS. The Chair now recognizes Judge Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman.

Thank you, Secretary Burwell, for coming today, and thank you for your testimony. I was present when you testified, a couple of hours ago I guess it was. But thank you for coming and thank you for all the work that you do, and especially your willingness to embrace the people of Flint, Michigan. You and I had a brief conversation about that last week, and I want to thank you publicly for your willingness to engage in that very, very sad situation.

Mr. Chairman, I want to go back to the issue of the Affordable Care Act. I know that is a subject that some on this committee have talked about endlessly. But I want to go back to it from my perspective and to continue to say that the ACA has made a positive difference for more than 18,000 constituents in eastern North Carolina, which is where I am from, 18,000 constituents.

More than 18 million Americans who now have quality, affordable health insurance, that is, by any definition, progress. But many Americans, including 700,000 in North Carolina, are still missing out on the benefits of the ACA because our state governments have refused to expand the Medicaid program. It is absolutely a shame, and I will continue to say it every chance I get, it is a shame that 19 states in the United States have failed to expand Medicaid. They continue to block people from accessing healthcare funding which they have paid taxes for and rightfully deserve.

I applaud the President's efforts to ensure that all states, regardless of when they decide to expand Medicaid, are eligible for 100-percent federal support for Medicaid expansion during the first three years of participation. Yesterday Congress Green and other Democratic members of this committee and I introduced legislation to codify the President's vision to incentivize Medicaid expansion.

I also appreciate the President's efforts to combat health disparities for African-Americans and other subgroups in the 2017 budget request. The prevalence of health disparities is alarming and can be seen in all areas of health from access to care to susceptibility to illness, to the lack of diversity in the healthcare workforce and in clinical trials. The 2017 budget includes meaningful investments which can help improve access to care for underserved communities, develop new cures for diseases which disproportionately affect African-Americans.

And so, as I close, Mr. Chairman, I simply want to ask the Secretary one, perhaps two, questions. At what point, Ms. Burwell, under current law will states that choose to expand Medicaid no longer be able to receive 100-percent federal support for their expansion? At what point do they lose it?

Secretary BURWELL. At this point they would not start with 100 percent in terms of next year. And so, that is why we have proposed the legislation, because I think we think it is important for any state, whenever they come in, to have that benefit of the 100 percent.

Mr. BUTTERFIELD. And so, it is your position and the President's position that this would help encourage the states to expand their program?

Secretary BURWELL. We do.

Mr. BUTTERFIELD. You call it incentivizes the states to do it?

Secretary BURWELL. We want to encourage the states. As I said many times in that same session that you heard, probably you heard me say to the governors, "I want to work with you to do it the way that works for your state." And that means a conversation one-on-one with every state, but we are willing to do that. This is that important. I am personally engaged with every governor who wants to have that conversation.

Mr. BUTTERFIELD. And I know you are, and I thank you for that.

I yield back.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from New Jersey, Mr. Lance, five minutes for questions.

Mr. LANCE. Thank you, Mr. Chairman.

Secretary, last August the Court of Appeals here for the District of Columbia Circuit issued a decision interpreting the Federal Vacancies Reform Act that would prohibit various acting federal officers from serving in positions for which they had been nominated but not yet confirmed by the Senate of the United States.

The Department of Justice filed a petition seeking further review by the entire D.C. Circuit, and that was denied. A Washington Post article recently covered the story and quoted the Justice Department in saying that the Circuit Court decision here in the District of Columbia "casts a legal cloud over a number of acting government officials," and I think it is in various departments, but your Department was cited.

Do you know, Secretary, who is in an acting position in your Department subject to Senate confirmation who has not yet been confirmed by the Senate?

Secretary BURWELL. I do. I do because my Deputy Secretary for the Department—and I think you all know we are having a budget

hearing. Right now, HHS is 25 percent of the federal budget. At HHS, it is over $1 trillion that we are managing. There is only one Deputy. At some departments, other departments, there are Under Secretaries. These are statutory constraints in terms of we have one Deputy.

The Deputy that we have that we have nominated, we cannot find in our records or in the records of the administration anyone who has not been confirmed or had a hearing for that——

Mr. LANCE. Is that the only official in your Department who is before the Senate?

Secretary BURWELL. No, no, no, no.

Mr. LANCE. How many are there? How many are there, Secretary?

Secretary BURWELL. I think it is actually important, though. This is an important part of the process of making sure that we can do—you are an important oversight committee. My ability to run the Department well is about my ability to actually have people in place.

The second person is Dr. Karen DeSalvo. Dr. DeSalvo has bipartisan support, has been voted out of committee, and it has a hold and hasn't been able to go to the floor because she has a hold. This is an ongoing——

Mr. LANCE. So, there are two officials in your Department?

Secretary BURWELL. This has been ongoing for an extended period of time. We are working with our committee Chairs. We are working with others on both sides of the aisle.

But the question of our ability to——

Mr. LANCE. No, I want to know how many there are. Are there two? Is that the answer to my question?

Secretary BURWELL. That is the answer to the question who have been awaiting Senate confirmation.

Mr. LANCE. And has your Department reviewed whether or not this violates the Vacancies Reform Act, as has been suggested by officials in the administration?

Secretary BURWELL. We work with the Department of Justice to make sure that we are in compliance, and we work with them. The Department——

Mr. LANCE. And do you believe you are currently in compliance?

Secretary BURWELL. We believe that our Secretaries, as they are in their positions, are appropriately acting, and work with the Department of Justice in terms of what will be the appropriate next step.

But I think it actually is important, though. As a government, this question of our ability to function, and the fact that not only that, and I am very thankful and appreciative that today I hope while we are in this hearing that Rob Califf will be confirmed for the FDA, and thanks for the bipartisan support on that one. But there are others as well, in terms of two times we nominated a head of——

Mr. LANCE. I have concerns about the fact that I think that all agencies have to follow the Federal Vacancies Reform Act. And if a person has not received confirmation, there may be, under the Federal Vacancies Reform Act, a cloud over that person's continuing in the office for which he or she has been nominated, not

yet confirmed. Obviously, the Senate is an equal partner in the process, confirmation, and initial appointment by the President. I would hope that your Department would review that.

Regarding medical device regulation, when are we going to have regulations regarding medical gas regulation? I am very concerned about that issue. The lack of regulations and lack of an approved label for medical gases has created confusion for both the FDA and the regulated community. I believe this has been going on for four years. We would like to work with your Department. Might you be able to discuss with us when the FDA could meet the statutory deadline for regulations that are supposed to be in place by July of this year?

Secretary BURWELL. I look forward to following up on specifically where we are in terms of that specific regulation.

Mr. LANCE. Very good. I think regulations have to occur by July, and I am concerned that——

Secretary BURWELL. And it is medical device?

Mr. LANCE. Medical gas regulation.

Secretary BURWELL. Medical gas?

Mr. LANCE. Yes.

Secretary BURWELL. Thank you. Thank you.

Mr. LANCE. Thank you. I will yield back 12 seconds.

Mr. PITTS. The Chair thanks the gentleman.

Now I recognize the gentleman from New York, Mr. Engel, five minutes for questions.

Mr. ENGEL. Thank you very much, Mr. Chairman.

Madam Secretary, welcome. I, too, received a call from, which I appreciated very much. I think it is just typical of your thoroughness and competency and the job you have done since you were appointed Secretary. And besides, my mother's name was Sylvia, so I had to like you from the beginning.

Secretary BURWELL. Thank you.

Mr. ENGEL. I want to just piggyback at first on a comment that Mr. Butterfield made because it is something that has really been bothering me. I know that a lot of our friends on the other side of the aisle don't like the Affordable Care Act, and we voted 62 or 63 times to repeal it, which I think is a waste of time.

Any major bills of this substance in the past have always been tweaked once the bill comes out and you see what works, what doesn't work. Nothing is going to work 100 percent. And so, if a bill is not doing everything we wanted it to do, we could make some legislative changes, and that is really the way to do it, not try to repeal it. But our friends on the other side of the aisle have refused to do that.

What also is frustrating is, again, when governors are refusing to expand the Medicaid program. My mother Sylvia used to have an expression, don't cut off your nose to spite your face. And that is exactly what the Republican governors are doing that have refused to expand the Medicaid program to really help the citizens of their states.

So, I am wondering if you could comment on anything I have just said.

Secretary BURWELL. So, you know, as we have spoken about a number of times in this hearing, I think it is so important to make

that progress in terms of the coverage, in terms of the benefits that we can see through expansion. We see that both for individuals, and I have had the chance to meet those individuals as I have traveled across the country, in terms of what it means for them, whether it was someone being diagnosed with cancer and actually catching the cancer and being able to treat it, in terms of an extreme situation, or just the security of knowing that they have the coverage and can do prevention as well.

But I think the economics are also equally important. That is about the individual, and that is important. But the economic issues in terms of hospital closures, in terms of uncompensated care, in terms of people's ability to pay their bills, are all things that are important consequences that we believe other states are already seeing the benefits from. We would like to see the rest of the states and, as I have said before, we are willing to work with any state on the approach that they think is right with them. We just want to make sure we meet the standards that you all have given to us statutorily, which is making sure that affordable care is available.

Mr. ENGEL. Thank you.

I would like to ask you a few questions involving Puerto Rico because you had mentioned Puerto Rico before. You mentioned it in your submitted testimony. Could you please describe the current economic situation there and how it has negatively affected the healthcare system there?

Secretary BURWELL. The economic situation is dire. Certainly, my colleague at the Treasury Department, Mr. Lew, has taken the lead in terms of both our talking about that issue as well as working with the Congress on fundamental issues that we think will make a difference to getting to a different place economically.

But the healthcare issues are very closely intertwined. And so, the issues of legislation to help in terms of a way forward on the economics are very intertwined. The success of that is intertwined with healthcare. It is because, traditionally, payments have not been equitable, and we talked about that, touched on that a little bit earlier in one of the questions in terms of the payments on the Medicaid side.

What that does is it leads to a number of things. Obviously, it leads to coverage issues in terms of what kind of coverage people get. It also leads to provider issues because providers aren't paid.

What we have proposed in our budget is a proposal that over time would bring the payments in Medicaid to a more equitable space and at the same time require reforms in terms of meeting certain standards of the performance of the Medicaid program. So, we think that we have a proposal before the Congress that can complement in an extremely important way.

I think right now with Zika, the numbers continue to rise. Today, this morning I got my briefing, 111 cases in terms of the U.S. In Puerto Rico right now, they are being spread by the mosquito there.

We know the penetration of both dengue and Chikungunya in Puerto Rico. And so, this health issue, if those children, if pregnant women get Zika and have children with microcephaly, the cost is between a million and $10 million per child.

Mr. ENGEL. So, it is really fair to say the situation in Puerto Rico is both an economic crisis and a healthcare crisis? That is what you are——

Secretary BURWELL. It is fair.

Mr. ENGEL. And the President has laid out what I think is a very reasonable approach to addressing the issues at hand, and I hope this committee will give the President's proposal serious consideration.

I want to ask you about your testimony. You described several steps the President has proposed to address the Puerto Rican crisis. Can you elaborate on his plan and what it does and how it aims to solve the problem?

Secretary BURWELL. So, I think the changes in Medicaid are the place where we have the most important proposal. It would do the changes over a period of time in terms of that payment. It would change the cap as well as change the payment matches over the period time, at the same time that reforms are required.

Mr. ENGEL. And then, my last question is, wouldn't you agree that Puerto Rico is a prime example of the tremendous risk we would face if Medicaid moved to a block grant system, because of Puerto Rico's financing design, it is really not equipped with the flexibility it needs to adapt to financial downturns?

Secretary BURWELL. Yes, which is why you see monies in the supplemental proposal that you will be reviewing from us. Yes is the answer, and that is part of why you will see funding in the supplemental, because now they have a crisis in Zika.

Mr. ENGEL. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

I recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

Thank you, Madam Secretary.

This morning a new GAO, Government Accountability Office, report released found that in 2014 CMS did not resolve inconsistencies related to incarceration status for about 22,000 applications, with $68 million in associated subsidies in the Federal Exchange. Some of these areas appear to have continued into 2015 and, with unresolved inconsistencies, CMS is at risk of granting eligibility to and making subsidy payments on behalf of individuals who are ineligible to enroll in subsidized coverage.

CMS told the Government Accountability Office "The agency elected to rely on applicant attestations on incarceration status." In other words, CMS is literally taking criminals at their word and relying on them to tell the truth.

I want to give you an opportunity, if you are familiar with that. But, based on that situation, you can understand, I would suspect, why Americans often don't trust the agencies to not cut corners on administering the ACA, when they are not even going through and doing the due diligence, according to the Government Accountability Office, on making sure that folks who are incarcerated aren't receiving subsidies.

Of course, I am concerned about this as a 28-year criminal defense attorney before I came to Congress. A lot of these folks are

not known for telling the truth, and you all are relying on just a statement from them that they are not really in prison.

Secretary BURWELL. So, with regard to this report, I think that this is a continuation of a previous study. And I apologize, but——

Mr. GRIFFITH. Yes, ma'am.

Secretary BURWELL [continuing]. I think I have seen preliminary. In terms of the recommendations in this in the preliminary, we fully agree with those.

But let me speak to the other. With regard to the issue of making sure the right people are getting any of the taxpayer subsidiaries, we take it very seriously. Last year alone, 1.6 million people were taken off or had chances because we didn't have the information that we needed. That was done within a window, the statutory window, that we have given, which is about between 90 and 95 days, and we continued. So, 1.6 million people in terms of aggressively working.

When the GAO report originally came out—and I think you know it was a secret shopper. So, the actions that were taken by these individuals, if you weren't the GAO, would have been criminal offenses that, as you know——

Mr. GRIFFITH. Yes, ma'am.

Secretary BURWELL. And I wasn't asking about that. My concern is—and, look, I do understand, so I don't want anybody out there watching on TV to think that you should have already read this report, because I had an opportunity to read it while you were answering everybody else's questions.

[Laughter.]

But it is of concern that it doesn't appear that some of the folks who work for you are taking it seriously when the folks who show up on the PUPS list, the Prisoner Update Processing System, you all have decided not to use that in the case of ObamaCare, but you are using it in the cases that relate to Medicare. You are using it for other purposes, but they decided not to use it in this case, and then, they are just relying on somebody's statement that they are not incarcerated. Each individual is different. Some may not be in there for a crime of moral turpitude but for some other crime, but, as a general rule, a lot of these folks are in jail because they lied about something in the first place or took money when they weren't supposed to. And we are just going to rely on their word?

I would ask you to check into it. I know you haven't had a chance to read it, so I am not saying that you should have a ready-made answer. But I would say that you need to read it and you need to let us know, and we will do it as a followup, if you would. When do you suspect or when do you expect these problems to be fixed? Again, I am not expecting an answer this morning, but I would like to get an answer at some point in time.

Secretary BURWELL. I would be happy to. Aggressively, as issues are raised, we want to take care of them.

Mr. GRIFFITH. I do appreciate that.

I had some other questions which I will have to submit. I see my time has run out and I don't even have time to finish the question, much less get an answer. We will submit those to you afterwards as well, but they relate to testimony previously in front of the committee relating to not giving the ability for states to have work pro-

grams as a part of the Medicaid and CHIP services. And we will follow up with that afterwards because——

Secretary BURWELL. Thank you.

Mr. GRIFFITH [continuing]. Like I said, it is a long question, and I don't even have time to get through it.

But I do appreciate your being here today and always being willing to answer our questions.

Secretary BURWELL. Thank you.

Mr. GRIFFITH. And I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

Now I recognize the gentleman from California, Mr. Cardenas, 5 minutes for questions.

Mr. CARDENAS. Thank you very much, Mr. Chairman.

In this committee we have been discussing the consequences of not properly investing in mental healthcare. The problem of insufficient mental healthcare shows up in our nation's jails more than anywhere else in the country, particularly jails where kids are locked up. Federal law does not allow kids enrolled in Medicaid to receive federal funds while in detention. But nowhere in the law does it say that these kids have to be kicked off of Medicaid. Yet, that is exactly what states are doing around the country. For them, permanently terminating Medicaid coverage is easier than suspending it temporarily. That is the states.

When kids who already were on Medicaid are allowed to resume their needed access to mental healthcare services once they return home, the government saves millions upon millions of dollars each year when crimes go down because these children have access to their mental healthcare instead of having to wait months and months and months to get back into the system.

Madam Secretary, can you talk about the Department's work to ensure that kids who are on Medicaid can stay on the program once they are back on the streets?

Secretary BURWELL. With regard to this issue, I think it is related to our broader criminal justice work and our second-chance work that the President and the Attorney General are both very focused on. We are working hand-in-glove with the Attorney General and the Department of Justice to make sure that, both with regard to Medicaid or the marketplace, that we both meet the standards that Mr. Griffith has talked about, but, as well, making sure that those who come out have the opportunities that they need with regard to having healthcare. And so, it is across the board that we are working with the Department of Justice on it.

Mr. CARDENAS. Thank you.

Access to reproductive healthcare for women and families is very, very important. I am glad to see that the President understands the value of critical reproductive health programs like Title X and the Teen Pregnancy Prevention Program and Personal Responsibility Education Program. It reflects in his budget proposal as well. I am glad to see that.

During a time where we continue to see attacks on the state level to restrict access to reproductive health, national investments in family planning, cancer screens, STD testing, and sex education are more important now than ever to keep our families and communities healthy and safe. Latinas, in particular, are more likely

to experience higher rates of reproductive cancers, unintended pregnancy, and face added cost and language barriers to getting healthcare.

Secretary Burwell, could you talk about why it is important to invest in women's health? Can you share any information about efforts to target hard-to-reach populations?

Secretary BURWELL. So, the importance of the preventative services, I think everyone knows what difference they can make, whether it is in the whole area of reproductive health, but women's health in general. Mothers often, they are the last to go in terms of taking care of those preventative services.

And so, there are a number of things that I would highlight. One is the importance that for all folks, because of the Affordable Care Act, that there are free preventative services without co-pays. So many people don't realize that and don't use those services, whether that is everything from your flu shot to some pre-cancer screenings.

I think particularly with hard-to-reach populations, one of the most important things that has happened over the last years is that the drop in uninsured in the Latino population is 4 million. So, those 4 million people now have access to quality, affordable care, and that is step one.

Step two means, though, we have to take that coverage and make it actually care. They have the insurance, and so, doing that. And so, some of the programs that you mentioned and some of that work is in CDC in terms of the Center for Disease Control and Prevention.

But we are working to make sure we are reaching those communities. We have something called Coverage to Care, which is an effort to make sure people who get that coverage understand how to access a primary care physician, understand how to go about using the care, because many people it may be for the first time they have it and they don't know. So, it is about the insurance, but it is also about the care and, then, it is about the public health issues that we are supporting and promoting.

A Million Hearts is another one where there is a disproportionate number in the Latino community who have heart disease. The Million Hearts efforts is specifically targeted toward heart disease.

Mr. CARDENAS. Thank you for explaining what we are doing and what we should be doing more of. So, thank you.

I was one of those uninsured for a portion of my life when I was a child.

One way to make sure that we improve ourselves as a country is we need to pass the EACH Woman Act and Women's Health Protection Act, two proactive bills that can turn the tide in the right direction. So, once again, thank you for doing what you can with the resources you have.

One of my colleagues mentioned what we are doing on ORR. My question is, what can Congress do and are we providing you the services necessary to do the job that you need to do?

Secretary BURWELL. We have a budget proposal with resources that we do need. So, I hope that will receive consideration.

Mr. CARDENAS. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it.

Thank you, Madam Secretary, for coming. And also, thank you for reaching out to us prior to the hearing as well.

I have a couple of questions. CMS recently released a final rule for the Medicaid-covered outpatient drugs, but also requested comments on the definition of line extension drugs. As you know, there is a strong Member interest in ensuring that any further Medicaid drug regulations for line extensions specifically exempt abuse-deterrent formulations of drugs such as opioids to incentivize continued development of abuse-deterrent formulations. We believe CMS can do this under current statute. However, the budget includes a proposal to tweak the statute in this case. Is the budget proposal intended to clarify the law or is it requested because CMS does not have the authority to clarify this administratively?

Secretary BURWELL. We would like statutory help with this.

Mr. BILIRAKIS. OK. Well, that is the answer I wanted to hear because we can do that.

Secretary BURWELL. We need that. We need the help. I think across the board this question of how we treat abuse-deterrent drugs, the recent changes we just announced at FDA for how we are going to review opioids, new opioids coming to market, that we will actually consider the issues of addiction as part of the decision, not just is this drug safe and effective for an individual. These are important things, and I think they weren't necessarily always considered.

Where we have administrative authority, we are going to use it. Where we believe we need some help, we are asking.

Mr. BILIRAKIS. Very good. Thank you. Thank you.

The next question, in the December of 2015 OIG report, the IG Office stated that CMS could not ensure that the advanced premium tax credit payments made to qualified health plan issuers were only for enrollees who had paid their premiums. CMS did not have a process in place to ensure that the premium tax credit payments were made only for enrollees who had paid their monthly premiums and was relying on insurance companies to provide that information. Does CMS now have policies and procedures in place to calculate premium tax credit payments on an individual level without relying on insurers' attestation and assurances?

Secretary BURWELL. Yes. We historically were using the processes we used for Medicare in terms of payments in that space, but we actually have gone ahead of that, and starting in January, it is on an individual basis. What that actually means—and you can see that it is happening—is the number——

Mr. BILIRAKIS. This past January?

Secretary BURWELL. This January.

Mr. BILIRAKIS. OK.

Secretary BURWELL. So, in place and we have seen the results in that the number of those enrolled in the marketplace actually is lower because we had more people come out. Because we are reconciling with the issuers on a real-time basis, on a policy basis, instead of an aggregate basis, is the answer to your question.

Mr. BILIRAKIS. Very good. Thank you.

The last question, on or about February 5th, CMS posted contractor instructions for its new demonstration that would test changes to the way Medicare reimburses Part B drugs—I know that Representative Shimkus touched on this—which currently uses the average sales price of the drug plus 6 percent. Those instructions appear to have been taken down at the moment.

What additional payment changes is CMS considering beyond the modifications to the ASP reimbursement rate? How will CMS select the drugs to which these additional payment modifications will apply?

Secretary BURWELL. So, with regard to that specific issue, it was an error. It went up. We will be coming out with followup on that soon.

I think probably the most important issue that CMS is considering in this space is actually in the budget. So, it requires statutory change. It is the issue of negotiating authority for the Department with regard to specialty and high-cost drugs in terms of ability for the Department to negotiate. And so, that is the most important one that, when you ask what are we considering, we have a budget proposal. Obviously, now that is with the Congress in terms of its consideration.

Mr. BILIRAKIS. All right. Thank you very much. I appreciate it, Madam Secretary.

I yield back, Mr. Chairman. Thank you.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions.

Mr. BUCSHON. Thank you, Mr. Chairman.

Thank you, Secretary Burwell, for being here.

The Affordable Care Act has resulted in about 30 million people still uninsured. Many, in fact, the majority of people gaining insurance are through Medicaid expansion, which, as a provider—I was a heart surgeon before—I can tell you it doesn't guarantee access to the healthcare system, other than through the emergency room.

On the exchanges, deductibles are increasing, premiums are up, insurance companies are losing billions of dollars, and there are reports that the administration, as was previously outlined by the chairman, is illegally making payments to prop up the exchanges.

Non-exchange policy costs are skyrocketing, pricing businesses out of the marketplace. That is not my opinion. Just ask any business that is dealing with this.

The 30-hour workweek requirements are hurting school districts, county governments, local governments on fixed budgets, resulting in loss of wages for the employees.

The Meaningful Use Program, which, by the way, I am a supporter of electronic medical records—we had them in our practice since 2005—but the Meaningful Use Program, in my view, clearly needs pause because there are significant problems with it. The Doctor Caucus gave this opinion also to Dr. DeSalvo a couple of weeks ago.

And the worst problem is the cost to healthcare is the biggest issue, in my view, and there is no significant effect on the cost of healthcare. Now that is true that payments through Medicare may

be globally down, but the individual costs for services actually continue to rise.

I am going to focus my question, though, on the Healthy Indiana Plan 2.0, which is, as you know, Indiana's answer to covering low-income citizens, which is a program that is working. Last month Congresswoman Susan Brooks, Senator Dan Coats, and I sent you a letter expressing our concern about CMS's decision to use what we consider a biased contractor to conduct "independent review" of Indiana's Healthy Indian Plan 2.0.

I know Governor Pence has been vocal about his concern with this second federal review led by a hired contractor that has a clear and documented bias against plans like Healthy Indian Plan 2.0.

Mr. Chairman, I have a letter from Senator Coats, myself, and Susan Brooks that I would like to submit for the record.

Mr. PITTS. Without objection, so ordered.

[The information was unavailable at the time of printing.]

Mr. BUCSHON. I just wanted to reiterate that I think it is the wrong approach since the contractor is previously on the record being critical of Indiana's model and now is supposedly going to objectively help evaluate it.

So, I am sure as you know, under the Federal Acquisition Rules, there are established organizational conflict-of-interest rules. In the interest of real objectivity, would you commit to sharing CMS's analysis of the contractor's adherence to those standards with the committee and myself?

Secretary BURWELL. Congressman, I think I have responded to that.

Mr. BUCSHON. You have and I have read that letter. I don't have it on me, but I have read your letter.

Secretary BURWELL. And in that response, I articulate that the individual that is mentioned in terms of the issue of conflict is not an individual that is part of the review with regard to that.

With regard to the broader——

Mr. BUCSHON. Well, that is different than our understanding, the Governor's, myself, our Senator, and a couple members of the Energy and Commerce Committee.

Secretary BURWELL. Then, we should go back. Our understanding of the individual that was mentioned in the communications that we have had, it may be——

Mr. BUCSHON. Well, it is the Urban Institute.

Secretary BURWELL. There is the issue of——

Mr. BUCSHON. So, how can CMS ensure the study is unbiased, given the Urban Institute's documented institutional bias against consumer-directed healthcare plans in Medicaid?

Secretary BURWELL. First, we run our usual contracting process, which you were referring to, in terms of that it is a separate contracting process, and Urban Institute does this type of work and has on a non-partisan basis for years.

The question of the bias was in reference to an individual that is not affiliated with this piece of work. And so, maybe we have a misunderstanding.

Mr. BUCSHON. Maybe we are at crosshairs there——

Secretary BURWELL. Yes.

Mr. BUCSHON [continuing]. But the Governor and myself——

Secretary BURWELL. Yes.

Mr. BUCSHON [continuing]. Congresswoman Brooks, and Senator Coats didn't quite see it that way.

Secretary BURWELL. So, let's go back and try to understand whether we are talking about a different individual——

Mr. BUCSHON. OK. I appreciate that.

Secretary BURWELL [continuing]. Or making sure we understand fully the——

Mr. BUCSHON. Yes. Can you, then, submit to my office a further clarification of that?

Secretary BURWELL. Sure. Absolutely.

Mr. BUCSHON. I would appreciate that.

RAC audits are an issue, and I know that was brought up. Both the contractors and in a couple of different areas, hospitals have millions of dollars sitting on the sidelines waiting after these audits saying they have improperly been paid through the Medicare program. And I have a list of the things that are supposed to be happening with the RAC audits to make sure they are accurate and fair, but I can just tell you that, from a practical standpoint, this is a big problem and they need to be reviewed further whether or not they are in compliance on an individual case-by-case basis.

For example, there is an issue with Herceptin, which you probably know about, right? I can tell you my wife continues to practice anesthesia, and this is about multi-patient vials, so to speak. And I will submit that question for the record because I am behind. But the point is, in practicality, even though it says that you can use one vial for multiple patients, from a practical standpoint for safety reasons, liability reasons, that is difficult to do. So, I will submit that question, but that needs to be reviewed.

Secretary BURWELL. And I think we have reached out to make sure that we get the information from your staff on those specific examples.

Mr. BUCSHON. You have, yes. Thank you.

I yield back.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the questions of the members present. We have time for one followup on each side. The Chair recognizes Ms. Castor for a followup on this.

Ms. CASTOR. Thank you, Mr. Chairman. And, Mr. Chairman, I want to compliment you for having this hearing today because I also serve on the Budget Committee. Unlike the Budget Committee, where there was a break with decades of tradition in not inviting the OMB Director to come before the committee to discuss the administration's budget, you understand the importance of having this dialog and the ability to have members on both sides of aisle ask questions. So, thank you very much for holding the hearing today.

And it is really too bad that the Budget Committee did not have that opportunity because, in order to tackle the long-term debt that faces this country, it is going to require bipartisan solutions. The CBO, the Congressional Budget Office, projects that the debt increase over the 10-year window will mainly be attributable to the aging of the population and its connected healthcare costs and Medicare and skilled nursing.

The number of people who are at least 65 will increase by 37 percent by 2026, from 48 million Americans to 66 million Americans. That is going to call on Medicare and skilled nursing like never before. So, we have got to work together to tackle these issues.

And the problem with the Republican budget that has come out of the Budget Committee and, then, passed on the floor in the past years is that those fundamental overhauls such as block-granting Medicaid or turning Medicare into a voucher simply shifts the cost to Medicare beneficiaries, families, and states. And those are overly-simplistic solutions that are not going to work for American families, and it is not going to give us the opportunity to make the reforms in Medicare that are necessary to tackle the long-term debt.

So, this is difficult. This requires bipartisan cooperation. There is no silver bullet.

Madam Secretary, I would like to ask you here at the end of this hearing and after a few years in your job and as OMB Director, what gives you hope in reform? Is it prescription drug reform, the Accountable Care Organizations, payment reform? What do you recommend to us to work on in a bipartisan way to tackle the tough long-term debt issues driven by the aging American population?

Secretary BURWELL. So, I think that what gives me energy and gives me hope is that I believe we are at a transformative time and what was passed was actually in terms of what you all passed and gave to us to implement, is tighter constraints than we even had before in terms of the rules and the changes, and how we will push through change. And so, we are working very hard to implement it. And so, those types of things are extremely important.

But what is happening right now, whether it is in the private sector or the public sector, whether it is the issuers and insurers or private companies, large self-employed companies, they are ready to make the change, because we all can't afford healthcare at these prices. And so, it is not just about Medicare. It is not just about the marketplace.

I was thrilled to hear the commitment on delivery system reform, because for me that is probably the most important thing I can do in the next 10 to 11 months—it is actually under 11 months now—is make sure that we put in place the changes. Some of that has to do, we talked about the data and the data blocking and getting the help we need there. Some of it has to do with the support for the expansion of ACOs, the bundling, some of these other issues, understanding where we can make it better in terms of some of the oncology stuff we heard today. But that working in partnership is what I believe will make the long-term difference.

And the other thing I think is extremely important, that this is owned by the Congress as well as the Executive Branch, because I think that will also make sure it is done in a way that is consumer-friendly and consumer-focused, as well as getting the change throughout the country. And it is not just about CMS or providers or insurers, but we can make it a broad change for the country.

So, I am optimistic. This is hard, but I believe we are taking some of the steps that we know are going to get us there.

Ms. CASTOR. Thank you very much.

Mr. PITTS. The gentlelady yields back.

Madam Secretary, as we have discussed on the phone, in hearings, several occasions, the California Department of Managed Health Care issued a directive mandating that all plans immediately include coverage for all legal abortions. And this has resulted in pro-life churches/schools being forced to pay for abortion coverage in their health insurance plans. This action by California is a direct violation of the Weldon amendment, which your Department is tasked with enforcing.

Last year when you testified before us, you said, "We have opened an investigation in the Office of Civil Rights at HHS to investigate. We take this seriously. We're trying to move through the investigation as expeditiously as possible."

Now this directive was issued 18 months ago. The investigation was launched 15 months ago. Still, no corrective action has been taken.

So, here is my question: first, would you consider this to be an expeditious investigation? And secondly, what specific details about the investigation can you provide? What steps have been taken? Why has this matter not been resolved? And will you set a date by which corrective action must be taken?

Secretary BURWELL. Mr. Chairman, as you know, when you called, actually, originally, before the investigation started, yours was one of the calls. There are a number of your other colleagues that called. There were two or three colleagues that called. When you all had called, at that point I talked to OCR and we opened the investigation, because I take seriously the issues that you have raised and we are going to continue.

The investigation is opened. It is not complete. Is it expeditious? I would have liked for it to have moved more quickly than it has moved, but the investigation is open and, until it is closed, I am not at a place to discuss in terms of what the investigation has yielded or will yield.

With regard to the issue of timing, as I said, I am not satisfied with our speed, continue to work on that issue, but don't feel I can give you a specific timeframe because it is an investigation and I need it to run its ability and its course.

Mr. PITTS. Thank you.

I will yield to Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. I will just take 30 seconds.

You talked about an engaged patient. The Commonwealth Fund talks about an activated patient. Consumer-directed health plans, HSA-type plans can help with this. There is the availability of a Medicare MSA, but it is impossible to find one. Nobody at 1–800–MEDICARE knows anything about them. No place on your Web site at medicare.gov can you go and get information on a Medicare MSA. My feeling is this is something where really you could involve the patient in helping to control cost and payment reform and product delivery.

So, we really do need to work on this. It is something that has been available since 1996, but they are just vacant on the Web site.

Secretary BURWELL. It is not what I am familiar with. So, I will check and follow up and see where that stands. We will get back to you.

Mr. BURGESS. All right. Thank you.

Mr. PITTS. Yield back.

That concludes the questions that we have today. We will have followup written questions. We ask that you please respond.

I remind the members they have 10 business days to submit questions for the record. So, they should submit their questions by the close of business on Wednesday, March the 9th.

Again, Madam Secretary, you have been very patient, very forthright. Thank you very much for coming. A lot of good information here today.

Without objection, the subcommittee hearing is adjourned.

[Whereupon, at 12:33 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Secretary Burwell's Hearing on
"The President's Fiscal Year 2017 Budget"
E&C Health Subcommittee
February 24, 2016

Attachment — Additional Questions for the Record

Note: All responses are accurate as of February 24th, 2016.

The Honorable Joseph R. Pitts

1. **Are you or anyone at HHS, working on an executive order with the White House to repeal the non-interference provision in Part D? If so, please expand.**

Answer: To my knowledge, we are not working with the White House on an Executive Order that would allow the government to negotiate prices.

Having said that, drug costs are not just the state and Federal governments' fastest growing cost, but are a real kitchen table issue for working families and retirees. Per capita Part D costs increased by 11 percent in 2014, driven primarily by increased spending on high cost drugs in the catastrophic phase of the benefit, which grew much faster than any other part of the program.[1] The extremely high cost of certain specialty drugs raises issues about whether beneficiaries have access to the drugs that they need most. The President's FY2017 Budget proposes one potential solution for this issue: allowing the Secretary to negotiate prices for high-cost drugs.

Over the past several months, HHS has engaged with consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from state and Federal government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients.

We welcome continued engagement and feedback as we work together to address this rapidly growing cost center, while continuing to support innovation and access.

2. **As you may be aware Chairman Upton, Brady, Hatch and Alexander wrote to CMS concerning the "Medicare Drug Spending Dashboard" launched on December 21, 2015. In that letter, the Chairmen expressed concerns about the selective nature of the data presented and if it would be helpful without context. It is my understanding that CMS intends to add a hyperlink on Medicare Plan Finder to the Medicare Drug Spending Dashboard, estimating implementation for 2017 Open Enrollment in Fall 2016. What do you plan to do to ensure that data related to the dashboard is presented in the appropriate context?**

[1] https://blog.cms.gov/2015/11/20/remarks-of-cms-acting-administrator-andy-slavitt-at-the-hhs-pharmaceutical-forum-innovation-access-affordability-and-better-health/

Answer: As you noted, CMS intends to add a hyperlink to the Medicare Drug Spending Dashboard on the Medicare Plan Finder on Medicare.gov, which estimates implementation for 2017 Open Enrollment in Fall 2016. The CMS webpage that includes the dashboard[2] provides detailed information on the methodology[3] underlying the data presented as well as background information providing the context for this data release. CMS is committed to increasing the transparency of our programs by making more data available to the public. The release of the Medicare Drug Spending Dashboard is another step CMS is taking to further transparency. Our goal is that more information sharing will inform health care decisions, policy considerations and encourage collective problem solving around the important issues of providing more affordable and accessible medications to beneficiaries.

The Medicare Dashboard is an important part of a larger story. By sharing this information and allowing people to analyze the data, we can increase the knowledge around drug spending and support efforts that to evaluate whether public dollars are being spent most effectively. While data on all Part B and Part D drugs are made available through our other annual public transparency releases, the Medicare Dashboard provides additional information and trends on a subset of significant drugs. Drugs are included in the dashboard if they are likely to have an impact on spending, noted by the highest total Medicare program spending, high spending per user, or large and impactful increases in their cost per unit. Thus, these drugs are likely to have an impact on spending and should spur public discussion of how these products are affecting the Medicare program.

We also seek to stimulate the release of additional data that will promote a more complete understanding of value and patient affordability. For example, the Agency for Healthcare Research and Quality's Evidence-based Practice Center reports are linked with the Medicare Dashboard, and synthesize the evidence regarding the effectiveness of some of these drugs when used by certain populations for specific conditions. We believe that there is complementary data now available from other entities on rebates, clinical effectiveness, pharmacoeconomics, comparative effectiveness, safety, formulary placement and discounts on these drugs. Our hope is that over time outside parties will release this type of information in order to broaden the understanding of these drugs.

At CMS, we are committed, as we always are when we publish data, to receiving input to make sure the data are accurate, fairly presented, constructive, and shown in a way that protects the identity of beneficiaries. Physicians, pharmacists, patients, manufacturers, researchers, and others are encouraged to provide us with feedback to inform our understanding of these data and ensure they are presented appropriately. We welcome your input; please do not hesitate to have your staff reach out to my team to discuss this issue further.

3. **On Friday, October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) released 2016 Medicare Physician Fee Schedule Final Rule. Within this rule were provisions relating to mandating the consultation of appropriate use criteria for select advanced imaging services under PAMA. This policy was scheduled to go into effect**

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Downloads/Drug_Spending_Methods.pdf

January 2017. CMS has announced that they will not be able to meet the January 2017 implementation deadline and in fact, stated that they will not commit to any date-certain for implementation. Please explain to the Committee why the Agency will not meet the implementation deadline of January 2017 and please tell the Committee a date certain as to when this program will be implemented.

Answer: We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. The number of clinicians impacted by the scope of this program is significant, as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) rulemaking process, we will begin to identify priority clinical areas and expand them over time. We anticipate including further discussions and adopting polices regarding claims-based reporting requirements in the CY 2017 and CY 2018 PFS rulemaking cycles. Also, in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals. We recognize the importance of moving expeditiously as well as ensuring transparency and working with stakeholders to accomplish a fully implemented program.

The Affordable Care Act established the Independent Payment Advisory Board (IPAB), a board of unelected bureaucrats that are to reduce Medicare spending once certain spending triggers are hit. The President and Congress have not nominated any members to the Board and thus IPAB's authority falls to you.

4. **Based on current forecasting, when do you expect the IPAB trigger will be hit?**

Answer: The Chief Actuary of the Centers for Medicare and Medicaid Services (OACT) determines in the annual Medicare Trustees' Report when IPAB is triggered. According to the 2015 Trustee's Report, IPAB will not be triggered for an implementation year before 2019.

As you know, the Patient Access and Medicare Protection Act of 2015 (PAMPA), P.L. 114-115, should have prevented cuts in the Medicare payment rate for about 170 complex rehabilitation technology (CRT) codes. Unfortunately, CMS has delayed action, as directed by this law, until July 1. As a "fix", CMS has suggested that CRT providers "rebill" for the difference in payment after July 1.

5. **What assurances do providers have from CMS that they will be able to recoup full payment as required by PAMPA? And how long will providers have to wait to receive that full payment from CMS?**

Answer: We appreciate your concerns regarding this issue. CMS began working on implementation of the Patient Access and Medicare Protection Act of 2015 (PAMPA) when it first passed Congress in late December. Since PAMPA was signed into law at the end of

December, it would not have been feasible for us to implement it on January 1, 2016. Given the amount of system changes required and the testing involved, the soonest we are able to implement this change is July 1, 2016. Until these changes are implemented, payments for these items will be based on the adjusted Durable Medical Equipment (DME) fee schedule amounts. The DME adjusted fee schedule rates are currently in a 50/50 blend during this six month transition period. The average reductions for these Group 3 complex rehabilitative wheelchair accessories are about 10 percent. On or after July 1, 2016, suppliers can adjust previously paid claims to receive the full fee schedule amount.

Because the changes to the Medicare claims processing system cannot be implemented any sooner than July 1, the Part B Medicare contractors are unable to process claims within established time limits and an advance payment may be available. Suppliers are able to submit a single advance payment request for multiple claims for an eligible period of time. To apply for an advance payment, the Medicare supplier is required to submit the request to their appropriate Medicare Administrative Contractor. If a provider in your district has concerns or needs additional assistance they should contact their appropriate Medicare Administrative Contractor.

CMS will be monitoring beneficiary access closely during this time to ensure that beneficiaries receive the wheelchairs and accessories that they need.

6. **For over half of the reimbursement codes, the "rebill" amount will be less than $20. It is important to bear in mind that the CRT provider's administrative cost for billing is at least $20. Therefore, won't these providers end up losing money when they rebill Medicare? I do not understand how CMS can say this is a "fix," especially when providers end up losing money.**

Answer: CMS wanted suppliers to receive some payment for their claims on a timely basis rather than holding claims until July 1, 2016, when the Medicare claims processing system could be updated to reflect this change given the amount of system changes and testing required. In addition, because the changes to the Medicare claims processing system cannot be implemented any sooner than that date and the Part B Medicare contractors are unable to process claims within established time limits; an advanced payment maybe available for suppliers. To minimize burden, suppliers may submit a single advance payment request for multiple claims during an eligible period of time, consolidating their administrative efforts, until system changes can be implemented.

On or after July 1, 2016, suppliers can adjust previously paid claims with dates of service on or after January 1, 2016, to receive the full fee schedule amount. Since these Group 3 complex rehabilitative wheelchair accessories are also used on other types of wheelchairs, suppliers would have to identify and submit previously submitted claims that would need to be adjusted on or after July 1, 2016. For these items, the average adjustment to the 2016 rates in the transition period is a reduction of about10 percent.

7. **Has CMS provided any information to beneficiaries, providers, or other payers to let them know that Medicare is underpaying for certain CRT equipment until July 1? And, has CMS offered any guidance on what the actual payment rates should be for CRT equipment?**

Answer: CMS has posted information regarding the delayed implementation of the PAMPA provision on the DME Spotlight web page, including a message to suppliers on how to receive advance payments until the system changes could be implemented. In addition to the DME Spotlight web page, CMS also alerted suppliers to the delayed implementation of PAMPA via two messages in newsletters in late January and earlier this month[4].

CMS will be releasing the list of HCPCS codes for wheelchair accessories affected by PAMPA soon. Once the HCPCS codes are identified, suppliers can calculate the payment rates using the 2015 DMEPOS fee schedule amounts multiplied by the 2016 DMEPOS fee schedule update factor available in the January 2016 DMEPOS Fee Schedule Update Change Request. The unadjusted 2016 fee schedule amounts for these wheelchair accessories will be posted as part of the July update to the DMEPOS fee schedule file. The July update files are typically posted in early June.

8. Shouldn't CMS, instead, be developing a process where CMS' contractors *automatically* reprocess these types of claims? That way, the provider would not have to rebill. Since this system would need to be operational by July 1, that gives CMS plenty of time to implement such a system. Do you agree?

Answer: CMS wanted suppliers to receive some payment for their claims on a timely basis rather than holding claims until the systems could be updated to reflect this change. Because the changes to the Medicare claims processing system cannot be implemented any sooner than July 1, the Part B Medicare contractors are unable to process claims within established time limits and an advance payment may be available. Suppliers are able to submit a single advance payment request for multiple claims for an eligible period of time.

On or after July 1, 2016, suppliers can adjust previously paid claims with dates of service on or after January 1, 2016, to receive the full fee schedule amount. Since these Group 3 complex rehabilitative wheelchair accessories are also used on other types of wheelchairs, suppliers would have to identify and submit previously submitted claims that would need to be adjusted on or after July 1, 2016. For these items, the average adjustment to the 2016 rates in the transition period is about a reduction of 10 percent.

Regarding reform of the Clinical Laboratory Fee Schedule (CLFS), as required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), statute required CMS to issue final rulemaking on CLFS reform by June 30, 2015, providing both laboratories and the agency with sufficient time to create the necessary systems to collect, certify, report, and calculate data, with new reimbursement rates going into effect January 1, 2017. CMS has failed to meet this schedule. A proposed rule was not issued until October 1, 2015, and there still is no final rule. A January 1, 2017 effective date seems unlikely.

9. What is the status of the final rule and what are CMS' plans to provide laboratories with sufficient time and guidance to comply with reporting requirements?

Answer: On October 1, 2015, CMS published a proposed rule to implement section 216 of the

[4] All responses are accurate as of February 24, 2016

Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare payment rates. In the proposed rule, CMS proposed to define the term "laboratory" according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. CMS also addressed how to meet the statutory requirement that an "applicable laboratory" receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, CMS proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

CMS is currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an "applicable laboratory". We will carefully consider those comments in developing a final rule implementing PAMA section 216.

The House of Representatives has demonstrated a strong commitment to precision medicine through our 21st Century Cures initiative, and we remain committed to working with the Administration to enact comprehensive precision medicine legislation. One issue providers have brought to our attention is the complex set of Medicare billing rules, specifically the CMS 14-day Rule, for molecular and advanced diagnostic laboratory tests performed on specimens collected from hospital outpatients. As you know, specialty care is increasingly moving towards the hospital outpatient department, however, many of these advanced diagnostic laboratory tests are performed by independent laboratories separate from the hospital. Under this complex set of rules, the hospital where the specimen was collected is required to bill for the test in most cases even though the hospital did not actually perform the laboratory test. We have heard from cancer centers and others that they do not want to bill for a test that the institution did not perform. Congress previously required CMS to conduct a demonstration project on this issue and CMS issued a report in December 2015 that failed to provide recommendations.

10. Would CMS be willing to address this issue as part of the annual rulemaking process this summer to modernize the rule so that the laboratory that performs the test bills Medicare for the test, which is consistent with how other diagnostic tests are billed when performed outside of the hospital?

Answer: Thank you for your leadership on 21st Century Cures and your commitment to advancing scientific innovation. In general, Medicare makes only a single bundled payment to the hospital for all services furnished to inpatients and outpatients, including laboratory tests on specimens stored for up to 30 days. The "date of service" rule limits this policy to tests ordered not more than 14 days after the patient's discharge from the hospital.

We are aware of challenges this policy may pose for laboratories performing certain advanced diagnostic tests on stored specimens. This was addressed through a two-year demonstration required by the Affordable Care Act, allowing separate direct payment to laboratories under certain circumstances. As you noted, CMS issued a report to Congress on this demonstration in 2015, which noted extremely low participation in the demonstration. Given such low participation, we were unable to conduct a thorough assessment of the demonstration's effects or make meaningful recommendations on changes to the policy.

Last fall, the Office for Civil Rights at HHS published a proposed regulation that is intended to implement section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Although the statute itself refers to any health program or activity that receives federal financial assistance, the proposed regulation goes much, much further by also, apparently, applying the new rules to employer-sponsored health plans that utilize the services of a third-party administrator.

11. This overreach of regulatory authority is striking. How do you justify this inappropriate new and costly burden on plans that do not actually receive any form of federal financial assistance and that already comply with a fully articulated set of rules in many of these areas, especially those with respect to individuals with limited proficiency in English?

Those employers sponsoring group health plans that utilize the services of a third-party administrator will most likely be forced to comply with the regulatory oversight of the proposed HHS nondiscrimination regulations under section 1557 of the Affordable Care Act. This will add significantly to the regulatory and compliance burden of these plans, from both an administrative and financial standpoint. Moreover, employer-sponsored plans in the future will likely try to avoid using the TPA services of insurers who offer plans through the Exchanges. If not concerned with the additional burden forced on plans, are you at least concerned with the potential impact on the Exchanges if more insurers were to exit as a result of this regulation?

Answer: While I appreciate your concern, the proposed rule to implement Section 1557 of the Affordable Care Act is consistent with the underlying statutory provision. It incorporates the long-standing civil rights principles under the four civil rights laws that Congress referenced in Section 1557. Accordingly, the proposed rule interprets the obligations under Section 1557 consistent with the Civil Rights Restoration Act of 1987 (CRRA), which establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. Therefore, it is consistent with existing civil rights laws and principles to hold a covered entity principally engaged in a health program or activity liable for all of its operations, as we do in the proposed rule.

The proposed rule also reflects careful consideration of input from a variety of stakeholders in response to OCR's Request for Information. It also reflects feedback provided during listening sessions, including input on application of the rule to employers who provide employer-sponsored group health plans that utilize the services of a third-party administrator. As a result of OCR's consultations with HHS components, other Federal agencies, and stakeholders to develop the proposed rule, we do not believe it will result in issuers exiting the Exchanges or employers using third-party administrators who offer plans offered through the Exchanges. In addition, as set forth in the Regulatory Impact Analysis to the proposed rule, the cost to covered entities is limited because most obligations already exist under other civil rights laws and OCR is minimizing costs to the extent possible by developing training and material that covered entities

can use to meet their obligations. For the latest information on Section 1557 please see http://www.hhs.gov/civil-rights/for-individuals/section-1557/.[5]

In your 2011 regulations regarding the enforcement of federal health care provider conscience protection laws, you stated that the Department of Human Services (HHS) sought to strengthen longstanding protection statutes by ensuring there is a clear process for enforcement. The Office for Civil Rights (OCR) of HHS is the designated department to receive and address complaints of discrimination and coercion in violation of statutory protections. I would like to ask you about the adequacy of this enforcement process.

12. How many complaints have been filed since 2011 when the enforcement regulations were finalized?

13. How many of those complaints have been resolved? How many remain outstanding?

14. On average, how long does it take to resolve a complaint under these regulations? On average, how long does it take to resolve a complaint filed under all other areas of OCR jurisdiction (Disability, Age, Religion, etc.)?

15. Is it acceptable if a complaint is never resolved?

16. Please provide a list of all actions taken by your department to notify the public and particularly health care providers of their rights under the abortion conscience laws covered in the 2011 regulation.

17. As a general matter, not specific to complaints regarding abortion conscience protections, please explain how complaints filed with OCR are handled. Specifically,

- **What happens when a complaint is filed?**
- **How are cases assigned?**
- **On average how many people serve on a typical team assigned to investigate an OCR complaint?**
- **What is the average length of time it takes to resolve a complaint filed with OCR?**
- **Does OCR have the authority to stop an alleged violation while the complaint is being investigated?**

18. Please provide information about abortion conscience complaints received and processed by OCR since 2011. Specifically,

- **How many abortion conscience complaints have been filed since 2011 when the enforcement regulations were finalized?**

[5] All responses are accurate as of February 24, 2016.

- **Is there a particular team assigned to these complaints?**
- **How many people serve on the team(s) assigned to investigate abortion conscience complaints?**
- **How many of those complaints have been resolved?**
- **How many remain outstanding?**
- **On average, how long does it take to resolve a complaint under these regulations?**
- **Is it acceptable if a complaint is never resolved?**

In 2014 you opened an investigation into complaints that California violated the Weldon abortion conscience protection when it required all insurance plans under the authority of the CA Department of Managed Care to cover abortion. With regard to the complaints filed in response to the abortion coverage mandate in California:

19. **How many people are assigned to investigate and resolve this issue? Please provide the names of the members of the team investigating and the amount of time each has spent on the investigation since it was opened. [alternatively if asking for names is risky: How many people are assigned to investigate and resolve this issue? Please indicate the cumulative amount of time that the team has spent on the investigation since it was opened.]**

20. **How many meetings has OCR held on the issue internally?**

21. **How many interviews or meetings have been conducted with the parties who have filed complaints (or their representatives) or California officials (or their representatives)?**

22. **Has OCR discussed this case with any person or group other than those who filed complaints (or their representatives) or California officials (or their representatives)? If so, please list the parties consulted.**

23. **How many times have you personally spoken with OCR staff regarding this complaint?**

Answer: The HHS Office for Civil Rights (OCR) ensures that individuals receiving services from HHS-funded programs are not subject to unlawful discrimination and that the privacy and security of individuals' health information is protected. OCR engages in investigations, technical assistance, voluntary compliance efforts, enforcement, policy development, and education to ensure that all people have access to health care and health services. As you are aware, OCR also enforces the Federal Health Care Conscience Protection Statutes, including the Church Amendments, the Weldon Amendment, the Public Health Service Act, and the Affordable Care Act.

If an individual feels they have been discriminated against because of their race, color, national origin, disability, age, sex, or religion in programs or activities that HHS operates or to which

HHS provides federal financial assistance, they can file a complaint with OCR. OCR receives more than 20,000 complaints per year; the length and scope of a particular investigation varies based on a number of factors, including the allegations of discrimination, the number of individuals or entities involved, and the types of legal issues that are raised by the complaint.

Once a complaint is received, OCR determines if it has the legal authority to review and investigate the complaint. When it becomes clear that OCR can accept the complaint, an investigation is opened and the complainant is notified. OCR has a variety of investigative tools that it can use, depending on the statute under which a complaint alleges discrimination. During the course of the investigation, OCR may interview the complainant, the covered entity, and any other parties that may have information relevant to the case. OCR may also obtain additional documentation through data requests and, if needed, can complete an on-site visit to the entity's location. Importantly, where areas of concern arise during an investigation, OCR may work with an entity to reach voluntary compliance.

When the investigation is completed, OCR may take several actions, which are tailored depending on the type of relief necessary and remedies available under the law. If OCR determines that no violation has taken place, OCR sends a letter to the complainant and the covered entity providing the results of the investigation and closes the case. If a violation has occurred, OCR may work with an entity to provide corrective action, including updating policies and procedures, training staff members, requiring a service to be provided, or restoring lost benefits. In the rare case where an entity is unwilling to take corrective action, OCR may recommend the initiation of enforcement proceedings, which are carried out by the Office for General Counsel or the Department of Justice. A final decision upholding a violation finding could result in the termination of Federal financial assistance to the recipient.

HHS supports clear and strong conscience protections for health care providers and entities that are opposed to performing abortions and is committed to enforcing these laws. Since January 2011, OCR has received eight complaints alleging discrimination under the provider conscience protection statutes, six of which are currently open and undergoing investigation. Among those filed, OCR received three complaints alleging that the California Department of Managed Health Care directive violates the conscience clause protections of the Weldon Amendment. OCR has an open investigation to examine the allegations in these complaints. Because these are open cases, we cannot comment on the status of the review.

Lastly, OCR includes information about its authority to enforce conscience protections in its overview of OCR's authorities when it does general outreach presentations. Notably, OCR has an entire section of its website dedicated to the provider conscience protection statutes. The website includes references to the laws it enforces, how to file a complaint, and detailed information about OCR's enforcement of these laws (including a PowerPoint presentation and a fact sheet).[6]

24. SAMHSA administers the Now is the Time Project AWARE program which gives out grants to Local Educational Agencies (LEAs) to support training of school personnel to detect and respond to mental illness in our youth. However, these federal dollars have been interpreted to narrowly only apply to one specific type of mental health awareness

[6] All responses are accurate as February 24, 2016.

program, in lieu of other ones listed in their National Registry of Evidence-Based Programs and Practices (NREPP). Can you state the reasons why SAMHSA currently restricts the eligibility for Project AWARE dollars to only one program administered by one organization in lieu of others listed in their Registry? Do you believe it would be better if state and local agencies would be able to choose the evidence-based and proven program that works best suit the needs of their schools and communities?

Answer: SAMHSA administers the Project AWARE Local Educational Agencies (LEA) programs in a manner that is consistent with Congressional direction. In the Consolidated Appropriations Act, 2014, Congress appropriated $15 million to SAMHSA for "Mental Health First Aid" and final Conference Report language directed SAMHSA "to focus on a broad public health safety approach when implementing the Mental Health First Aid program that offers training for both school officials and the range of actors in the public sphere that interact with youth." Consistent with Congressional direction, SAMHSA implements Mental Health First Aid training. This training is for teachers and other adults who interact with youth to detect and respond to mental illness in children and young adults, including how to encourage adolescents and families experiencing these problems to seek treatment.

25. CMS told GAO it expects to issue guidance outlining how the Marketplace will determine whether an applicant has demonstrated a good faith effort to obtain the required documentation, and expects good faith extensions for applications for 2016 coverage to be very limited. So, what *precisely* is CMS's policy for resolving inconsistencies now? And, based on past problems identified, are you confident CMS's actions will *eliminate* the problems GAO identified with CMS protocols and processes for 2014 and 2015?

Answer: The FFM takes action on a monthly basis for consumers with unresolved data matching issues who have not provided adequate documentation within 95 days for citizenship or immigration status data matching issues and within 90 days for household income inconsistencies. Consumers who do not submit sufficient documentation to resolve their annual household income data matching issue will have a recalculation of their APTC and/or CSRs based on available tax data. Individuals who have not provided the necessary documentation for their citizenship or immigration status will have their enrollment through the Marketplace terminated. As discussed in the response to the GAO, decisions to grant an extension under 45 CFR 155.315(e) have been made on a case by case basis for a small number of applicants.

CMS learned from the first year of implementation and made improvements in advance of and during the second and third open enrollments. CMS is continually improving its policies and procedures in order to fulfill its responsibility to protect taxpayer funds, while providing coverage to eligible consumers. Since May 2015, consumers have been able to call the Marketplace call center and representatives have access to near real-time data on the documents consumers have submitted to address their inconsistency. These program improvements will help address the issues raised by the GAO.

26. The committee has been told that if a consumer who has exchange coverage wants to make a simple change to their coverage, say for example, to update their address, they must go through the entire exchange enrollment/eligibility process again. How long is

the average call or time online for consumers wanting to make a simple change like this? Why is CMS's process so difficult for consumers?

Answer: CMS continually works to improve the customer experience including making it simple for consumers to keep their Marketplace information up to date. Consumers can report changes to their Marketplace coverage in three ways: online, by phone, or in-person. Consumers are not required to go through the entire enrollment process again for a simple change in contact information such as an email address or phone number. If a consumer's address change involves a change in ZIP code or county that results in access to different qualified health plans, the consumer may qualify for a Special Enrollment Period, in which case a new eligibility determination is required. Other changes that may impact eligibility and therefore require a new application include change in income or eligibility for other forms of health coverage. We encourage consumers to report income or household changes as soon as possible, since it may affect the coverage or savings for which they are eligible. We have also made an online tool available to give consumers a better sense of how changes will impact their premium tax credit amount.

27. **Next year, States that have expanded Medicaid to childless adults will start paying 5% of the costs for that population, as the full federal financing for this population declines. Your predecessor made headlines in recent months, criticizing one state's decision not to expand Medicaid under the ACA as "morally repugnant and economically stupid." I appreciate that you've often had a better tone than your predecessor. Isn't the budget proposal to extend to states that have not expanded Medicaid the full federal financing for newly eligible adults –isn't that proposal an implicit omission that State governors and legislators are not "economically stupid" but are actually making decisions based in part on their own economic interest?**

Answer: State decisions to extend Medicaid coverage to low-income adults have been proven to expand insurance coverage, reduce the uncompensated care burden on health care providers, and save states money. As of January 2016, 30 states and the District of Columbia have elected to expand Medicaid, and more states are actively discussing expansion (Louisiana will make the 31st state). Through November 2015, an additional 14.1 million individuals have gained Medicaid or CHIP coverage, including over 335,000 Pennsylvanians; many of whom would not have been eligible for coverage absent Medicaid expansion[7].

Research shows that expansion makes good fiscal sense for states and their residents. Medicaid coverage offers low-income families a set of affordable and comprehensive health benefits from preventive screening to prescription drug benefits. Adults with Medicaid report that they are able to access care and can afford the services they need. People with Medicaid coverage report also very high satisfaction, even higher than those who receive health insurance through their place of employment. Medicaid expansion has not only increased access to quality care, but it has also reduced costs for hospitals and other medical providers that may otherwise have burdened providers or be passed on to taxpayers and already insured individuals. According to the Council of Economic Advisers, if all states fully expanded Medicaid, uncompensated care costs would be about $8.9 billion lower in 2016 than they would be if no states expanded Medicaid. In

[7] https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/november-2015-enrollment-report.pdf

Kentucky, for example, expansion has been projected to add 40,000 jobs and $30 billion to state economy through 2021.

As you say, the President's Budget includes a proposal to provide all states, regardless of when they choose to expand Medicaid, the same federal share as states that expanded right away by providing three years of full Federal funding for newly eligible adults. We believe that continuing to incentivize states to expand Medicaid coverage will benefit millions of people across the country, reduce the uncompensated care burden on urban and rural providers, and stimulate state economies. As you know, I am personally committed to working with states to find solutions that work best for their residents, while protecting certain fundamentals of the program.

28. Today, under Medicaid expansion, it's a fact that many medical and law students in states that expanded Medicaid are enrolled in the program. That's in part because universities have dialed back their private coverage programs, due to Medicaid expansion. I worry this is just one more example of how the ACA's Medicaid expansion can often crowd out private coverage. Would CMS survey newly-eligible Medicaid beneficiaries to see what coverage they had before their current coverage?

Answer: Research shows Medicaid expansion does not "crowd out" private coverage. While some colleges and universities may have dialed back their private coverage, much of this is attributable to the Affordable Care Act extending coverage under parents' health plans up to age 26 and to elimination of low-benefit plans that once provided many students with subpar coverage. Not only does Medicaid expansion not "crowd out" other coverage, but it also increases the number of low-income Americans receive coverage through private insurers. Many of these individuals would otherwise have been unable to afford private insurance. Research from Oregon showed that an expansion of Medicaid coverage was associated with a 25 percentage point increase in the probability of having insurance during the study period. This net increase in insurance appears to come entirely through a gross increase in Medicaid coverage, with little evidence of crowd-out of private insurance.

In most of the states that have expanded Medicaid, newly eligible adults are enrolled in private managed care plans that contract with state Medicaid agencies to serve this population. And in states like Arkansas that have expanded using a premium assistance approach, some of the newly eligible adults receive coverage through private insurers through the Marketplaces; their premiums are paid by the state Medicaid program, with a contribution from the individual.

As reflected in the President's FY 2017 Budget proposal to provide all states, regardless of when they choose to expand Medicaid, the same federal share as states that expanded right away, the agency is focused on decreasing the number of low-income Americans who are still without insurance coverage in states that have not yet decided to expand their Medicaid programs.

29. The Committee has been very interested in CMS's vague criteria for approving 1115 waivers. In responses to the Committee, CMS admitted "we do not apply a standard federal definition of 'low-income.'" In fact, CMS went on to say that "in some cases, we have approved state requests for demonstrations involving populations at higher incomes levels when we determine that the program furthers the objectives of title XIX

in that state." CMS went on to explain that "approving a program that serves individuals with income above 250 percent FPL can further the objectives of title XIX, if the program helps keep individuals healthy, especially those who may be at risk of developing medical conditions that could cause them to lose income, which may cause the individuals to become Medicaid eligible." Given the positive correlations between participation in the labor force and health outcomes, why is CMS so ideologically opposed to states testing the utility of work requirements for the non-disabled population?

Answer: Section 1115 of the Act authorizes the Secretary to waive provisions of section 1902 of the Act to enable states to conduct demonstrations that would, in her judgment, be likely to assist in promoting the objectives of Title XIX. We have used this authority to enable states to conduct demonstrations that promote the objectives of the Medicaid program. Since 2009, we have approved new demonstrations in 29 states[8] and approved 86 renewal actions.[9] However, the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work or receive job training because that is not an objective of Title XIX.

We are committed to working with states interested in pursuing new and innovative policy approaches in their Medicaid program. We do consider encouraging work an important state objective, and to that end we have worked with states to develop approaches that encourage work and job training participation. However, the structure of the ACA is built on every American having a guarantee of access to affordable health insurance. We cannot condition that access on any requirement, including work. It is also notable that nearly three out of four (72%) of the uninsured adults who could gain Medicaid coverage in non-expansion states live in a family with at least one full-time or part time worker and more than half (57%) are working full or part-time themselves.

30. I have a question about Medicaid's approval of funding for designated state health programs through 1115 waivers. I know CMS has explained that States deduct from their waiver requests any existing federal funding the state may have. But why is it appropriate for CMS to approve Medicaid federal financing of state-based healthcare workforce training and loan repayment programs, when there are already federally-funded programs to do the same thing through HRSA? This is clearly duplicative of the existing federal funding stream—just within HHS.

Answer: CMS and HRSA work together on the 1115 waiver approval process to ensure that appropriate review to prevent duplication occurs. The 1115 waiver program is a research and demonstration mechanism for states to improve Medicaid and CHIP programs. These 1115 waivers may include components related to workforce with the purpose of stabilizing and strengthening access to care for Medicaid and low-income populations in the state.

HRSA workforce and loan repayment programs are statutorily defined programs through separate authorities and for a different purpose than 1115 waivers HRSA provides grants to academic institutions and other entities to train the health care workforce across the entire

[8] AL, AR, AZ, CO, DC, GA, IA, ID, IL, IN, KS, LA, MI, MN, MO, MT, ND, NH, NJ, NM, NV, OH, PA, RI, TX, VA, WA, WI, & WV

[9] All responses accurate as of February 24, 2016.

training continuum. States are not eligible to compete for all HRSA-administered programs. . These programs provide separate but complementary efforts, which both work to address the Nation's healthcare workforce shortages.

31. To help ensure the accuracy of eligibility determinations for the aged and disabled population in Medicaid, in 2008, Congress passed legislation that required States to implement electronic asset verification systems to verify the assets of aged, blind, or disabled applicants for Medicaid. The law provided for States' implementation of these systems to occur on a rolling basis, with all states required to have systems in place by the end of fiscal year 2013. The law also specifies that federal matching payments for expenditures for the populations subject to asset verification must be withheld should states fail to implement the required asset verification system, unless the State demonstrates a good faith effort to comply, submits a corrective action plan to remedy such noncompliance, and fulfills the terms of the corrective action plan within 12 months. It is now fiscal year 2016, yet CMS does not even know which states have implemented these statutorily required systems intended to ensure the accuracy of Medicaid eligibility determinations. Does HHS or CMS not believe that the accuracy of Medicaid eligibility determinations is a high priority? Why hasn't CMS required states to submit corrective action plans within the time frames outlined in the law?

Answer: The accuracy of Medicaid eligibility decisions is a high priority and CMS has implemented a number of strategies to ensure program integrity. Pursuant to CMS regulations, states have implemented strategies to electronically verify a number of factors of eligibility, including income, citizenship, and eligible immigration status.

Since 2011, all states have either built new eligibility systems or have dramatically re-engineered legacy systems to implement new Medicaid eligibility rules. These new systems present an opportunity to automate the asset verification systems (AVS). However, states have faced a number of obstacles in the implementation of AVS. These include the cost of the product and availability of state funds, a limited number of vendors with an appropriate product, and, in some states, a reluctance/refusal of financial institutions to participate and provide data.

CMS has been working to promote faster progress across states. In order to help states move toward full implementation of an AVS, CMS has issued guidance on AVS and provided extensive technical assistance to states. They have, for example, facilitated state-to-state discussions of ways to overcome implementation obstacles. Additionally, CMS is evaluating states' Advanced Planning Documents to ensure that plans for electronic asset verification are integrated into current and future system development/build schedules.

CMS has approved Medicaid state plan amendments (SPA) to implement asset verification systems in 31 states[10]. To date, 7 of these states have fully implemented an AVS and another 13 expect to be live before the end of 2016. CMS requested that each of the remaining 20 states

[10] These 31 states are Alabama, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Kentucky, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, Utah, Vermont, Virginia, Washington, Wisconsin and Wyoming.

submit a SPA to CMS for approval, along with a detailed work plan and timeline for full implementation. CMS is evaluating whether each state that has not yet implemented an AVS is making a good faith effort to comply with the statutory requirements. Any state determined not to be making a good faith effort will be required to submit a corrective action plan.

As more states re-engineer their eligibility systems for the aged, blind, and disabled populations, CMS expects that more will commit resources to complying with asset verification

32. According to GAO, State Medicaid Directors raised concerns that Medicaid eligibility determinations made by the federal exchange were incorrect. Despite these concerns, at the time of their work, GAO noted that CMS was not assessing the accuracy of federal eligibility determinations, but that CMS officials indicated that the agency was planning to begin looking at such determinations in August 2015. What is CMS doing to examine the accuracy of federal eligibility determinations and what has CMS found?

Answer: CMS agrees that it is important that determinations made by the FFM are accurate, and has a number of processes in place to support this goal. First, all business requirements for the FFM's systems were developed by federal subject matter experts who were involved in drafting the guiding regulations, particularly those pertaining to eligibility requirements. Second, as part of the normal CMS systems development lifecycle, FFM code goes through developer and independent testing, including regression testing as changes are introduced. Third, CMS routinely engages with a number of issuers who are able to do end-to-end testing of the eligibility and enrollment process to ensure accurate eligibility determinations and correct enrollment information. In this vein, CMS is leveraging this process to also ensure that Medicaid eligibility determinations are accurate by implementing a pilot program to test complex eligibility scenarios in three states. CMS will use this pilot program to refine the eligibility testing process and will gradually add more FFM states with routine, scheduled testing windows throughout the year. Lastly, CMS is constantly reviewing issues reported to our help desk and through other channels to determine whether improvements are required, and also receives continual feedback from state Medicaid and CHIP agency staff on any potential concerns.

33. According to GAO, Medicaid quarterly expenditure reviews only assess whether expenditures for an enrollee that a State claims to be newly eligible is submitted under the newly eligible expenditure category. It does not whether the enrollee is *truly* newly eligible. Given the 100 percent federal funding for the newly eligible, States obviously have a financial incentive to increase the proportion of applicants and expenditures for that population. As such, what is CMS doing to ensure that expenditures claimed under the higher federal matching rate are indeed for individuals that are newly eligible? Can you also speak to CMS's oversight of matching rates with respect to CHIP, since many states have a very high CHIP matching rate?

Answer: CMS is committed to ensuring that federal financial participation (FFP) paid to states for Medicaid and CHIP expenditures is accurate and appropriate. To ensure federal funding is provided at the appropriate Federal Medical Assistance Percentage (FMAP) and expenditures were for covered services CMS conducts expenditure reviews that contain a series of management controls and validation activities as oversight of states. These expenditure reviews do not include eligibility reviews which are handled by a separate process. However, the two

complementary processes collectively serve to provide appropriate oversight of the FFP paid for state expenditures. The reviews for CHIP reported expenditures follow the same quarterly review and oversight process that is conducted for all claims for Federal matching funds.

To specifically address oversight needs for the newly eligible expenditure category, CMS implemented new quarterly CMS-64 expenditure reporting and review procedures for the new adult group. CMS developed new financial reporting forms where states must separately report expenditures for newly eligible individuals and also provided significant training and guidance to states about how to accurately track and report these expenditures. CMS is also conducting rigorous financial management reviews of these expenditures. CMS samples claims and generalizes the results obtained from the sample review for purposes of deferring federal funding, as necessary, to ensure appropriate claiming and proper state corrective action. The deferral process allows CMS to withhold federal funding from a state while obtaining additional documentation from a state or requesting state corrective action, including the return of FFP when appropriate. CMS is also exploring additional ways to reinforce for Medicaid and CHIP enrolled consumers the need to report application changes to the applicable state agency.

34. Last year CMS did not check for Medicaid coverage for the 1.96 million individuals who the agency auto-enrolled in qualified health plan for plan year 2015. This likely resulted in duplicate coverage and inaccurate federal payments. With open enrollment for plan year 2016 having just ended, what, if anything, did CMS do this year to check for Medicaid coverage before automatically enroll people?

Answer: The Marketplace checked whether enrollees were dually enrolled in Marketplace coverage with APTC and Medicaid or CHIP prior to Open Enrollment for 2016. Consumers who were identified as dually enrolled were notified that they should end their Marketplace coverage with APTC. In spring 2016, we will check again whether Marketplace enrollees with APTC are also enrolled in Medicaid or CHIP. Notices will be sent in May to consumers who were enrolled in both.

36. Medicare expenditures this year will total nearly $570 billion, and are expected to roughly double over the coming decade.[1] The budget includes very modest structural changes to Medicare, but they would not be sufficient to make Medicare solvent. In fact, according to CBO, the Medicare Hospital Insurance Trust Fund will be insolvent in 2026—meaning the next president will inherit a program rapidly hurtling toward going belly up and jeopardizing care for millions of Americans.[2] As a former budget official, are you content with this Administration's record on shoring up the Medicare program to protect it for current and future beneficiaries?

37. I know we all agree Medicare is a critical program for Americans. There have been bipartisan proposals in the last eight years that would make needed changes to help save Medicare—plans like those from the president's fiscal commission; Rivlin-Domenici; Wyden-Ryan, and Lieberman-Coburn. Unfortunately, the Administration largely ignored these plans and used Medicare savings to make Obamacare look like it

[1] https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf
[2] https://www.cbo.gov/about/products/budget_economic_data#5

reduced the deficit. Yet, the insolvency of the Medicare hospital trust fund is within sight, and Medicare continues to consume more general revenue. In addition to a few of the bipartisan proposals in the president's budget, do you acknowledge more needs to be done to help save Medicare?

38. **Each day about 10,000 baby boomers age into the Medicare program. The present value of Medicare taxes for a married couple earning the average wage and retiring at 65 is approximately $140,000 in payroll taxes but the lifetime average benefit is $422,000 roughly 3 times what is paid in payroll taxes. Can the current financial condition of the Medicare program sustain this growth?**

39. **One could argue that the most serious threat to the nation's long-term prosperity is the rapid and unfinanced growth of entitlement spending. Left unchecked, spending commitments for these programs will consume future revenue. According to CBO, Medicare spending in 2015 "rose by $34 billion, or nearly 7 percent—the fastest rate of growth recorded for the program since 2009." This spending growth is expected to continue at roughly the same level over the next 10 years. Does the Administration believe that the current Medicare program is sufficiently financed to be able to handle this growth without significant cuts to providers or decreases in benefits?**

40. **The first Baby Boomers aged into the Medicare program 5 years ago with 10,000 more joining every day. By 2030 75 million seniors will be in the program, living longer than ever before while retirement age has stayed constant. While the budget proposes savings it is near silent on large structural reform designed to protect future benefits, why hasn't the Administration supported structural reforms such as raising the retirement age to correspond with Social Security?**

Answer: This Administration has taken historic steps to help change the trajectory of health care spending. The Affordable Care Act is contributing to the recent slow growth in health care costs, while expanding coverage and improving the quality of care for millions of people across the country – including through the provisions that reduce Medicare excessive payments and shift toward payment models that promote high-quality, efficient care. The continuation of slow growth for years after the recession and slow growth in Medicare, which is insulated from broader economic trends, both point to a major role for structural changes in the health care system in explaining recent slow health care cost growth. Work by outside researchers has reached similar conclusions.

Since August 2010, the Congressional Budget Office's projection of Medicare spending under current policy in 2020 has fallen by $123 billion. This decline represents a 15 percent reduction in projected spending and primarily reflects the recent slow growth in health care spending. Medicare spending per beneficiary rose just 1 percent in nominal terms in 2015, according to projections from the Centers for Medicare and Medicaid Services. This would make 2015 the sixth consecutive year in which per-enrollee Medicare spending was near or below economy-wide inflation. From 2000 to 2010, per-enrollee Medicare spending exceeded overall inflation by an average of 3.6 percent per year, even after adjusting for the introduction of Medicare Part D.

Since the enactment of the Affordable Care Act nearly 10.7 million Medicare beneficiaries have received discounts over $20.8 billion on prescription drugs – an average of $1,945 per beneficiary. In 2015 alone, nearly 5.2 million seniors and people with disabilities received

discounts of over $5.4 billion, for an average of $1,054 per beneficiary. This is an increase in savings compared to 2014, when 5.1 million Medicare beneficiaries received discounts of $4.8 billion, for an average of $941 per beneficiary.

That said, we know we still have important work ahead. The Budget presents a balanced set of proposals aimed at creating a health care system that spends money in a smarter way, provides better care, and leads to healthier people. Specifically the Budget proposals promote high-quality, efficient care, improve beneficiary access to care, address the rising cost of pharmaceuticals, align payments more closely with costs of care, and create incentives for beneficiaries to seek high-value services.

The Budget also includes some structural reforms to Medicare, including increasing income-related premiums under Medicare Parts B and D, modifying the Part B deductible for new beneficiaries, introducing home health copayments for new beneficiaries, and encouraging the use of generic drugs by low-income beneficiaries.

Together, the Medicare budget proposals would save a net $419 billion over ten years, slowing down the average annual growth in Medicare spending by approximately one percent. These proposals, plus additional tax proposals included in the Budget, would extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years. I believe that the proposals in the Budget represent progress toward curbing Medicare spending, but I recognize that there is more that can be done. For instance, in January 2015, the Administration set a goal of tying 30 percent of traditional Medicare payments to quality or value through alternative payment models by the end of 2016 – a goal which HHS estimates it has already met ahead of schedule, and tying 50 percent of payments to these models by the end of 2018. I believe that the enactment of the Medicare Access and CHIP Reauthorization Act will help us achieve our goal by promoting participation in alternative payment models. I look forward to working with Congress on more bipartisan efforts to help ensure that the Medicare program is sustainable for current and future generations.

The Honorable Marsha Blackburn

1. **In a report issued last October, the Congressional Budget Office stated that the growth of obesity in the US since 1980 poses "a significant public health challenge." CBO further stated that "obesity is associated with numerous diseases and higher than average health care spending."**

2. **Is the department taking specific steps to address the impact of obesity on health care spending? Do you believe legislative proposals to address the obesity crisis might be useful in impacting incidence of obesity and the growing impact of obesity on other chronic conditions, and spending associated with obesity?**

Answer: The Department shares your concern about obesity. Currently, the Office of the Assistant Secretary for Health convenes a monthly HHS inter-agency workgroup on Healthy Weight, Nutrition and Physical Activity (HWNPA). Representatives from across HHS share information on their agencies' HWNPA activities, which range from school nutrition, childhood obesity, and healthy weight measures to walking and walkability. CMS is part of this workgroup.

In partnership with National League of Cities, HHS's Let's Move: Cities, Towns and Counties Initiative has engaged over 500 local municipalities. These cities have committed to improving nutrition standards and increasing physical activity, with a goal to reverse the tide of childhood obesity in a generation. Over 80 Million Americans now live in a city, town or county that have logged over 3000 local, voluntary policies ("promising practices") committed to this action. This includes a goal focused on increasing access to healthy nutrition programs in schools.

Additionally, The Dietary Guidelines for Americans (DGAs), issued jointly by HHS and USDA every five years and most recently in January 2016, are the cornerstone of Federal nutrition policy and nutrition program activities. DGAs inform USDA and HHS food programs, from the National School Lunch Program to nutrition programs for older adults. Other departments, including the Departments of Defense and the Department of Veterans Affairs, also use the DGAs to inform things like menu standards in military dining facilities.

Medicare covers diabetes self-management training for diagnosed diabetics, as well as diabetes screening tests for those with risk factors for diabetes (including obesity). Medicare also covers medical nutrition therapy for persons diagnosed with diabetes or renal disease. In addition, Medicare covers intensive behavioral therapy for obesity in primary care settings. The availability and importance of these services would also be highlighted, as appropriate, in the one-time "Welcome to Medicare" visit and the Annual Wellness Visit.

Medicare also covers several types of bariatric surgery for beneficiaries with a Body Mass Index (BMI) of 35 or greater and at least one co-morbidity related to obesity who have previously been unsuccessful with medical treatment for obesity. Medicare also covers intensive behavioral counseling for obesity for individuals with a BMI of 30 or greater.

Beyond these activities, proposals to ensure funding to scale up key proven obesity prevention initiatives are important to maintain the declines that are being observed in children aged 2-5 years and to stabilize the obesity growth observed in older youth and adults which is diminishing worker productivity and leading to health care spending on obesity and its related health conditions.

CDC has promising strategies to address obesity. Although multiple individual factors can influence obesity, strategies have primarily focused on changing the energy balance opportunities including caloric reduction and increased physical activity.

The scientific literature shows us that we need a variety of approaches, not one single approach, to reduce obesity. These include behavioral changes and changes in the food and physical activity environment. Reports by a number of experts and expert bodies including CDC, the Institute of Medicine, the Surgeon General and the National Resource Center for Health and Safety in Child Care and Early Education have identified strategies based on the best available evidence combined with expert opinion.

- Overall, these experts support a multi-component approach to addressing key behaviors that impact weight gain and healthy growth. These include the need to address both physical activity and diet, and the need to strengthen supports for

making healthy choices in the multiple places where people eat and have the potential to be active.

In addition to these population level reports, the Clinical Preventive Services Task Force, as well as other expert medical groups, has recommended screening for obesity for all aged 6 years and older combined with referrals to intensive family-based pediatric weight management programs with nutrition and physical activity behavioral interventions for those at risk. CDC is working to promote adoption of these recommendations to promote reductions in BMI.

CDC conducted the Childhood Obesity Research and Demonstration (CORD) project (2011-2016) that focused on linking low-income children who have obesity to integrated primary care and community weight management initiatives. Early results show BMI reductions for children 6–12 years of age. CDC is supporting these obesity prevention strategies, in part, through our Division of Nutrition, Physical Activity and Obesity which includes work with national partners, states, communities, and land grant universities to increase access to and consumption of healthy foods and beverages and promotion physical activity, particularly walking and the creation of walkable communities.

On November 13, 2013 the FDA released a proposed rule on labeling changes for ANDA holders titled Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500. The proposed rule mandates that generic drug firms unilaterally change their labels for drugs under approved ANDAs by submission of a Changes Being Effected Supplement – 0 days (CBE-0) to add warnings, precautions, adverse reactions, contraindications and certain other information [hereafter collectively referred to as "warning(s)" even if the corresponding branded company has not implemented the same labeling change.

3. **Secretary Burwell, your Administration and many of my colleagues on this Committee, have pointed out that more and more Americans are concerned with the rising cost of prescription drugs. In fact, the President's FY17 budget proposes a number of solutions for Congress to consider as solutions to the problem. However, I'm concerned the Administration is talking out of both sides of their mouth on this issue. Since 2013, the FDA has considered finalizing a proposed rule on labeling changes for approved medicines. The rule takes an unprecedented approach to long standing laws and regulations requiring generics to have the same label as the brand. By some estimates, this change would increase the costs on the generic pharmaceutical industry by as much as $4 billion annually. And your Agency, in spite of receiving more than 23,000 comments on the proposed rule, has never met with industry representatives to discuss it, nor have you made any effort to make a realistic estimate the rule would have on prescription drug costs and access. How can you tell me you're concerned about the rising cost of prescription drugs on one day, and then turn around and tell patients that you're going to finalize a rule that could add another $4 billion to the cost of their prescription drugs tomorrow?**

Answer: I share your concern regarding the rising cost of drugs, and like you believe that drug costs are not just the state and Federal governments' fastest growing cost, but also a real kitchen

table issue for working families and retirees. Per capita Part D costs increased by 11 percent in 2014, driven primarily by increased spending on high cost drugs in the catastrophic phase of the benefit, which grew much faster than any other part of the program. The extremely high cost of certain specialty drugs raises issues about whether beneficiaries have access to the drugs that they need most.

Our goal is to protect consumers' access to important drugs while encouraging research and innovation, and we have taken several steps to address this. The Affordable Care Act took steps to make Medicare drug coverage more affordable by closing the coverage gap – and 9.4 million seniors and people with disabilities saved over $15 billion on prescription drugs as a result. This year's the President's Budget also proposes to give the Secretary the authority to negotiate prices under the Part D program for biologics and high-cost drugs.

Over the past several months, HHS has engaged with consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from state and Federal government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients. This included a forum that brought together key stakeholders to share information focused on how to meet the overall goals of encouraging pharmaceutical innovation, assuring access to medications, and managing costs for Federal, state, and private health care purchasers. We welcome continued engagement and feedback as we work together to address this rapidly growing cost center, while continuing to support innovation and access.

At the same time, we are focused on bringing new drugs to the market and encouraging competition – and FDA is an important part of that work. FDA programs such as fast track and priority review help expedite getting new drugs and biologics into the hands of patients. The role of FDA is to ensure the safety and effectiveness of prescription drugs, both branded and generic. The proposed rule you reference is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), health care associations, drug and pharmacy associations, brand and generic drug companies, law firms, state governments, and Congress. These comments include proposals of alternative approaches to communicating newly acquired safety-related information in a multi-source environment. FDA received approximately 200 comments; along with the one comment with over 23,000 signatures that you mention. These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association on September 8, 2014, to listen to their comments and views regarding the proposed rule.

In addition, in March 2015, FDA held a public meeting at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve communication of important, newly acquired drug safety information to health care professionals and the public. In the February 2015 notice announcing the public meeting, FDA reopened the comment period for the proposed rule until April 27, 2015, to allow the submissions of written comments concerning proposals advanced during the public meeting.

FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting. Any final rule will reflect FDA's consideration of public comments and be accompanied by an updated analysis of the economic impact of the regulatory change.

4. **During Dr. Robert Califf's confirmation hearing in the Senate HELP Committee he was asked about the status of finalizing the Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products labeling rule currently pending at FDA. In response to that question he said finalizing the rule was a "top priority" and added that "[FDA needs] to make sure that if there are problems with generic drugs that come up later, and they do, with better surveillance systems, that there's a way of making sure the labels are up-to-date and *consistent across similar products.*" [emphasis added.] I believe the pending rule would require the generic company that identified the adverse event to unilaterally change their drug labeling information prior to the review and approval of the FDA, but would NOT require the remaining generic companies or the brand to change their labeling; thus, continuing to allow for all labels of similar products to not be consistent – and conflicting directly with the Hatch-Waxman statute requiring "sameness", thwarting the law's objectives, and imposing significant confusion and costs on patients. In light of your desire to assure consistency and timely updates of information across similar products – a goal I share with you – why do you believe this proposed rule is necessary?**

Answer: The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

Under current regulations, there is a difference between the brand and generic drug labeling during the period when FDA is reviewing a brand drug manufacturer's "changes being effected" or "CBE" supplement. Once FDA approves a change to the brand drug labeling, the generic drug manufacturer is required to revise its product labeling to conform to the approved labeling of the corresponding brand drug. FDA advises that this update should occur at the very earliest time possible; however, there may be a delay of varying lengths. The proposed rule, if finalized, would generally reduce the time in which all generic drug manufacturers make safety-related labeling changes by requiring conforming labeling changes within a 30-day timeframe.

5. **I am aware this proposed rule has been delayed 3 times. While I welcome those delays, the pharmaceutical industry deserves clarity on the Agency's intentions, especially in the closing months of this Administration. When will you make a final determination on whether to move forward with this rule?**

Answer: The Unified Agenda[11] currently lists an anticipated publication date of July 2016 for the final rule on "Supplemental Applications Proposing Labeling Changes for Approved Drugs

[11] Available at *http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=0910-AG94*

and Biological Products."[12] The dates for rules in the Unified Agenda are projected dates that may be adjusted to reflect ongoing work on specific rules.

6. **On January 22, 2014 Chairman Alexander and Chairman Upton lead a letter signed by twenty-eight House and Senate lawmakers noting grave concerns regarding the FDA's proposed rule on generic drug labeling, which would depart from more than two decades of established Hatch-Waxman "sameness standard" by allowing generic companies to unilaterally change their drug labeling information – conflicting directly with the Hatch-Waxman statute, thwarting the law's objectives, and imposing significant costs on health care consumers. Both in the proposed rule, and in the agency's response to this letter, the claim is made that the U.S. Supreme Court's 2011 decision in Pliva v. Mensing somehow "alters the incentives for generic drug manufacturers to comply with current requirements to conduct robust post-marketing surveillance" – but the agency's response letter contradicts that statement by noting that the proposed rule "neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive." It seems to me that the proposed rule is a solution in search of a problem. Does the FDA have any evidence or data to suggest that generic drug manufacturers are not complying with current reporting requirements? Has there been any reduction in adverse event reporting since the 2011 Supreme Court decision?**

Answer: The proposed rule focuses on the obligation to update labeling to reflect newly acquired information, not on the legal duties to report adverse drug events to FDA or more generally to meet postmarket surveillance requirements associated with adverse event reporting obligations. As the Agency has explained, the proposed rule neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive. FDA has received a great deal of public input from stakeholders during the comment period on this proposed rule.

- **In the agency's response to this letter signed by twenty-eight Senate and House lawmakers outlining our concerns with the FDA's misguided proposed rule on generic drug labeling, the claim is made that during its review of a generic manufacturer's labeling changes in a CBE-0 supplement, the FDA "would make an approval decision on proposed labeling changes for the generic drug and the corresponding brand drug at the same time" to ensure the sameness of the labels, but labels could potentially be different for an indeterminate period of time. I am concerned that this explanation assumes that the FDA would receive only a single labeling change, from a single generic manufacturer, at a time. But we could easily imagine a scenario where multiple generic manufacturers – out of an overabundance of caution under the uncertain and unpredictable regulatory and legal environment created by this rule – submit multiple, potentially contradictory labeling changes to FDA at different times. How would the agency handle multiple labeling changes, received from multiple different generic manufacturers? And wouldn't this scenario result in multiple, different labels for identical products over an extended period?**

[12] All responses are accurate as of February 24, 2016.

Answer: In the proposed rule, FDA considered the scenario in which generic drug manufacturers submit CBE-0 supplements with labeling changes that differ from each other and from the corresponding brand drug. FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment.

7. **In a Senate HELP letter to the FDA regarding the agency's generic drug labeling rule, the Committee raised concerns with the provision in the rule that creates a public website where proposed label changes would be published before FDA consideration, since it would undermine the FDA's current role as the gatekeeper and deciding authority for changes to a drug's label. I remain concerned that by publishing this information prematurely, without FDA approval, the rule could provide the public and health care providers with potentially inaccurate and misleading information. How can health care providers, and the public, have confidence in the accuracy of this information?**

Answer: FDA's current regulations permit certain labeling changes based on newly acquired information about an approved drug to be implemented upon receipt by FDA of a supplemental application that includes the change. These supplements are commonly referred to as "changes being effected" or "CBE" supplements. FDA allows drug manufacturers to communicate certain safety-related labeling changes upon receipt by FDA of a CBE supplement -- and prior to FDA approval of the proposed labeling change -- in the interest of public health. FDA carefully reviews any labeling change proposed in a CBE supplement, as well as the underlying information or data supporting the change, and FDA has the authority to accept, reject, or request modifications to the proposed changes as the Agency deems appropriate.

The Honorable Tim Murphy

1. **Section 223 of the Protecting Access to Medicare Act of 2014 creates a demonstration project for new Certified Community Behavioral Health Clinics and one of the requirements for these new outpatient mental health clinics is that they "improve availability of, access to, and participation in assisted outpatient mental health treatment in the State." Now that the planning grants have gone out, can you please detail how this their criteria was in the decision making process for awarding the grants under Section 223 of the Protecting Access to Medicare Act of 2014?**

Answer: Award of the planning grants was based on the requirements in the statute. As you know, Pennsylvania was one of the funded states. Planning grant requirements are to solicit input with respect to the development of such a demonstration program from patients, providers, and other stakeholders; certify clinics as certified community behavioral health clinics (CCBHC) for purposes of participating in a demonstration program; and establish a prospective payment system for mental health services furnished by a certified community behavioral health clinic participating in a demonstration program. Selection of states participating in the demonstration program will be prioritized based on State plans that best meet the requirements in the law.

2. **Section 224 of the Protecting Access to Medicare Act of 2014 establishes an Assisted Outpatient Treatment Grant Program For Individuals With Serious Mental Illness which was funded at the end of last year. Can you please provide an update on where the grants established under the stand in terms of being able to award the funds?**

Answer: The funding opportunity announcement will be issued this Spring, with an anticipated award date before the end of the fiscal year.

3. **When and how was the Common Data Platform (CDP) developed for the Substance Abuse and Mental Health Services Administration (SAMHSA)?**

Answer: Throughout the life of the contract, the CDP had several Contracting Officer Representatives (CORs) and Alternate CORs overseeing the contract implementation. These individuals were part of CBHSQ and reported up the chain of command to the CBHSQ Deputy and Center Director, who reported to the Office of the Administrator.

The oversight of the CDP project was done by SAMHSA personnel; however, as the CDP's technical difficulties became increasingly evident, aspects of the approach to rectify the situation, including the decision to shut down the system and procure a new contract, were overseen and monitored by personnel from the Department. In addition, staff from the Department provided assistance and oversight in developing the next procurement.

SAMHSA has taken steps to ensure a more comprehensive management approach. The new effort involves leadership across SAMHSA and is managed by a cross-Agency Governance Council comprising Deputies from all four Centers as well as the Office of Financial Resources.

4. **What was its intended purpose within the grants management system?**

Answer: The intended purpose of the Common Data Platform (CDP) was to enable SAMHSA to collect and report data uniformly across its non-formula-based grantees. The intention was to provide SAMHSA staff access to uniform reports by which to manage its grant programs as well as to provide staff and leadership access to aggregate information across SAMHSA's grant programs. The effort was also intended to ease grantee burden for those who had grants from multiple SAMHSA Centers.

Please describe:

5. **Under which legislative or regulatory authority were CDP-related funds allocated?**

Answer: CDP funding was appropriated under the statutory authorities Sections 501 and 505 of the Public Health Service Act, 42 U.S.C. 290aa and 42 U.S.C. 290aa-4. This funding is part of the Performance and Quality Information Systems funding line of Health Surveillance and Program Support.

6. **When and why the solicitation notice for CDP was developed and published?**

Answer: The CDP solicitation was published to procure a system for SAMHSA to provide access to uniform information, management reports, and data as described above. The solicitation, via a Request for Task Order Proposal, was issued on May 3, 2013.

7. Which grant program(s) is/was CDP intended to support?

Answer: CDP was intended to support SAMHSA's non formula-based grant portfolio across its three programmatic Centers.

8. What were the specific deliverables and tasks required of the contractor in the CDP contract?

Answer: The primary tasks and deliverables of the contract were the development and implementation of a real-time data entry and reporting system for the collection and reporting of SAMHSA discretionary grant data. Specific tasks included: management, reporting, existing data management and archival database work, development and implementation of common data collection and reporting system, training and TA, and transition services.

9. What procedure(s) were used to develop and award this contract?

Answer: SAMHSA issued the Request for Task Order Proposal using the NIH NITAAC CIO-SP3 Small Business vehicle. NITAAC is an OMB-authorized government-wide acquisition contract (GWAC) for IT acquisitions. Once proposals were received, offerors' proposals were rated using an objective Technical Evaluation Panel (TEP) of federal employees. The contract was awarded to the offeror with the highest technical score and the lowest bid.

10. Which contractor won the bid and is/has administered CDP for SAMHSA grantees?

Answer: ACE Info was the contractor who won the bid and administered SAMHSA's CDP.

11. Have additional contracts or contractors been engaged to supplement the original process? If so, why?

Answer: Other contracts were not engaged to supplement the original CDP. A corresponding contract to provide training and technical assistance was released at the time of the CDP and was part of the original process. No additional contracts were used to supplement the CDP during the system's operation.

12. Who at SAMHSA is/was responsible for overseeing the CDP contract? Was there oversight by the HHS Secretary or other authorities other than SAMHSA personnel?

Answer: Throughout the life of the contract, the CDP had several Contracting Officer Representatives (CORs) and Alternate CORs overseeing the contract implementation. These individuals were all part of CBHSQ and reported up the chain of command to the CBHSQ Deputy and Center Director, who reported to the Office of the Administrator.

In order to ensure a more comprehensive management approach, the new effort involves leadership across SAMHSA. The new effort is managed by a cross-Agency Governance Council comprising Deputies from all four Centers as well as the Office of Financial Resources.

The oversight of the CDP project was only done by SAMHSA personnel; however, as the CDP's technical difficulties became increasingly evident, all aspects of the approach to rectify the situation, including the decision to shut down the system and procure a new contract, were overseen and monitored by personnel from the Department. In addition, staff from the Department provided assistance and oversight in developing the next procurement.

13. How many grantees (actual number and percentage of total) had significant problems using CDP to enter consumer data that they are legally required to collect and submit to SAMHSA during FY2015? How many phone calls, emails and letters were received by SAMHSA from grantees that were unable to use CDP to report required information?

Answer: SAMHSA received over 450 grantee notifications of technical difficulties to a central SAMHSA mailbox. In addition to these contacts, GPOs across SAMHSA received numerous phone and email contacts for all grant portfolios reporting issues. Some grant portfolios, e.g. Addiction Technology Transfer Centers and Access to Recovery, opted to utilize a single point of contact to relay concerns directly to SAMHSA leadership on behalf of the entire grant program.

14. Has SAMHSA communicated with grantees in a prompt and clear manner about resolving any data collection problems involving CDP and/or to provide alternative reporting methods?

Answer: Yes, SAMHSA Project Officers were communicating regularly with grantees regarding CDP and issues grantees were having. SAMHSA leadership communicated formally with grantees in May, July, and October of 2015 alerting them to the status of the CDP and the plan to revert to legacy systems for reporting. All SAMHSA grantees are currently using legacy systems for reporting. SAMHSA has received no inquiries or concerns from grantees on these systems.

15. After months of advising grantees to retrain their staff to use a previous "Legacy" data collection tools (in lieu of the CDP-compatible tool), why did SAMHSA wait until the day after SAMHSA's own deadline (wasting precious grantee resources) to rescind this instruction?

Answer: SAMHSA has not rescinded its instruction for grantees to use a previous legacy data collection tool; SAMHSA grantees are currently using legacy tools on which they have all been trained.

16. Were General Project Officers (GPOs) given sufficient information and support to assist Grantees who were unable to use CDP to report data that they are legally required to report?

Answer: Project Officers were given initial training on the CDP; however, technical difficulties proved too great to enable GPOs to use the system effectively.

17. Were GPOs or their supervisors admonished to limit communications with grantees complaining about CDP for extended periods of time? Why was a GPO or their supervisor criticized for thoughtfully writing to (assigned) grantees to mitigate confusion about the contingency plans and data collection tools SAMHSA suggested (and then reversed) when CDP became unusable?

Answer: SAMHSA leadership was never made aware of any admonishment of GPOs for communicating about CDP. No guidance was ever given to supervisors or Center leadership to deliver such admonishment.

18. Did SAMHSA relieve grantees of their legal reporting burden?

Answer: Grantees were not relieved of any statutory or legal reporting burden. Grantees were required to continue official reporting such as continuation application, financial reports, and progress reports. Grantees were directed to continue to collect performance data for future submission once system issues were resolved.

19. What specific outcome data has been developed from SAMHSA grantee data collected through CDP during FY 2015? How does the quantity and quality of SAMHSA's outcome data differ from the quantity and quantity of outcome data that was expected from grants? How much money has SAMHSA expended on CDP to date?

Answer: FY 2015 outcome data were not available through the CDP. The data collected through the CDP were not usable for outcomes reporting. The quality of the data collected through the CDP differed greatly from the quality collected through previous legacy systems which contained automated validation and verification checks on the data. The CDP did not contain these automated checks. The total spent on the CDP from the inception of the contract through its completion was $10,558,388.

20. How much money did SAMHSA spend in FY2015 trying to resolve CDP problems or (in efforts) to replace the CDP system? Did this money come from administrative or service program allocations? How were funds to fix or replace CDP identified, by whom, and were these approved by appropriate oversight authorities?

Answer: SAMHSA spent an additional $1.8M for a modification to the ACE Info contract to attempt to resolve issues with the development and implementation of the CDP. In addition, SAMHSA spent $7.6M to restore the legacy systems to cover a critical gap and assure continued compliance with reporting. Funding for these activities was primarily generated from delayed implementation of various initiatives within the CBHSQ portfolio.

21. Is each state that receives a Projects for Assistance in Transition from Homelessness (PATH) grants required to document what they had spent on services for their homeless citizens (with behavioral health problems) and submit documentation that the state had continued its spending level at the same or greater level that it had prior to

receiving this federal money, or in other words required to show a "maintenance of effort (MOE)"?

Answer: Yes, states that receive a PATH grant are required to document what is spent on services, and submit an assurance that they are meeting the maintenance of effort requirement.

22. How has SAMHSA instructed states to establish and submit documentation of their baseline spending levels and compliance with the PATH MOE?

Answer: Since FY 2012, SAMHSA has been assessing state MOE compliance during the fiscal and programmatic site monitoring visits. If it is determined that a state has not adequately met the requirement, SAMHSA issues a required follow-up action statement in the site visit report. States who have received these statements are addressing the required corrective actions. Further guidance has been developed and will be issued to all states in summer 2016.

23. How many states that received PATH funding submitted their baseline and yearly MOE documentation to SAMHSA? How many were required to do so by law? Has SAMHSA received requests from states for help in fulfilling this reporting obligation?

Answer: There is no specific statutory requirement for states to provide baseline data. The submission of baseline data will be requested through the SAMHSA-developed MOE guidance once we share it with states. All states submitted signed assurances regarding MOE compliance. SAMHSA has received requests for technical support, and as indicated above, guidance is forthcoming.

<u>The Honorable Michael C. Burgess</u>

The Office of Refugee Resettlement (ORR) is responsible for taking temporary custody of unaccompanied children crossing the border, and for placing them with a custodian capable of caring for them while immigration proceedings are underway. ORR officials have acknowledged that, in recent years, their office relaxed standards for background checks of potential sponsors. ORR only checks on children after they are placed with sponsors in a small number of cases. There have been reports of these children becoming victims of human trafficking, being neglected and abused, and being lost in the system forever. Over the course of several years I have had several meetings and asked very specific questions, but been unable to gain specific information from this Administration about the processes and policies in place to ensure it is not prioritizing volume over integrity in dealing with these children. In multiple meetings with ORR, and in a briefing to Committee staff, ORR has claimed that HHS has no statutory authority to take action to ensure the safety and wellbeing of a child post-placement, but ORR has failed to cite any statute limiting such authority. A February 11, 2016, letter sent by members of the Energy and Commerce Committee to the Secretary requested specific information to explain the Department's legal position by February 25, 2016—HHS has failed to provide such information. Please provide a response to the following questions:

1. **On what grounds does HHS claim the Department has no statutory authority to ensure for the well-being of children after they are placed with sponsors? Please explain HHS's legal position. How is this position consistent with the Department's policy to follow up**

with some unaccompanied children after they are placed with sponsors in limited cases? If HHS has no authority, which agency does? Has HHS discussed this issue with other agencies such as the Department of Justice or the Department of Homeland Security? Explain.

Answer: HHS's longstanding view across administrations is that, under the authorities governing the Unaccompanied Children Program, once a child is released to a sponsor, ORR's legal and physical custody terminates. ORR's Unaccompanied Children Program is authorized by and operated in accordance with the Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) The program is also operated consistent with the *Flores Settlement Agreement*. The authorities and the resources given to the Unaccompanied Children Program in ORR establish a system that is intended to temporarily care for children while in our physical custody, and releasing children to appropriate sponsors as expeditiously as is safely possible.

But the fact that ORR's custody ends upon release does not mean that its commitment to providing resources, connecting children and sponsors to services, and protecting vulnerable children from abuse or exploitation ends. HHS has authorities that permit it to provide a range of services and resources after a child is released from the agency's custody, and it makes use of that authorization to establish policies and procedures that, among other things, are intended to protect those children that may be vulnerable to abuse or exploitation. ORR's ability to provide these services is hindered by the uncertainty of the total program needs compared to resources available. Budgeting for the unaccompanied children's program is particularly challenging for HHS because funding for the program is set at the beginning of the fiscal year, when the number of children who will require services and the timing of their referral to HHS is unknown. For these reasons, the President's FY 2017 Budget again proposes a contingency fund that would provide additional resources to serve unaccompanied children, if referrals exceeded what could be accommodated within existing resources. If enacted, the contingency fund would help ensure ORR had sufficient capacity to adjust to large and unpredictable fluctuations in need and more deliberately plan for all components of the program including post-release services.

Within its current authorities, ORR deploys its resources in order to provide post-release services as effectively as possible. ORR provides post release services for any child who received a home study on a case-by-case basis if it is determined the child has mental health or other needs.

In July 2015, ORR began a pilot project to provide post-release services to all unaccompanied children released to a non-relative or distant relative sponsor, as well as children whose placement has been disrupted or is at risk of disruption within 180 days of release and the child or sponsor has contacted ORR's hotline.

In May 2015, ORR expanded the capability of an existing telephone hotline, which had traditionally been used to help parents locate children in ORR custody. Now the hotline accepts calls from children with safety-related concerns, as well as from sponsors with concerns or who need assistance connecting to community resources. Every child released to a sponsor is given a card with the hotline's phone number on it (Spanish language access as well) and all providers and sponsors are also provided with the hotline phone number.

Starting last summer, care providers now call each household 30 days after the child is released from ORR care to check on the child's wellbeing and safety.

If any of ORR's provider grantees or staff has reason to believe that a child is unsafe, they comply with mandatory reporting laws, state licensing requirements, and federal laws and regulations for reporting to local child protective agencies and/or law enforcement.

2. **Section 218(b) of the Protecting Access to Medicare Act (PAMA) (PL-113-93) established criteria to mandate the consultation of appropriate use criteria (AUC) by ordering physicians prior to referring Medicare patients for select advanced diagnostic imaging services. This PAMA legislative policy, which passed the Congress with strong bipartisan and bicameral support, was scheduled to go into effect January 2017. This policy was intended to ensure proper utilization of advanced imaging studies based on clinical evidence, rather than merely burdening access with arbitrary restrictions. Despite the passage of PAMA AUC provisions, the Obama Administration's Fiscal Year 2017 Budget for the Department of Health and Human Services, once again, calls for the implementation of a Medicare prior authorization program. Can you please update the committee on the January 1, 2017 effective date for the PAMA imaging AUC policy? Will the agency meet the January 1, 2017 effective date by which ordering physicians must begin consulting imaging appropriateness criteria as a condition for Medicare payment? If the Agency will not be meeting the January 1, 2017 deadline, please explain why a delay is necessary, as well as when CMS expects to finalize implementing regulations?**

Answer: We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. The number of clinicians impacted by the scope of this program is significant, as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) rulemaking process, we will begin to identify priority clinical areas and expand them over time. We anticipate including further discussions and adopting polices regarding claims-based reporting requirements in the CY 2017 and CY 2018 PFS rulemaking cycles. Also, in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals. We recognize the importance of moving expeditiously as well as ensuring transparency and working with stakeholders to accomplish a fully implemented program.

<u>The Honorable Leonard Lance</u>

Last August, the U.S. Court of Appeals for the D.C. Circuit issued a decision interpreting the Federal Vacancies Reform Act of 1998 that would prohibit various acting federal officers from serving in positions for which they have been nominated. The Department of Justice filed a petition seeking further review of the case by the entire D.C. Circuit, which

was subsequently denied. A *Washington Post* article covering this story quoted the Justice Department saying a recent D.C. Circuit court decision casts a "legal cloud" over a number of acting government officials. The Justice Department wrote "the service of approximately a dozen current acting officers would be subject to question under the panel's opinion, including senior officials in the Department ... of Health and Human Services."

1. **Have you been briefed, or have you asked for a briefing, about the impact of the court's decision on the Vacancies Reform Act on the actions of certain senior HHS acting officers? If not, will you ask for such a briefing? When?**

2. **Have you requested what changes will be made to be in compliance with the Vacancies Reform Act? If not, why not?**

I'm particularly concerned about this as it relates to the Anti-deficiency Act. As you know, this Act prohibits federal employees from making or authorizing an expenditure from, or creating or authorizing an obligation under, any appropriation or fund in excess of the amount available in the appropriation or fund unless authorized by law.

3. **According to a recent HHS financial audit "HHS's management determined that it may have potential violations of certain provisions of the Anti-Deficiency Act related to FY2014 and F2015 obligation of funds for conference spending and a potential violation related to the appointment of a presidentially-nominated official with the required information." Are you aware of these potential violations? Has any action been taken to address them?**

Answer: We are aware of both matters and I have discussed the Vacancies Reform Act with the Office of the General Counsel. On conference spending, the consolidated appropriations acts for each of FYs 2013- 2015 included a government-wide general provision that limited the availability of funds appropriated in those acts, or any other acts, for expenses of conference activities that are not in compliance with OMB's memorandum M-12-12, dated May 11, 2012; which requires that such expenses be approved by certain specified agency officials prior to use of funds for such purposes. HHS has worked intensively to assure compliance with those appropriations acts provisions that restrict the use of funds for conference expenses. Currently, the Department is reviewing the use of ACF's appropriations to award contracts for the performance of services in support of an ACF conference to determine if such obligations complied with the applicable appropriations acts provisions. With respect to the appointment of the agency official to which the audit referred, HHS is reviewing whether an HHS appropriation was used to pay for the services of an individual who was carrying out the responsibilities of a position that required Senate advice and consent after the second nomination for that individual was returned to the President in violation of a government-wide general provision that prohibits the use of appropriations for such purpose. We are committed to being responsible stewards of taxpayers' funds in these areas and across our programs.

<u>The Honorable Brett Guthrie</u>

I am a cosponsor of Rep. Reichert's legislation, H.R. 2649, the Medicare Secondary Payer and Workers' Compensation Settlement agreements Act. This legislation includes

language to authorize payment of amounts for future medical in workers' compensation settlements to be paid directly to meet MSP future medical obligations. HHS included in its FY 2017 budget request a provision to enable CMS to accept sum certain payments to meet Medicare Secondary Payer obligations, which projects $63 million in savings over the budget period.

1. **Would you please provide the data and assumptions used to determine the budget savings?**

2. **In addition, has CMS provided technical assistance regarding H.R. 2649 to Congressional supporters and stakeholders? If not, would you please work with Congressional supporters and stakeholders on this issue?**

Answer: CMS has received a request for technical assistance on this legislation, and would be happy to discuss further with your office.

<u>The Honorable Morgan Griffith</u>

The Center for Medicare and Medicaid Innovation (CMMI) will be testing enhanced medication therapy management (MTM) models designed to find innovative approaches to MTM that will result in more efficient outreach and targeting of beneficiaries and create better alignment of program incentives.

1. **Given the important role retail community pharmacies play in medication management, how does CMMI plan to ensure that there is robust community pharmacy participation in the enhance MTM models?**

Answer: CMS believes that pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use the prescription drugs upon which they rely. The Enhanced MTM model aligns financial incentives and grants flexibility for basic, stand-alone Prescription Drug Plans (PDPs) to test MTM interventions that could include increased reliance upon the pharmacist as a trusted community resource to ensure that targeted beneficiaries are taking their medications accurately and appropriately.

When announcing the model, CMS noted that it expects sponsors to rely more heavily on more personalized strategies, such as contacts from trusted community pharmacists or their medical providers, because in many cases these will be more effective than call-center or mail contacts from the PDP.

Moreover, CMS noted that it expects to see plan sponsors suggest protocols involving multi-pronged, proactive, and persistent efforts to make contact with Medicare beneficiaries and ensure their on-going participation and engagement, as well as use of diverse communication modalities such as person-to-person interactions, phone calls, and trusted community contacts and relationships (including community pharmacists and prescribers) to achieve significant engagement rates.

2. **Will the agency partner with Part D plans that propose to utilize retail pharmacies in their enhanced MTM model?**

Answer: CMS is granting basic, stand-alone PDPs the flexibility to design enhanced MTM programs that incorporate interventions beyond the standard MTM programs under Medicare. As a result, plans may propose an expanded range of MTM activities, including contracting with pharmacists to provide enhanced engagement or other services. Any financial compensation to pharmacists under this model would be provided by the participating PDP or contracted vendors, not CMS.

3. **Additionally, does CMS plan on using its authority to expand successful approaches to the entire Part D MTM program before the end of the five year testing period?**

Answer: Under statute, successful Innovation Center models can be expanded if they either reduce Medicare expenditures without reducing the quality of care or improve the quality of care without increasing expenditures. If the Enhanced MTM model proves successful and satisfies these criteria, it could potentially be expanded (including on a national basis) under this authority.

In addition to possible formal expansion, the results of this model could also be used to inform policy in other ways. Specifically, lessons from this model could inform potential changes to MTM policies and rules in integrated care models, or be adopted by other types of health plans, such as those in state Medicaid programs or exchange plans.

In responses to Questions for the Record from testimony before the committee in July, Vikki Wachino, the head of the Centers for Medicaid and Chip Services (CMCS), claimed "the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work or receive job training because that is not an objective of Title 19." Yet, at the same time, CMS has approved federal funding under 1115 waivers for designated state health programs (DSHP) [or "DISH-pee"] that provide job training. For example, one funded DSHP provides pre-vocational services for individuals with disabilities to help prepare them for paid employment. CMS states that this promotes Medicaid program objectives because the services can lead to better outcomes for Medicaid and low-income individuals.

4. **So, could you explain why you think CMS can fund pre-vocational services, but not approve required vocational engagement for the non-disabled population?**

Answer: Pre-vocational services for people with disabilities are a long-standing element of Medicaid's benefit package. They involve services supporting improved function, including both physical and cognitive therapies. Pre-vocational services are designed to facilitate the ability of individuals to attain and maintain competitive employment. As such, they should be provided for a time-limited period in which individuals with disabilities are given the skills necessary to seek employment according to their strengths and preferences, such as: effective communication with supervisors, colleagues and customers; workplace conduct; the ability to follow directions and complete tasks; and problem solving skills. Medicaid funds pre-vocational services primarily through the home and community-based waiver and state plan authorities. This is one example

of a way in which CMS promotes employment among Medicaid beneficiaries without requiring employment as a condition of Medicaid eligibility.

5. **Since CMS has denied several requests from governors to utilize work requirements for the non-disabled population, I assume CMS examined this issue in some legal depth. Can you share such analysis with the committee?**

Answer: In reviewing state proposals for section 1115 demonstration programs, CMS does consider encouraging work an important state objective and has worked with states to develop approaches that encourage work and job training participation. Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve demonstration projects only if they promote the objectives of the Medicaid and CHIP programs. However, requiring Medicaid beneficiaries to work or receive job training is not an objective of Title XIX. Consequently, 1115 demonstration programs may include services such as pre-vocational services that aim to promote the overall health of Medicaid beneficiaries involved, but Medicaid funding may not be used for work requirements or other work programs that have the primary goal of promoting work rather than promoting health. As noted earlier, the structure of the ACA is built on every American having a guarantee of access to affordable health insurance. We cannot condition that access on any requirement including work. I also noted earlier that we have approved demonstrations in which states promote employment through state programs outside of Medicaid.

6. **What do you make of the various studies that show how employment can help boost self-esteem, health, and lead to better outcomes for low-income individuals?**

Answer: Most Medicaid beneficiaries are employed or are in households where someone is working. In 2013, 79 percent of children who were Medicaid beneficiaries lived with at least one worker; 65 percent lived with at least one full-time worker. That year, 65 percent of adults with Medicaid were in a family with a worker; half were in a family with at least one full-time worker. Adults who qualify for Medicaid may be working but earning low wages and may not be able to afford private coverage. With Medicaid, such workers have health coverage and are likely to have a usual source of care, which helps them stay healthy and remain productive on the job. Such studies support section 1115 demonstrations including limited programs that help prepare beneficiaries for the workforce as a means of improving the health and wellbeing of those beneficiaries. This includes pro-vocational services for individuals with disabilities. The Medicaid program contains a number of incentives for beneficiaries to enter the workforce or to increase their hours.

Additionally, health coverage through Medicaid promotes individuals' health and ability to participate in the workforce. There are several examples of how Medicaid promotes employment: First, in the case of individuals with disabilities, Medicaid disregards a certain amount of earnings in determining their eligibility for benefits; this enables these individuals to retain their Medicaid coverage while working. Second, for individuals with serious mental illness, Medicaid can provide supportive employment services to help these individuals find and maintain employment. I also note that as a result of Congressional action on MACRA, Medicaid continues to provide up to one year of transitional coverage for individuals who lose cash assistance due to earnings from employment.

The Honorable Gus Bilirakis

HHS's FY2015 financial audit noted that HHS management determined that it may have potential violations of certain provisions of the Anti-Deficiency Act related to Fiscal Year 2014 and Fiscal Year 2015 obligation of funds relating to conference spending, and a potential violation related to the appointment of a presidentially-nominated official without the required confirmation.

1. What conferences and what presidentially-nominated officials are in question?

Answer: HHS is currently reviewing obligations incurred for expenses of the Administration for Children and Families' Community Economic Development Conferences. The appointment matter in question relates to payments that HHS made for services performed by the former Acting Director of the Indian Health Service that may have been in violation of section 749 of Pub. L. No. 111-8, div. D, title VII, 123 Stat. 680, 693 (2009).

2. Has HHS actually determined if there was a violation?

Answer: The Department is reviewing whether the obligations incurred for the ACF conferences violated provisions in the appropriations acts that restricted the use of appropriations for expenses of conference activities not in compliance with OMB M-12-12. The relevant appropriations act provisions require that the Deputy Secretary approve in advance any conference sponsored or hosted by the agency (or by other Federal or non-Federal entities) where the net conference expenses to be paid by agency will exceed $100,000. The Department plans to complete its review, and to the extent any violations are determined, it will issue the required reports. As to the appointment matter, the Department is in the process of finalizing its review.

3. Can you provide more information about this potential violation?

Answer: For the two conferences in question, HHS is investigating whether the amount of the obligations incurred or the amount of payments made exceed $100,000, and if so, whether ACF obtained the Deputy Secretary's approval prior to using its applicable appropriation for the conferences as required by the government-wide general provisions in the appropriations acts. For the appointment matter, section 749 of division D of Public Law 111-8 prohibits the use of appropriated funds to pay an individual to act in a position after that individual's nomination to that position had been withdrawn or returned twice. As soon as HHS learned there was a potential problem, the former Acting Director of the Indian Health Service was reassigned.

The Honorable Renee Ellmers

1. **As a nurse, I am committed to our seniors having a strong Medicare Advantage program. Today, encounter data by Medicare Advantage plans includes information on beneficiary diagnoses and medical services received, similar to fee-for-service claims data. These encounter data are reported to CMS, and beginning with CY 2016 are used to determine Medicare Advantage enrollee risk scores for the purpose of risk adjusting plan payments. Currently, CMS calculates risk scores using a blend that includes 10%**

encounter data. However, in the 2017 Advanced Notice which came out Friday, CMS proposes to increase this amount to 50%. Although plans have been collecting and reporting encounter data to CMS since 2012, ongoing operational issues have prevented plans from submitting accurate data in a timely fashion to CMS and receiving data back from CMS necessary to understand how their enrollee risk scores will be impacted. How does CMS propose to implement such sweeping changes to the data sources used to calculate enrollee risk scores before resolving the slew of operational issues faced by the Agency in both data collection and reporting?

Answer: I appreciate your feedback and know that CMS understands the challenges regarding the use of encounter data for risk adjustment. CMS has been and continues to work in good faith with plans and other stakeholders on technical and operational issues to address encounter data acceptance, completeness, and quality. CMS is also working closely with health plans to respond to their questions and make changes, where needed, to address the issues cited. CMS's goal is to transition entirely from using diagnoses submitted to Risk Adjustment Processing System (RAPS) to using diagnoses from encounter data, and CMS intends to continue transitioning away from a reliance on RAPS data for calculating risk scores

Encounter data submission rates have steadily increased while error rates have steadily decreased. CMS expects this trend to continue to improve as more experience is gained and for the data to stabilize by the time this blend would be in effect.

2. **The need for our country to be better prepared against biological threats is clear and has been recognized by this Committee and many policy experts, including the recent Blue Ribbon Study Panel on Biodefense. This need follows numerous failures to deal adequately with a series of recent global health threats: both naturally occurring, including the H1N1 and H5N1 influenza pandemics, SARS, Ebola and now Zika; and bioterrorist threats like anthrax and smallpox. There is no reason to expect these threats will subside. Each of these threats provoked emergency actions and an accelerated response from many stakeholders, often in an uncoordinated way. In all cases, the response required massive efforts from the private sector racing against the clock. This scramble was often highly disruptive, and required companies to stop ongoing research and development programs, as well as manufacturing. This situation is sub-optimal and unsustainable. An alternative platform-based approach could allow for more timely readiness when a threat arises. It is my understanding that vaccine platform technologies could now be called upon to quickly develop a Zika vaccine and in general respond more expeditiously to the next outbreak or threat. What is BARDA/HHS doing to support and facilitate platform-based technologies against known and emerging threats?**

Answer: ASPR/BARDA has made it a high priority to support advanced development and implementation of platform-based technologies to more rapidly and efficiently develop vaccines for existing and newly emerging threats. As part of its long-term strategy, ASPR has targeted investment in flexible and nimble capabilities designed to meet novel challenges like those posed by Ebola and now Zika. Specifically in response to current challenges, in October 2015, ASPR/BARDA issued a Board Agency Announcement in support of medical countermeasures platform development. ASPR/BARDA has engaged extensively with the private sector in the

area of platform-based technologies and is currently reviewing proposals that will utilize these approaches to develop Zika vaccine candidates as well as to make these platforms available to respond to other existing or emerging threats.

3. **One of the most urgent and predictable threats we face as a nation is pandemic influenza. As you know, the 2009 H1N1 pandemic, a relatively mild pandemic, killed 18,000 Americans and sickened 600,000 more. Pandemic influenza is not just a public health threat, it is indeed a national security threat. But unfortunately, preparedness against pandemic flu threats has been largely episodic since 2009. The vast majority of funding provided to HHS for pandemic flu was in emergency supplemental legislation during an outbreak. Since that time, sustained resources for HHS' pandemic flu readiness programs have dramatically declined. This has led to an aging stockpile that HHS has demonstrated doesn't match currently circulating strains, domestic manufacturing capabilities that must be sustained, and private sector partners who see waning a commitment and aren't sure if HHS is committed to this partnership that so critical to our readiness. We need to be prepared for the next pandemic BEFORE it happens. Do you believe HHS is ready to handle another outbreak like H1N1 despite dramatic decreases in pan flu preparedness budgets? What steps are you taking to improve HHS' pandemic influenza preparedness programs?**

Answer: HHS has made significant investments and progress toward pandemic preparedness, including the build out of critical infrastructure that will provide significant increases in the production capacity of influenza vaccine needed to respond to a pandemic outbreak. HHS has also supported the development and licensure of new influenza vaccines, including cell-based, recombinant and adjuvanted vaccines that will allow us to respond more quickly with a diversified portfolio of available vaccines in the event of a pandemic. HHS is continually exploring and implementing strategies to ensure that the USG will be able to respond to a pandemic outbreak. These strategies include the implementation of the established Centers for Innovation in Advanced Development and Manufacturing (CIADMs) as well as the Fill Finish Manufacturing Network (FFMN) as part of the National Medical Countermeasure Response Infrastructure (NMRI). These CIADMs and the FFMN offer flexible and nimble approaches that include surge capabilities to address urgent vaccine needs in the event of a pandemic.

ASPR/BARDA has a Broad Agency Announcement open solicitation for the advanced development of medical countermeasures for pandemic influenza. This solicitation supports the advanced development of pandemic influenza medical countermeasures including personal protective equipment and ventilators, influenza test systems and diagnostic tools, therapeutics and vaccines.

HHS is working closely with industry partners to develop and evaluate improved influenza vaccines with universal potential. These improved influenza vaccines will be broadly cross-protective and elicit longer, more durable immune responses as compared to existing influenza vaccines.

4. **HHS' efforts to prepare for and respond to pandemic flu are unclear, unorganized, and underfunded. I am disappointed that your 2017 budget request does not address these problems. Let me read you a quote from last year's budget where you said: "[The**

current funding level of $72 million] impedes HHS' ability to maintain existing programs for pre-pandemic influenza vaccine stockpiling and development of influenza antiviral drugs and immunotherapeutics, which are central programs to address critical vulnerabilities for U.S. pandemic preparedness." Given that nothing has changed since last year, can you describe how our preparedness against pandemic influenza has suffered as a result? What are you doing to ensure HHS sustains readiness efforts against this threat?

Answer: The FY17 Budget requests an increase of +53 million, for a total of $125 million to support activities to address pandemic influenza threats. These activities include the advanced development of new vaccines and therapeutics, international collaboration and capacity building, stockpiling of existing medical countermeasures, and vaccine manufacturing improvements. We appreciate the support that has been provided to develop new influenza vaccines, therapeutics, diagnostics and other medical countermeasures needed to address a pandemic influenza outbreak. We have made significant investments and progress toward pandemic preparedness, including the development of critical infrastructure that provides a significant increase in the production capacity of vaccine needed to respond to a pandemic outbreak. HHS has prioritized the development to licensure of new influenza vaccines, including cell-based, recombinant and adjuvanted vaccines that will allow us to respond more quickly with a diversified portfolio of available vaccines in the event of a pandemic. HHS has also supported the advanced development of new influenza diagnostics, antiviral drugs, ventilators and personal protective equipment.

HHS has expanded our stockpile program to include vaccines that will generate immunity to avian influenza viruses that are perceived to pose the greatest risk to humans. This is determined by a USG interagency review of emerging viruses with pandemic risk, through the implementation of the Influenza Risk Assessment Tool. In addition, to address the material in the stockpile that has been in long-term storage, HHS has and continues to conduct clinical studies to assess the safe and effective use of these vaccines should they be needed to respond to a pandemic outbreak. These clinical data are compiled with additional analytical data on the long-term stability of the stored vaccines. HHS has determined that influenza vaccines and adjuvants stored in the stockpile remain stable, safe and immunogenic beyond what was originally anticipated from prior limited data; therefore extra funding is not currently needed to replace these vaccines and adjuvants. We thank you for your interest in this critical issue, and recognizing we still have much work to do, look forward to working with you to build on this progress as we move forward.

5. **Larry Summers recently said that global security for infectious diseases outbreaks is an area where the "urgent has crowded out the profoundly important." By this he means that we shouldn't let the threat of the moment – whether it be Ebola or Zika – overshadow our efforts to prepare against more predictable threats like pandemic influenza. As you know, the 2009 H1N1 pandemic killed 18,000 Americans and sickened 600,000 more. Pandemic influenza is not just a public health threat, it is indeed a national security threat. What are you doing to ensure the threat of pandemic influenza continues to be addressed in the midst of the urgent demands of the Zika outbreak and ongoing Ebola and MERs outbreak efforts?**

Answer: HHS is committed and dedicated to sustaining the level of pandemic preparedness and readiness that has been built to respond quickly in the event of a pandemic influenza outbreak. This includes the sustainment of: critical infrastructure to produce and manufacture available influenza vaccines; a National Pre-pandemic Influenza Vaccine Stockpile that contains vaccine and adjuvant to meet requirements as set out in the HHS Pandemic Influenza Plan; the National Medical Countermeasure Response Infrastructure that includes flexible manufacturing capabilities; clinical, non-clinical, and regulatory support for rapid surge response capabilities; and other core capabilities needed to respond to a novel infectious disease. I am personally briefed on this topic, even as I continue my extensive involvement in our response to the Zika virus and other critical issues.

6. **Public Health England - England's Center for Disease Control and Prevention - is taking the assertive stance that e-cigarettes are hugely less harmful than combustible cigarettes. In fact, Public Health England estimates that e-cigarettes are 95% less risky than combustible cigarettes. Public Health England thinks that it is critical for adult smokers to know this and consider shifting away from burning cigarettes. Do you share Public Health England's view? Do you think it would be appropriate for FDA to prepare and implement a similar program to tell current adult smokers that the health risks associated with smoke-free tobacco products, specifically e-cigarettes or electronic nicotine delivery systems, are significantly lower than the risks associated with cigarette smoking? Broadly speaking, what is your agency doing to encourage smokers who will not quit to move to less harmful forms of nicotine?**

Answer: Much remains to be learned about the health risks or benefits of e-cigarettes. They could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. On the other hand, e-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective products (such as exploding batteries). Anecdotes illustrating both benefits and harms abound, but it is definitive scientific evidence that should drive the actions taken with respect to e-cigarettes.

It is important to be aware that there are notable differences between the U.K. and the U.S. e-cigarette marketplace. These include the sharp increase in youth usage of e-cigarettes in the United States.

The 2015 National Youth Tobacco Survey found that between 2011 and 2015, current e-cigarette use among high school students increased nearly 900 percent. This sharp increase in youth usage in the United States is of great concern. While youth usage in the U.K. has gone up, it hasn't gone up 900 percent.

FDA is tasked with understanding the population level impact of e-cigarettes, which includes an assessment of the potential benefits and potential harms of e-cigarettes. FDA is committed to using an evidence-based approach in applying the principles of harm reduction to tobacco

regulatory policy. Pre-market review of new tobacco products is one of FDA's core consumer protection responsibilities. Scientific evidence may demonstrate that certain products are less harmful than others at an individual level, but under the law FDA must also take into account the impact of the products on the health of the population as a whole, including both users and non-users of tobacco products, in making regulatory decisions about these products.

The Honorable Susan Brooks

Secretary Burwell, as you know, Congress created Project BioShield's Special Reserve Fund (SRF) in 2004 for material threats and over the last decade, SRF funds have been used to stockpile millions of doses of drugs and vaccines against threats like anthrax, smallpox, nuclear radiation – and hopefully soon against Ebola and Zika.

HHS released a budget last year for the SRF where you planned to procure over $870 million in medical countermeasures in 2017. Yet this year's budget request only asks Congress for $350 million, about 40% of this amount. This request would decimate Project BioShield and our nation's preparedness against numerous biological threats and is actually in direct contradiction with your previous MCM plans.

1. **Do you understand the tremendous uncertainty you've created for your private sector partners by asking Congress to gut Project BioShield?**

2. **Which MCM projects are you planning to scrap if Congress reduces funding for the SRF?**

3. **What threats will we fail to be prepared for as a result?**

Answer: Project BioShield represents the government's commitment to industry that a market will exist for medical countermeasures targeted against agents for which Material Threat Determinations (MTDs) have been issued. Because most of these agents do not produce disease in civilian populations under normal circumstances, many of the medical countermeasures directed against them have no or next to no commercial market. HHS understands the importance of the Project BioShield commitment and the uncertainty that may be caused by fluctuations in the annual appropriation provided by Congress.

The FY 2017 President's Budget will enable us to make meaningful progress on vital medical countermeasure procurements. Unlike a grant or research program that supports a steady and recurring level of effort, the Project BioShield budget is made up of a different set of discrete procurements in any given year when medical countermeasures are mature enough in development to meet FDA requirements for accessibility under Emergency Use Authorization. In FY 2017 the new resources will enable the Department to procure several new chemical, biological, radiological and nuclear medical countermeasures, including:

- New Ebola vaccines and immunotherapeutics for the prevention and treatment of Ebola infections;
- New high throughput biodosimetry devices to measure internal radiation exposure following a detonation;

- New antibiotics for the treatment of bacterial biothreats and high priority antimicrobial resistant bacteria;
- New diagnostics for the detection of anthrax in exposed persons; and
- Replenishment of anti-neutropenia cytokines for the treatment of radiation-induced blood illnesses.

At this time, ASPR is not planning to eliminate any medical countermeasure acquisition programs as a result of the reduced request. ASPR is currently working with the Department of Homeland Security to refresh the Material Threat Assessments (MTAs) and medical consequence modeling that inform HHS's medical countermeasure requirements and acquisition targets. The new requirements will incorporate: 1) updated threat information, including a range of plausible scenarios identified in the new Anthrax MTA, 2) revised public health and medical consequence assessments, 3) consideration of desired MCM product characteristics, and 4) assessment of the national ability to effectively use anthrax MCMs in an emergency. These updated requirements, and the acquisition targets stemming from them, will be incorporated into research and development funding priorities and procurement decisions, including the 2016 Strategic National Stockpile (SNS) Annual Review (which will inform sustainment and procurement decisions for the SNS as early as FY17). The revised MTA process underscores the fact that preparedness represents a spectrum; there are few threats for which we are fully prepared and none for which we are entirely unprepared. The challenge the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) faces, given the inevitable funding constraints, is to allocate resources in a way that provides the greatest degree of preparedness against the greatest range of threats.

ASPR and the PHEMCE are committed to maintaining our national preparedness and making sure that medical countermeasures are available when needed. Maintaining stockpiles of medical countermeasures typically entails large procurement costs and is associated with substantial carrying costs. In an era of constrained resources, BARDA and its PHEMCE partners are mindful of the need to meet established requirements, sustain preparedness, and be good stewards of the taxpayers' investments. To this end, the PHEMCE is currently working to refresh the material threat assessments that form the foundation for our requirements, many of which have not been reassessed in years. ASPR, for its part, emphasizes innovative approaches to total lifecycle cost-containment and strives to decrease the long-term costs of stockpiling medical countermeasures.

Secretary Burwell, just last week our colleagues on the Appropriations Committee sent a letter to the Office of Management Budget in response to the Zika virus funding request for $1.8 billion. The letter specifically spells out the fact that $1.4 billion is unobligated at HHS and $1.031 billion is unobligated at CDC.

4. Can you please expand on what funds are currently available for the Zika response?

Answer: The Administration is committed to taking necessary steps, as quickly as possible, to protect the American people from the Zika virus. On February 23, HHS notified Congress of our plans to transfer and reprogram a total of up to $50 million in Fiscal Year 2016 resources within the Centers for Disease Control and Prevention for immediate Zika response needs. This included up to $5.75 transferred from the Strategic National Stockpile (SNS) and up to $44.25

million re-programmed from the Public Health and Emergency Preparedness (PHEP) Cooperative Agreement.

Without reimbursement, the $5.75 million reduction of SNS will result in decreased acquisition of 20,000 vials of anthrax vaccine that would be used to treat or provide prophylaxis to 67,000 individuals exposed to anthrax. The $44.25 million reduction of PHEP will result in reduced preparedness awards to states and cities.

In addition, CDC is making available $18 million in unobligated balances from the Public Health Prevention Fund for Zika control efforts, primarily in Puerto Rico.

But, these repurposed funds are not enough. They only allow us to address the most immediate needs until Congress acts on the Administration's supplemental request. Emergency supplemental funding continues to be urgently needed for a robust and complete response to the Zika virus.[13]

5. Do you need Congress to legislate to allow for the flexible use of these unobligated funds from HHS? Please elaborate on how these funds are currently being used.

Answer: The repurposed funds referenced above are being used for initial activities in the areas of mosquito control, surveillance, lab capacity, development of diagnostics and vaccines, and time-sensitive research activities.

HHS currently has the flexibility needed to use these funds as indicated above. However, there are not sufficient funds to support the full range of activities needed to prevent, detect, and respond to further transmission of the Zika virus; and additional authorities requested in the Administration's supplemental request are needed to ensure the most effective response, including:

1) The ability to add products purchased with the supplemental funds to the Strategic National Stockpile;
2) Overseas auto purchase and insurance authority to allow supplemental funds to be used overseas for car purchase and usage;
3) Flexibility to avoid burdensome matching requirements on grantees related to mosquito control;
4) Construction authority for grantees to allow state and local health departments and other grantees to use funds for facilities that may be necessary to Zika response and prevention, such as laboratory facilities; and
5) Funding transfer authority to allow CDC to move supplemental funds across CDC accounts to be able to more quickly respond to health security issues.

In addition, several General Provisions also support CDC's response:

[13] All responses accurate as of February 24, 2016.

- **Expanded overseas facilities authority**: This proposal would allow CDC to "acquire, lease, construct, alter, renovate, equip, furnish, or manage facilities" overseas without having to send payments through the Department of State.
- **Hiring authorities**:
  a. Personal service contracts: This authority would authorize CDC to use personal service contracts for response staffing. Although this authority has already existed globally, it does not currently exist domestically. People working under personal service contracts would NOT be Federal Government workers.
  b. Direct hire authority: This authority would allow expedited hiring authority for emergency positions.
- **Reimbursement authority**: This authority will allow CDC to use emergency funds to backfill transfers and reprogramming used before supplemental funds were available.

The FY17 budget request proposes to combat opioid abuse by providing significant new resources to the Substance Abuse and Mental Health Services Administration (SAMSHA) within HHS. However, the request includes a $16.9 million reduction to the Screening, Brief Intervention and Referral to Treatment (SBIRT) program – from $46.9 million in FY16 to $30 million in the FY17 request.

The SBIRT program helps reduce the number of individuals who misuse drugs and alcohol and intervenes early to ensure individuals improve their health and overall quality of life. The Indiana University School of Medicine (IUSM)'s SBIRT Medical Residency Program, funded by SAMHSA through its SBIRT program, plays a key role in educating future physicians about problematic substance abuse.

6. Why does your agency propose to cut the SBIRT program at a time when these funds are in such drastic need by medical schools throughout the nation?

Answer: Programs of Regional and National Significance, which includes the Screening, Brief Intervention and Referral to Treatment (SBIRT) program, are intended to be test new and innovative approaches. The SBIRT program has been proven to be a successful model, and states therefore can use Substance Abuse and Prevention Block Grant funding to support these services. Lessons learned from these efforts will be used by SAMHSA to develop an implementation package for SBIRT to encourage its development and sustainability across healthcare settings.

7. How will SAMSHA absorb the proposed reduction?

Answer: The President's Budget request for the SBIRT program will serve 145,000 individuals in FY 2017, and continues support for all existing grants. Given SBIRT's proven success, SAMHSA will continue to encourage its implementation and sustainability across healthcare settings.

The President's budget request includes a ten percent cut to Indirect Medical Education—amounting to $17.8 billion in cuts over the ten-year budget window. Many academic medical centers, like Indiana University Health in Indiana, already fund residency slots beyond the amounts reimbursed by Graduate Medical Education, and bear the additional

costs associated with educating the future doctors my state and our nation need to meet the growing demand for health care providers.

8. **How can the ten percent cut to IME be anything but contradictory to the administrations stated goal to increase access to care?**

Answer: HHS recognizes the importance of graduate medical education and indirect medical education funding. Nonetheless, like any other category of Medicare spending, payments to teaching hospitals must be justified by incurred costs. This proposal in the President's Budget will help graduate medical education programs promote high quality primary care services that address relevant public health needs by allowing the Secretary to target funding to training activities most effectively. HHS believes this proposal brings these payments closer to the appropriate level and provides incentives for promoting high-quality primary care.

In addition, the Teaching Health Center Graduate Medical Education (THCGME) Program provides funding for residency training in primary care medicine and dentistry in community-based, ambulatory settings. The THCGME Program seeks to not only bolster the primary care workforce through support for new and expanded primary care and dental residency programs, but also to improve the distribution of this workforce into needed areas through emphasis on underserved communities and populations. The FY 2017 Budget includes $60 million in funding appropriated in MACRA, and an additional $527 million over FYs 2018-2020 to support up to 876 residents.

The Honorable Chris Collins

1. **With the recent release of the final rule on Medicaid Covered Outpatient Drugs, CMS has altered pharmacy reimbursement through newly formulated Federal Upper Limits and the use of Average Acquisition Cost-based reimbursement. How will CMS ensure that Medicaid patients continue to have access to their critical pharmacy services under the provisions of this final rule? I have heard concerns about how the President's budget proposal seeks to calculate Federal Upper Limits based only on generic drug prices, thereby jeopardizing fair and adequate pharmacy reimbursement. How will CMS address these concerns?**

Answer: We expect Medicaid beneficiaries will benefit from the finalized provisions of the Medicaid Covered Outpatient Drug regulations, which are designed to help control drug costs and ensure adequate pharmacy reimbursement through the transition to a pharmacy reimbursement system based on an actual acquisition cost (AAC) and a professional dispensing fee. These changes will provide adequate reimbursement to pharmacies, as states are required to calculate reimbursement prices based on the prices actually paid by pharmacy providers. Further, CMS affords the states the flexibility to adjust their professional dispensing fees, when necessary, to assure sufficient access.

When states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, they are required to ensure that total reimbursement to the pharmacy provider complies with the statute. They must provide adequate data such as a state or national survey of retail pharmacy providers, or other reliable data other than a survey, to

support any proposed changes to either or both of the components of the reimbursement methodology. Prior to the publication of the final rule with comment, many states were already basing their ingredient cost reimbursement on an AAC methodology without causing pharmacies to leave the Medicaid program or having other adverse effects on patient care.

With respect to the calculation of the Federal Upper Limits (FULs), CMS uses the most current monthly National Average Drug Acquisition Cost (NADAC) data that we collect, and compare this data to the FULs calculated at 175 percent of the weighted average of average manufacture prices. In situations where that FUL amount is less than the NADAC, CMS establishes the FUL using a higher multiplier so that the FUL amount equals the NADAC. This ensures that pharmacy providers have an upper limit reimbursement that is benchmarked to an acquisition cost.

The President's budget proposal would exclude innovator multiple source drugs from the calculation of the FUL. The FULs should only be calculated using non innovator multiple source drug prices. Including the brand name drug (innovator multiple source drug) in the weighted average unduly inflates the FUL since the brand name drug is usually significantly more expensive than the generic equivalents. The FUL price also does not apply to the brand name drug, as it is obtained through a brand medically necessary override, and then paid at the state payment rate for non-FUL drugs. Clarifying that only the non-innovator multiple source drugs will be used in the calculation of the FUL provides reasonable reimbursement to pharmacies while ensuring that the FUL remains cost efficient. In addition, to encourage the use of generic drugs, states can pay pharmacies a higher dispensing fee for generic drugs than for brand name drugs.

2. **The Center for Medicare and Medicaid Innovation (CMMI) will be testing enhanced medication therapy management (MTM) models designed to find innovative approaches to MTM that will result in more efficient outreach and targeting of beneficiaries and create better alignment of program incentives. Given the important role retail community pharmacies play in medication management, how does CMMI plan to ensure that there is robust community pharmacy participation in the enhance MTM models? Will the agency partner with Part D plans that propose to utilize retail pharmacies in their enhanced MTM model? Additionally, does CMS plan on using its authority to expand successful approaches to the entire Part D MTM program before the end of the five year testing period?**

Answer: CMS believes that pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use the prescription drugs upon which they rely. The Enhanced MTM model aligns financial incentives and grants flexibility for basic, stand-alone PDPs to test MTM interventions that could include increased reliance upon the pharmacist as a trusted community resource to ensure that targeted beneficiaries are taking their medications accurately and appropriately.

When announcing the model, CMS noted that it expects sponsors to rely more heavily on more personalized strategies, such as contacts from trusted community pharmacists or their medical providers, because in many cases these will be more effective than call-center or mail contacts from the PDP.

Moreover, CMS noted that it would expect to see plan sponsors suggest protocols involving multi-pronged, proactive, and persistent efforts to make contact with Medicare beneficiaries and ensure their on-going participation and engagement, as well as use of diverse communication modalities such as person-to-person interactions, phone calls, and trusted community contacts and relationships (including community pharmacists and prescribers) to achieve significant engagement rates.

CMS is granting basic, stand-alone PDPs the flexibility to design enhanced MTM programs that incorporate interventions beyond the standard MTM programs under Medicare. As a result, plans may propose an expanded range of MTM activities, including contracting with pharmacists to provide enhanced engagement or other services. Any financial compensation to pharmacists under this model would be provided by the participating PDP or contracted vendors, not CMS.

Under statute, successful Innovation Center models can be expanded if they either reduce Medicare expenditures without reducing the quality of care or improve the quality of care without increasing expenditures. If the Enhanced MTM model proves successful and satisfies these criteria, it could potentially be expanded (including on a national basis) under this authority.

In addition to possible formal expansion, the results of this model could also be used to inform policy in other ways. Specifically, lessons from this model could inform potential changes to MTM policies and rules in integrated care models, or be adopted by other types of health plans, such as those in state Medicaid programs or exchange plans.

The Affordable Care Act provided for the establishment of CO-OPs, which were to be non-profit health insurers to compete with private insurers. At the beginning of the program, the federal government spent $2.4 billion on 23 CO-OPs. One of these CO-OPs was Health Republic in New York, which officially failed in November of last year, costing taxpayers over $265 million.

Immediately following the failure, the Oversight Subcommittee and I contacted the HHS Office of Inspector General as well as your office in order to obtain the documents your office used 1) to approve Health Republic as a CO-OP in the first place and 2) to approve an additional $91 million grant to Health Republic after it lost $35 million its first year. Your office has provided the first of these documents, but not the second.

3. **When will you provide my office and the committee the report HHS used as a basis to grant Health Republic additional funds?**

Answer: My staff is happy to work with your staff on this request.

4. **Why was Health Republic not put on a corrective plan like other failing CO-OPs, even though it had wasted more taxpayer than other CO-OPs?**

Answer: CMS did not issue a corrective action plan to New York prior to the decision to wind down the CO-OP. However, CMS regularly uses enhanced oversight plans (EOPs) and

corrective action plans (CAPs) as part of our CO-OP monitoring and oversight process, as laid out in the CO-OP loan agreements and recommended by the HHS OIG. CMS places a CO-OP on an EOP or CAP when it identifies an issue that can be resolved through corrective action.

CMS ordered an independent audit of Health Republic in summer 2015 based on early warning signs about the CO-OP's finances. This independent auditor found higher losses than the CO-OP had expected or projected in its financial reporting to CMS. In this case, the financial problems confronting Health Republic appeared to be too severe to address or correct through a CAP. In the interests of consumers and taxpayers, CMS worked with the State Department of Financial Services, which is the primary insurance regulator, to wind down the CO-OP and to ensure that consumers would have coverage through the end of the year.

Madam Secretary, I understand that on January 15, the World Health Organization (WHO) issued draft "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children." The guidance proposes to establish significant new restrictions and prohibitions on the promotion and marketing of milk products for young children up to three years of age without providing any evidence, scientific substantiation or an impact analysis to justify the measures. I don't understand the logic of these recommendations, as we continue to hear that milk and milk products are good for our health, most recently in HHS' own Dietary Guidelines which note that a healthy eating pattern includes fat-free or low free-free dairy, including milk, yogurt, cheese, and/or fortified soy beverages. The HHS guidelines apply to individuals age 2 and older. The WHO also appears to contradict the nutritious food provided to children under three in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

5. **Does HHS support these WHO draft guidelines? Why?**

6. **What is HHS's role in influencing WHO in this process?**

7. **How can we work together to ensure the WHO is developing science-based guidance to prevent unintended negative health consequences for young children and potentially violate World Trade Organization (WTO) trade rules, including imposing restrictions on the use of intellectual property by brand owners?**

Answer: As requested by Member States through a 2012 World Health Assembly (WHA) resolution, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children, and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting breastfeeding and supporting appropriate and timely complementary child feeding during the first three years of life, a critical window for health and nutrition outcomes. The voluntary guidance is a technical document, which is not subject to negotiation by Member States, and is not binding on Member States or on other actors.

The draft guidance does not seek to prohibit the marketing of all milk products consumed by young children or to limit product availability. The guidance aims to complement, not replace, domestic and global recommendations for feeding infants and young children, including the WHO Code of Marketing of Breast-milk Substitutes and 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 three years of age.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comments.

HHS is leading a process to solicit input from relevant federal agencies and prepare a technical comment submission to WHO. HHS also met, individually and with other agencies, with multiple stakeholders on the matter. HHS will transmit comments and discuss them with WHO's Nutrition Department, conveying that revisions are needed to present countries with clear, evidence-based recommendations. We will continue to follow the issue closely as WHO revises the draft guidance for Member State consideration, and will discuss WHO's revised document, when available, with other agencies and with impacted stakeholders.[14]

The Honorable Gene Green

1. **Have the monies allocated by Congress in 2013 and in 2014 been fully released to the FDA when the BsUFA user fee trigger of $20 million was reached in 2015? I appreciate that the 2015 funding was released to the FDA, and also understand that the 2013 and 2014 allocations were carried over to the next budget when the trigger amount was not reached in those years. Please explain the current status of these funds.**

Answer: The BsUFA program has met its spending trigger for all three years. Any funds not expended remain available to FDA and have been rolled over into the new fiscal year as carryover. Those funds will be used to support the process for the review of biosimilar biological product applications in the current or a future fiscal year.

2. **How much money is currently allotted for vector control in the United States? Given the challenges with vector control, how much new money is needed for vector control? What percentage of this funding should be set aside innovative techniques, as opposed to older chemicals, which you have said are not very effective, to suppress the Aedes Aegypti mosquito?**

Answer: As many of these resources are from local and state sources, it is difficult to estimate the total funds available for vector control across the nation. CDC has issued Zika vector control guidelines based on the principle of Integrated Vector Management (IVM). IVM principles include approaching mosquito control through careful planning, using a variety of interventions targeting both larval and adult mosquito control, and including both chemical and non-chemical methods. Properly planned and executed, IVM ensures a more effective level of control than can be achieved by one single approach.

[14] All responses accurate as of February 24, 2016.

With supplemental funds, CDC-supported investments in mosquito control will help States and cities identify and address areas where mosquitoes breed in order to drive down mosquito populations. Continued CDC work on development of innovative mosquito control tools, such as promising new products that may be safer and more effective than today's methods, will help States reduce the population of mosquitoes that can spread Zika and other diseases. In February, the Administration submitted to Congress a request for $1.9 billion in emergency supplemental funding to support the full range of activities aimed at preventing, detecting, and responding to further transmission of the Zika virus to protect the American public.

The Honorable Frank Pallone, Jr.

The Food Safety Modernization Act (FSMA) charged the FDA with transitioning our food safety system to one that was reactive, to one that is preventive. Despite receiving no additional funding as a part of this legislation, FDA has worked tirelessly to implement it, including finalizing five key rules related to Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Animal Food; standards for growing, harvesting, packing and holding produce; Foreign Supplier Verification Programs for Importers; and accreditation of third-parties to conduct food safety audits. The agency has also actively been working on guidance related to Voluntary Qualified Importer Program, and has conducted outreach to those impacted by FSMA's requirements.

1. **The President's budget includes $1.5 billion for food safety activities and proposes user fees for food imports, food facility registration, and inspections. Will you please provide additional details regarding how this increased funding will assist the agency in implementation of FSMA? Further, will you please explain how the proposed user fees will be critical to the sustainability of FDA's food safety activities?**

Answer: The FY 2017 President's Budget includes two proposed user fees to support FSMA implementation. The first proposal, the import user fee, would enable FDA to modernize its import oversight program in ways that would facilitate the entry of safe food. These resources will benefit foreign food producers, U.S. food importers, and the general public. For importers in particular, the fee will result in an improved import program, and greater efficiency and predictability for their businesses. The improvements to the import process will not only facilitate the entry of safe products but also improve public health by enabling FDA to focus its attention on higher risk products. The ultimate result will be improved confidence in the safety of food from abroad, thus encouraging future trade opportunities in food.

The fee would support several key areas:

- Importer Support: To improve the safety of imported food, FDA will establish new systems to prevent the import of unsafe foods earlier in the process rather than detaining a product at the border. Additional funds will support the establishment of a "Help Desk" that would assure importers of an available, responsive communications system to help address their concerns and answer their questions about the status of their shipments.

- Port-of-Entry Streamlining: To help enhance food importers' ability to trade competitively, these funds will help develop and maintain improved risk analytics and IT systems that will allow FDA to target the highest risk imports, thus resulting in fewer detentions and less delay for lower-risk entries. This will include better integration with U.S. Customs and Border Protection (CBP) IT systems, and continuous improvement of FDA's import screening system. These systems will decrease reliance on paper notices and improve FDA's ability to exchange information electronically with industry during the import review process. These funds will also be used to expand the use of analytical tools deployed on-site for faster screening and better targeting of high-risk samples going to traditional laboratories for lengthy analysis. These tools will include technology such as hand-held scanners and small, portable on-site testing capability.

- Increased Border Staffing: Additionally, these funds will increase FDA border coverage and extend hours of operations at high-priority locations. The result will be fewer instances when FDA investigators are not available to process an entry and will help facilitate a timely response.

Second, the Food Facility Registration and Inspection user fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models, and information technology to improve targeting and risk-based efficiency of inspection. This investment will complement the investment in inspection modernization and training that can be achieved with the budget authority request and ensure that modernization is fully achieved on a timely basis.

The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide. With this investment, FDA will be better able to make sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply.

2. What activities has FDA undertaken to work with the States in relation to an integrated national food safety system to enhance FSMA implementation?

Answer: The National Integrated Food Safety System is crucial to successful implementation of FSMA because it will help ensure the quality, consistency, and effectiveness of local, state, and Federal efforts to protect the food supply. Funding in this area supports the goal of making state governments full partners in implementing the key preventive controls and producing safety components of FSMA.

The requested FY 2017 increase will be used primarily to enhance state capacity to support implementation of the produce safety rule through funding of state cooperative agreements and grants. Successful implementation of FSMA's new produce safety standards is especially dependent on partnerships between FDA and the states, both to deliver education and technical assistance and to provide on-going compliance support and oversight. Because of their relationships with and knowledge of local farming communities and practices, FDA believes the states can provide this oversight efficiently and effectively.

FDA has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan state support for implementation of the produce safety rule. Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation is actively participating in the development of these practices. NASDA will help facilitate industry training and will also play a role in delivering training to state regulators.

3. **Can you please provide additional detail regarding the activities the $20.2 million in new user fee will support? Further, will you provide additional information about the number of new full-time employees (FTEs) that the new user fee will support and the capabilities FDA will be hiring for?**

Answer: FDA would conduct Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA) activities with the new user fee resources. The fees provide $13 million and 42 FTE for CFSAN to establish and maintain a Mandatory Cosmetic Registration Program; acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards and review ingredient safety; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry and consumers. The fees provide $4.7 million and 18 FTE for ORA to refine inspection and sampling of imported products and apply risk-based approaches to postmarket monitoring of domestic and imported products, inspection, and other enforcement activities. Examples of skills and capabilities that FDA would target in recruiting additional staff include analytical chemists, toxicologists/pharmacologists, microbiologists, IT specialists, risk analysts, regulatory project managers, dermatologists, and consumer safety officers. The fee also includes $1.1 million and 3 FTE for program support activities and $1.5 million for rent activities.

I know that there have been good and continuing discussions that FDA has had with the over-the-counter (OTC) medication industry. I understand that both the FDA and industry agree that the OTC Monograph system has slowed to an unworkable degree and that changes are necessary.

4. **I encourage FDA and the OTC industry to continue those conversations and hope that Congress can be helpful in aiding a solution to these problems that benefits consumers.**

Answer: Thank you. Yes, FDA continues to discuss with industry and stakeholders ideas to reform the Over-the-Counter (OTC) review process. We appreciate Congress' interest in this important area.

5. **What funding is available to FDA currently to fulfill its mission for OTC drugs? How has funding levels for OTC drug activities changes over the past 5-10 years?**

Answer: For OTC Monograph review activities, FDA expended approximately $7.9 million in FY 2014, $7.4 million in FY 2015 and is on track to expend $8.2 million in FY 2016. None of these funds come from user fee programs, since the Agency is not permitted to expend user fees on OTC monograph work, and there are currently no user fees collected for OTC monograph work. These expenditures reflect non-user-fee work in the OTC monograph space, including the

work reported for sunscreens. The funding levels for OTC drug activities have remained relatively flat over the past 5-10 years.

Many stakeholders have criticized FDA for not acting sooner to help address the opioid epidemic in this country. I was pleased when FDA released a multi-prong Opioids Action Plan. This plan is intended to take a number of steps towards addressing opioid abuse, such as: including additional warnings and safety information on labeling for immediate-release opioids, strengthening post-market requirements, providing guidance on the development of generic abuse-deterrent formulations, and reassessing the risk-benefit framework for approval of opioids. There is no one silver bullet for addressing opioid abuse and addiction, but it is clear that FDA has an important role to play as it weighs approval of new opioids.

6. **Will you please elaborate on how the funding request included in the FY 2017 budget to address the opioid epidemic will help support implementation of FDA's Opioid Action Plan? Further, can you also comment on how you will encourage a collaborative and collective approach throughout HHS in addressing this epidemic?**

Answer: HHS, including the FDA, is deeply concerned about the growing epidemic of opioid abuse, dependence and overdose in the United States – and it is a personal priority for me as Secretary. In response to this crisis, at my direction the agency developed a comprehensive action plan to take concrete steps toward reducing the impact of opioid abuse on American families and communities. Our initiative aims to improve prescribing practices, expand the use of naloxone, and expand the use of Medication-assisted Treatment (MAT).

The President's FY17 Budget included critical investments to intensify efforts to reduce opioid abuse and overdose, including an increase of $1.1 billion in mandatory and discretionary funding to build on these and other investments proposed by the Administration and funded by the Congress in FY 2016. The prescribing aspect of the opioid epidemic is an important part of this complex public health issue, and using all of the tools available to us within HHS is a key part of our initiative to address opioid abuse and overdose.

The Initiative is a coordinated, multi-faceted approach across the Department that relies on education, prevention and treatment strategies with the strongest evidence base. Assisting health care professionals in making informed prescribing decisions, increasing the use of naloxone and expanding access to medication-assisted treatment for opioid use disorder are the key areas where we are focusing our efforts through the initiative, to deliver the greatest impact. At the same time, it is critical to balance combatting opioid misuse with the use of these drugs for legitimate purposes and supporting appropriate pain management. We are working to get all these tools into the hands of local health professionals and law enforcement officers through grants in CDC, SAMHSA, and by approving new formulations of naloxone at FDA.

As you note, FDA is taking steps to combat opioid abuse. The Agency has committed to work more closely with its advisory committees before making critical product and labeling decisions; enhancing safety labeling; requiring new data; and seeking to improve treatment of both addiction and pain. At the same time, the FDA will fundamentally re-examine the risk-benefit paradigm for opioids and ensure that the agency considers the wider public health effects. The

FDA is committed to taking all of these steps transparently and in close cooperation with its sister agencies and stakeholders. The FDA's actions include:

- Expanding the use of advisory committees;
- Developing warnings and safety information for immediate-release (IR) opioid labeling;
- Strengthening postmarket requirements;
- Updating the Risk Evaluation and Mitigation Strategy (REMS) Program;
- Expanding access to abuse-deterrent formulations (ADFs) to discourage abuse;
- Supporting better treatment; and
- Reassessing the risk-benefit approval framework for opioid use.

The Vice President's Cancer Moonshot Initiative would direct FDA to develop a virtual Oncology Center of Excellence to help support the development of cancer diagnostics and therapies. This center would pull together the expertise of regulatory scientists and reviewers across the various programs at FDA – drugs, biologics, and devices – to encourage an integrated approach to the evaluation of next generation cancer treatments, such as combination products and immunotherapies. The Center will also serve as a resource to investigators at the National Cancer Institute offering advice and support in the development of new treatments.

7. **Will you discuss how the proposed Oncology Center of Excellence and its integrated approach could help to expedite the development of novel cancer treatments?**

Answer: Increasingly, diagnostics and multiple therapeutic modalities, including drugs, biologics, and devices, are being used simultaneously or sequentially in the treatment of cancer. The optimal development and review of novel cancer therapies involves a thorough understanding of the overall disease context as well as the scientific basis of emerging diagnostics and therapeutic modalities. By integrating the perspective and expertise of the clinical reviewers from all of the medical product centers, teams from the Oncology Center of Excellence will readily be able to evaluate products in the context of existing diagnostic and therapeutic modalities, and be able to provide sponsors and other interested parties with the most informed advice regarding how to advance the development of novel products. This interaction will help to expedite the development and approval of important new cancer diagnostics and treatments. In addition, the Oncology Center of Excellence will serve as a single point of contact in the agency for all interested stakeholders, including patients, advocacy groups, medical societies, and industry.

Cancer continues to effect far too many in this country with a more than 1.6 million people expected to be diagnosed with cancer in 2016, and more than 600,000 expected to succumb to this deadly disease. The cost of treating cancer is also continuing to rise predicted to reach $156 billion by 2020.

We know that there are promising new developments in the cancer treatment space – such as companion diagnostics, cancer immunotherapies and combination therapies, and new genetic tests. In order to further encourage the development of these treatments, and ensure future patient access, we must also ensure that FDA is able to utilize all the regulatory tools the agency needs to in order to keep pace with the science.

8. Will you please discuss how the FY2017 budget request for the National Cancer Moonshot initiative will help to improve the evaluation of these new products within FDA?

Answer: FDA is committed to establishing a cross-center program with the overall goal of fostering innovation, improving the evaluation process, and enhancing regulatory research.

Funding in 2017 will enhance FDA's efforts to continue modernizing and integrating FDA's management and review of oncology-related activities and foster collaboration and transparency, both internally and externally.

Advancing precision medicine is one goal I know that many members on this Committee support. I believe that moving away from a "one-size-fits-all" treatment model to getting the right treatment to the right patient at the right time will greatly help to improve the way we treat complex diseases and conditions, while also improving how we deliver care in this country.

Since the launch of the Precision Medicine Initiative last year, FDA has approved a number of new Precision Medicine-based therapies and has been working with industry to help encourage the development of targeted therapies. One such effort has been the launch of precisionFDA, a platform to help both the commercial and academic communities collaborate on testing and piloting new approaches to genetic tests to help inform treatment options. These are just a few of the ways the agency has played a role in advancing precision medicine.

9. Greater collaboration between the public and private sectors can play a critical role in improving how we discover and develop innovative treatments to treat disease in this country. Will you discuss how the FY 2017 budget request will help facilitate public-private collaboration in the area of precision medicine?

Answer: The FY 2017 budget includes a request of $4.4 million, an increase of $2 million above FY 2016 for activities including supporting precisionFDA, working with the scientific community to develop new reference datasets for validating genetic tests, and developing a national device evaluation system.

In the last year, FDA has approved several new Precision Medicine-based therapies and launched precisionFDA, a platform for academic and commercial collaboration. These efforts directly support precision medicine activities across HHS.

FDA will use the requested FY17 increase to facilitate public-private partnerships through our continued work with the National Medical Device Evaluation System Planning Board to establish the National Medical Device Evaluation System. We envision that the proposed system would, among other attributes, help identify patients who would benefit from specific types of devices based on an evaluation of premarket and postmarket data, thereby advancing Precision Medicine. The device evaluation system will leverage real world data generated as a part of routine clinical practice to spur medical device innovation, allow for more timely patient access to safe and effective technologies, help identify medical devices associated with adverse events,

and reduce costs to the U.S. healthcare system. FDA will also continue to invest in precisionFDA, which provides a crowd-sourced, cloud-based platform to advance regulatory science around next generation sequencing based analytical tools and datasets.

10. The President's FY2017 budget request proposes $18.4 million for compounding activities. Will you please provide additional details regarding how this proposed funding will assist with oversight of compounded drug products, including how such funding will be used to enforce the requirements outlined in DQSA?

Answer: FDA will continue oversight of human drug compounding through inspections and enforcement, policy development and implementation, and state collaboration and coordination. Increased efforts in these areas will help to prevent patient injury and death associated with poor quality (e.g., contaminated) compounded drugs, and will provide clarity to compounders regarding FDA's expectations for compliance with the compounding provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the DQSA.

FDA continues to identify serious insanitary conditions at compounding facilities. For example, FDA recently recommended that a compounder cease operations and recall all sterile products within expiry when, during a surveillance inspection, FDA investigators identified the use of non-sterile drinking water for use in making injectable drug products; the use of non-sterile, non-pharmaceutical grade ingredients in making an injectable drug product; and the presence of dog beds and dog hairs within the facility, including in close proximity to the compounding room. To protect the public health, it is critical that FDA have sufficient resources to continue its inspection and enforcement efforts to address substandard practices and conditions for drug production that could compromise patient safety.

In addition to continuing its inspection and enforcement efforts, numerous policy issues must be addressed in implementing the provisions of the FD&C Act applicable to compounding. For example, FDA intends to use funds to promulgate specific current good manufacturing practice requirements for outsourcing facilities, promulgate regulations to implement the DQSA, and develop the list of bulk drug substances that may be used in compounding under section 503B.

Outsourcing facilities are also required to report adverse events associated with their products and FDA needs resources to review these reports and investigate the adverse events as appropriate.

11. Office use compounding continues to be an area of debate related to implementation of DQSA. In response to inquiries from Congress, FDA has said that "to qualify for exemptions from certain requirements, such as having to submit a new drug application, a compounder must obtain a prescription for an individually identified patient." Will you please provide additional information regarding the Department's position on office use compounding?

Answer: The Department shares your concern about the safety issues associated with compounded drug products. Since enactment of the DQSA in 2013, FDA has conducted over 250 inspections of compounders. During many of these inspections, FDA has identified serious

insanitary conditions that create a lack of sterility assurance of purportedly sterile drugs at the facility, prompting numerous pharmacies to recall purportedly sterile drug products and cease sterile drug production. FDA has also responded to serious adverse events associated with both sterile and non-sterile drugs compounded by state-licensed pharmacies that were as much as 1,000 times their labeled potency.

In April 2016, FDA issued for public comment a draft guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. As discussed in this draft guidance, compounding under section 503A of the FD&C Act must occur either after the receipt of a prescription for an identified individual patient (section 503A(a)(1)), or in limited quantities before the receipt of a prescription for an identified individual patient (section 503A(a)(2)). Section 503A does not provide for the distribution of a compounded drug without the compounder first receiving a prescription for an identified individual patient (e.g., for office use).

In contrast, entities that are registered with FDA as outsourcing facilities under section 503B of the FD&C Act can distribute compounded drugs to health care facilities without receiving patient-specific prescriptions for office use.

The prescription requirement in section 503A of the FD&C Act is critical to protecting patients. Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Because such compounders generally do not register their compounding facilities with FDA and are not under routine FDA surveillance, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination. As noted above, the limited number inspections that FDA has conducted of state-licensed pharmacies of which the Agency is aware have revealed serious deficiencies in drug production practices and conditions that could put patients at risk.

For these reasons, patients should only receive compounded drugs if their needs cannot be met by an FDA-approved drug product. The prescription requirement is critical to ensure that compounding by state-licensed pharmacies and physicians under section 503A is based on individual patient need, to differentiate such compounding from conventional manufacturing, and to differentiate compounding by pharmacists and physicians who are primarily subject to state regulation from compounding by outsourcing facilities, which are primarily subject to FDA regulation. Compounding for office stock by 503A facilities would undermine the incentive for compounders to become outsourcing facilities, removing a critical measure in place to prevent another outbreak on the scale of the 2012 fungal meningitis outbreak, which resulted in over 60 deaths and 750 cases of infection.

In the Food and Drug Administration Safety and Innovation Act, FDA was directed to issue final regulations revising current medical gas regulations no later than July 9, 2016. If the agency does not act by the statutory deadline, FDA is directed to incorporate by

reference voluntary consensus safety and labeling standard developed by an accredited standard development organization until final regulations are issued.

12. FDA's recent report to Congress on the regulation review identified that regulation changes for warning label statements and adverse event reporting may be needed. Will you please provide an update regarding FDA's current progress in finalizing regulation changes for medical gas and identify what additional topics, if any, the agency is considering for regulation changes?

Answer: In 2006, FDA proposed a rule to address medical gas mix-ups that included revisions to the medical gas labeling regulation. These revisions, once finalized, may largely satisfy a FDASIA provision indicating that "warning statement[s]" for designated medical gases are to be promulgated through regulation. FDA is working hard to publish this rule by the FDASIA-imposed deadline for rulemaking on medical gases (July 9, 2016). FDA is continuing to consider whether rulemaking is needed to address adverse event reporting for medical gases, and will continue to evaluate the need for targeted rulemaking in other areas, for medical gases as with other drug products, on an as-needed basis. However, as explained in our report to Congress[15], FDA generally thinks medical gases can be appropriately regulated under the existing regulatory framework. In addition to the applicable regulations, FDA will utilize guidance documents (to provide recommendations) and inspection practices, and will continue our productive working relationships with state regulators, industry, and other stakeholders. Given numerous competing agency priorities, we do not see a compelling need to undertake the sweeping regulatory overhaul requested by the medical gas industry.

FDA is working hard to ensure that medical gases continue to be appropriately regulated. In addition to our efforts to finalize the 2006 proposed rule, FDA has successfully implemented the key FDASIA medical gases provision - the new certification program for designated medical gases. Over 60 products have been certified. We are also actively revising, and will ultimately finalize, the existing draft guidance document on this topic – the 2003 draft guidance on current good manufacturing practices (CGMPs) for medical gases - to provide updated recommendations.

The September 2012 report released by FDA, "Strengthening Our National System for Medical Device Postmarket Surveillance", proposed a National Medical Device Surveillance System for improving and addressing limitations in the agency's current system for monitoring device safety. In 2015, FDA took a number of steps to lay the groundwork for national system including implementation of the unique device identification rule for high-risk devices, building registry capabilities, and establishing a Medical Device Registry Task Force to develop new and more efficient methods to study medical devices.

13. Will you please provide additional information regarding the agency's progress in establishing a National Medical Device Surveillance System? What activities does the agency have planned for FY2017 to further facilitate the development of a national

[15] Available at *http://www.fda.gov/downloads/regulatoryinformation/legislation/significantamendmentstothefdcact/fdasia/ucm453727.pdf.*

system? Further, what additional resources, if any, will be needed to assist with the development and implementation of this system?

Answer: The current medical device reporting system – which relies on an individual to detect an instance of actual or potential patient harm, then make the connection between the harm and a device, and report the event – is important, but also has important limitations.

FDA's Center for Devices and Radiological Health (CDRH), in collaboration with other stakeholders, is working to develop an *active* surveillance system, the National Evaluation System for Health Technology (NEST). This system would help generate evidence to enhance product development, innovation and safety; and support patient healthcare needs. Device manufacturers from across the spectrum – larger companies, and smaller manufacturers and startups – patients, and the entire ecosystem would benefit from the postmarket information provided by the system, as well as the premarket advantages it would provide, including potential reductions in manufacturers' evidence generation for device approval or clearance.

This system would not be owned or run by FDA, but rather would be operated by an independent public-private partnership, and governed by a board with representation from the primary medical device ecosystem communities, e.g., patients, providers, payers, industry, and government. Because the NEST is not an FDA-run system, we continue to work toward broad support in the medical device ecosystem, including from Congress, for this to be effective.

FDA has worked collaboratively with patient and consumer advocacy groups, health care providers, payers, and industry to lay the foundation for a national evaluation system for medical devices. Over the past five years, FDA has completed or engaged in approximately 50 projects and spent more than $10 million to help establish the national evaluation system.

In 2012 and 2013, CDRH set out a strategy and next steps toward creating the system; in 2015, two multi-stakeholder groups issued reports that endorsed the CDRH vision and made recommendations providing further direction for establishing the system; as part of its 2016-2017 goals, CDRH will build on its accomplishments to move closer to achieving the ultimate goal of a robust, fully functional system.

To accomplish these goals, CDRH will take several steps including:

- Resources permitting, establish an organizational structure and development of infrastructure for the NEST as envisioned in the report[16] of the Engelberg Center for Health Care Reform Medical Device Postmarket Surveillance Planning Board and the Medical Device Registry Task Force Report.[17]
- Develop a framework for the incorporation of real-world evidence into CDRH regulatory decision making.

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[16] Available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf.*

[17] Available at *http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm459368.pdf.*

- Develop real-world evidence education and training for CDRH staff and industry.
- Develop metrics to track progress on building a national evaluation system.

The principal barrier to implementing the NEST is funding.

Congress and industry invested in the Sentinel system for drugs and biologics, but there has not been a similar investment in NEST for medical devices. For the national evaluation system to become operational and become a valuable resource for patients, providers, payers, government, and industry, funding is needed to continue the work FDA and others are already doing.

14. When will pilots begin to explore the feasibility of including UDI on claims forms? What would pilots look like and when will they begin? What additional resources, if any, does the agency need to begin this process?

Answer: We share the important goal of improving patient safety through post-market surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC's approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, incorporating UDIs into EHRs will allow the use of a device to be linked with a patient's experience with that device, thereby generating better information to enable patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

15. Please explain how open enrollment has gone over this past year, including the volume of interest and timing of their health plan enrollment? What can Congress and HHS do going forward to make open enrollment even more successful? What, if any, additional resources would help with the ACA's success?

Answer: HHS' priority is to provide Marketplace customers with access to quality, affordable coverage. CMS currently operates federal Marketplaces in 34 States and supports four State-based Marketplaces that use the HealthCare.gov platform. The Budget requests $535 million in budget authority, along with $1.6 billion in projected user fee collections, to maintain Marketplace operations in FY 2017 at approximately the same level as FY 2016. This funding supports oversight and operational activities for eligibility determination, enrollment, consumer outreach, quality improvement, and the supporting information technology.

At the end of open enrollment in January, about 12.7 million Americans selected or were automatically reenrolled in affordable, quality health plans for 2016 coverage through the Marketplaces.[18] Based on analysis through late December 2015, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit for the 2016 plan year.

4 million *new* people enrolled in coverage in HealthCare.gov states. Of the 9.6 million consumers who got coverage through HealthCare.gov, about 42 percent were new to the Marketplace in 2016.

More than ever, Marketplace consumers were engaged and satisfied with their coverage. About 60 percent (2.4 million) of new enrollees in HealthCare.gov states signed up for January 1 coverage compared to about 40 percent (1.9 million) of new enrollees last year. Instead of waiting until the last moment, as we saw in previous years, people signed up for coverage by the first deadline because they wanted coverage to start as soon as possible.

About 7 in 10 consumers with 2015 coverage came back to HealthCare.gov and actively selected a plan for 2016. Last year, about half of returning consumers actively selected a plan.

More than 3.6 million people used the total cost calculator, provider or drug look up tools – yet another sign of the seriousness and time they put into their decisions – and a sign that these tools were useful to them.

Finally, this year, 2.7 million people ages 18 to 34 are signed up for coverage in HealthCare.gov states, and the percentage of new customers in that age range is higher than last year. The overall percentage of plan selections for those ages remains stable.

Secretary Burwell, we hear a lot on this Committee about controlling costs and ensuring our programs are available for future beneficiaries. However, the Medicaid program is among the most efficient programs we have. And, it must be said that the open-ended financing nature of the Medicaid program is critical to allowing it to expand and contract with need.

17. Secretary Burwell, isn't it true that over the past 30 years, Medicaid costs per beneficiary have tracked with costs in the health care system as a whole, public and private?

Answer: From 1984-2014, Medicaid expenditures per enrollee increased at an average annual rate of 4.5 percent, which was slower than the rate of growth for Medicare enrollees (5.7 percent) and private health insurance (7.0 percent).

18. And, isn't it true that Medicaid's costs per beneficiary are substantially lower than private insurance and Medicare, and in recent years these costs have grown far more slowly than per-beneficiary costs under both private employer coverage and Medicare?

[18] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-04.html

Answer: Since 2008 per enrollee Medicaid spending has increased approximately 3 percent ($7,293 in 2008 to $7,523 in 2014). During the same time frame, Medicare per enrollee spending grew by about 11 percent ($10,520 in 2008 to $11,707 in 2014). Likewise, private health insurance expenditures per enrollee grew by about 27 percent ($4,108 in 2008 and $5,208 in 2014).[19]

19. Ensuring Medicaid sustainability should mean promoting value-based care for beneficiaries, states and the federal government. Please describe CMS initiatives in the Medicaid program that promote value-based care for beneficiaries, states and the federal government.

Answer: Medicaid is a payer with inherent flexibility and CMS has long supported states wanting to deliver services that improve the value of care. For decades, Medicaid has moved to change the delivery of long-term care from institutions to home and community based settings, highly valued by Medicaid beneficiaries for better meeting their long-term care needs in a more cost effective manner. Medicaid programs like the PACE program, Money follows the Person (MFP), Real Choice Systems Change Grant Program (RCSC), and the provision of telehealth services have all helped states and providers to transform the delivery of long-term care to locations that better serve the needs of beneficiaries. In fact, today more than half of Medicaid long-term services and supports are provided in home and community-based settings.

The Affordable Care Act, in addition to expanding coverage for more Americans, created additional opportunities for states to deliver value-based care. The law strengthened and expanded the MFP program allowing more states to apply and created the Medicaid "Health Homes" program. The Affordable Care Act created an optional Medicaid State Plan benefit for states to establish Health Homes to coordinate care for people with Medicaid who have chronic conditions. This new programs allows states health home providers to operate under a "whole-person" philosophy. Health Homes providers integrate and coordinate all primary, acute, behavioral health, and long-term services and supports to treat the whole person.

In 2012 CMS released a series of new guidance on how states could move from fee-for-service reimbursement to "Integrated Care Models" (ICM) under current Medicaid authorities – outlining pathways using both non-waiver authority (e.g., state plan authority) and waiver authority. ICMs are described as accountable care delivery and payment methodologies aligned across payers and providers to ensure effective, seamless, and coordinated care. CMS specifically provided guidance on how states could structure shared savings models, episode based models and primary care case management programs.

In addition to states providing care through established authority and state plan amendments (SPAs), Medicaid also supports innovative value-based care delivery models through a variety of 1115 waivers, too numerous to detail here.

The Medicaid Managed Care proposed rule further supports states provision of value-based care by encouraging managed care plans, through their contractual agreements, to develop and participate in broad-ranging delivery system reform or performance improvement initiatives.

[19] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html

This approach acknowledges the role of the managed care plan as an important partner in such initiatives and would provide the managed care plan the ability to participate as an equal collaborator with other payers and participants.

In addition to encouraging participation in VBP activities, the proposed managed care rule authorizes states to require the managed care plan to establish reimbursement standards or fee schedules for providers that deliver a particular covered service to support timely access to care. The regulation also proposes to clarify states' ability to use incentive arrangements for managed care plans that meet quality or performance targets established through the contract and use withhold arrangements to encourage managed care plans to meet quality or performance targets established through the contract.

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) created the State Innovation Models (SIM) initiative for states that are prepared for or committed to planning, designing, testing, and supporting evaluation of new payment and service delivery models in the context of larger health system transformation. The SIM is providing financial and technical support to states for the development and testing of state-led, multi-payer health care payment and service delivery models that will improve health system performance, increase quality of care, and decrease costs for Medicare, Medicaid and CHIP beneficiaries. In Round One of the SIM Initiative, nearly $300 million was awarded to 25 states to design or test innovative health care payment and service delivery models in the form of Model Design, Model Pre-Test, and Model Test awards. In Round Two, the SIM initiative is providing over $660 million to 32 awardees (including 28 states, three territories, and the District of Columbia).

To further spur innovation between CMS and the states, CMS created the Medicaid Innovation Accelerator Program (IAP) with the goal of improving health and health care for Medicaid beneficiaries by supporting states' ongoing payment and service delivery-reform efforts. Through the IAP, states can receive targeted program support designed around their ongoing delivery and payment system innovation efforts. To date, IAP is providing direct support to 28 state Medicaid programs through its four program areas, as well as its Medicare-Medicaid data integration support efforts. IAP will provide additional federal tools and resources to support states in advancing Medicaid-specific delivery system reform and by sharing lessons and best practices.

These are exciting times of forward movement for the Medicaid program as access to coverage is broadened, making the investment in delivery system and payment reform even more critical.

20. Secretary Burwell, we have heard a great deal on this committee about the limitations of Medicaid data writ large. Please describe the work of CMS to transition to a more modernized Medicaid data structure, and any recommendations the Department has for future improvements in this area.

Answer: CMS has been working actively to transition states to the Transformed-Medicaid Statistical Information System (T-MSIS) from the Medicaid Statistical Information System (MSIS). T-MSIS is a monthly, automated feed to CMS of states' beneficiary utilization and claims data as well as other key Medicaid and CHIP program information about providers and health plans. These data enable the agency to keep pace with the data needed to improve

beneficiary quality of care, assess beneficiary access to care and enrollment, improve program integrity, and support states, the private market, and stakeholders with key information.

The federal side of T-MSIS is ready for state submissions. There are seven states/agencies currently in production as of February 2016. CMS anticipates the majority of states to be complete with T-MSIS transition by December 31, 2016. However, this is predicated on state engagement and completion. Achieving state implementation will make national T-MSIS data available for stakeholder users.

Examples of expected analysis include examination of nationwide data, including encounter, claims, and enrollment data trends, understand access to and the cost of care and monitor changes in beneficiary utilization of Medicaid and CHIP services. T-MSIS will also help streamline the reporting process by reducing the number of reports and data requests CMS currently requires of states. The enhanced data available from T-MSIS will support improved program and financial management, program integrity, and more robust evaluations of demonstration programs.

Contrary to popular belief, health insurance and/or Medicare only covers very limited Long term care services and supports (LTSS). Most Americans who receive formal LTSS and don't qualify for Medicaid have to pay out-of-pocket. Individuals purchasing formal LTSS services will pay an average of $140,000 out of pocket, many until resources are depleted enough for Medicaid coverage. More than 70 percent of individuals over the age of 65 will need LTSS. As the baby boomer wave continues, by the year 2050, the population of Americans over age 65 is expected to double and the population above 85 will triple. This will result in approximately 90 million Americans over age 65 by 2055, with half of these individuals over 75. At this trajectory, LTSS expenses are predicted to double as a share of the economy over the next 30 years.

21. Long term care financing is truly in a crisis state. Please describe the pilot long term care state plan option, and any other recommendations the Department has to address this issue. Please include in your response any recommendations to rebalance care in less expensive and often preferable home and community based settings.

Answer: The President's FY 2017 Budget includes several proposals to address LTC financing and increase states' use of home and community-based services. The proposal to pilot a Comprehensive Long Term Care State Plan Option for up to five states, with enhanced match, would pilot a single comprehensive long-term care Medicaid state plan option. This pilot program would eliminate the current institutional bias and fragmented service systems, replacing them with a simplified benefit providing equal access to all types of long term services and supports, based on assessed need and choice. It will test a comprehensive solution to Medicaid LTC service delivery and financing, which would be of interest to states that have reached limits in reforming LTC under the present rules. [20].

Currently, children under 21 receiving inpatient psychiatric services are excluded statutorily from coverage of comprehensive preventive and medically necessary items and

[20] Cost projections based on the Long Term Care Scorecard.

services to which Medicaid enrolled children are otherwise entitled. However, the Department issued guidance in 2012 to mitigate this exclusion somewhat.

22. Please describe, in light of 2012 guidance, why this proposal in the budget is critical to ensuring that children receiving inpatient psychiatric care receive the Medicaid benefits to which they are entitled.

Answer: Section 1905(a)(16) of the Social Security Act provides a limited exception for individuals under the age of 21 to the general exclusion of federal financial participation (FFP) for Medicaid beneficiaries who are patients of an Institution for Mental Diseases (IMD). This exception authorizes coverage and payment for only inpatient psychiatric services furnished to individuals under age 21 but not for other medically necessary services they may need pursuant to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, which requires that states provide all medically necessary 1905(a) services to eligible individuals under age 21. Due to this exception, children who receive inpatient psychiatric services for individuals under age 21 have had to go without needed services during a stay in an inpatient psychiatric hospital, an inpatient psychiatric program of a hospital, or a psychiatric facility that meets the requirements of federal law.

The provision of quality, intensive behavioral health services to children, including in these inpatient settings, has been and continues to be a national priority. Amending the statute to provide Medicaid coverage for the full range of EPSDT services to children under age 21 who are receiving inpatient psychiatric services will ensure that children in inpatient psychiatric facilities do not lose access to coverage for critical preventive services, physical and behavioral health screenings, diagnostic and treatment services. It will also reduce the financial burden on states and Medicaid families associated with receiving related services from multiple facilities.

23. The budget references a technical correction to the statute for Medicaid drug rebates with respects to abuse deterrent formulations. Please describe why this technical fix is critical in the fight against opioid abuse.

Answer: There are two separate issues being addressed by this item in the budget. The first issue is a technical correction to the formula for the alternative calculation of the rebate liability that is required to be performed for line extension drugs. This technical correction would affect any drug identified as a line extension drug, and may result in a higher rebate liability. The current law was drafted using a formula that results in fewer drugs being subject to the higher rebate than was initially intended. The technical correction seeks to fix that formula so that the intended higher rebates may be collected.

The second issue is not a technical correction, but rather a change to the identification of line extension drugs, which determines whether the alternative calculation is required. Currently, the Medicaid law defines a line extension drug as "a new formulation of the drug, such as an extended release formulation." Manufacturers and other stakeholders have challenged the notion that abuse deterrent formulations (ADFs) should be subject to higher potential rebates due to the reformulation of a non-ADF drug. ADFs are generally new formulations of drugs that contain properties that make them resistant to abuse. However, the statute does not exempt ADFs from the definition of line extensions and, therefore, ADFs may be subject to higher rebates under Medicaid.

The change proposed in the President's Budget for the definition of "line extension" will help address opioid abuse. Including ADFs in the definition of line extension drugs may discourage manufacturers from being innovative because these products will potentially be subject to higher rebates. Accordingly, the President's Budget asks Congress to revise the definition of line extension to exclude ADFs, thereby eliminating the potential disincentive for manufacturers to invest in ADF technology.

Secretary Burwell, as you know the misuse and abuse of prescription opioids and of illicit drugs has become a true public health crisis, with overdose deaths quadrupling since 1999. I applaud you and the President for your work addressing this epidemic.

One area that often gets lost in this debate is primary prevention. This is a critical part of our efforts to address opioid abuse – stopping it before it starts. Research supported by the National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC) has found that early intervention can reduce risky behaviors during the teen years that lead to substance abuse.

The research shows that we need to start prevention efforts at a younger age than we are now, before problems emerge. Addressing the very early risk signs – such as behavior and academic concerns in preschool or elementary school — and providing services that support parents as well as young children can have some of the biggest long-term payoffs. These interventions will not only help reduce substance misuse, they will also improve academic performance and reduce bullying, depression, violence, suicide, unsafe sexual behavior and other problems.

There is 40 years of research behind a prevention first approach and there are models underway right now that are working, but most prevention strategies are not in widespread use. Making investments to bring innovations to scale and help communities implement proven approaches that promote positive protective factors – like safe, stable families, homes, schools and communities – will help prevent youth substance use before it develops. My questions are:

24. **The Institute of Medicine has called for 10 percent of public funds spent on young people to be directed toward effective prevention interventions that promote healthy behaviors. Can you tell us what percentage of the President's opioids initiative would be directed toward prevention? Or what percentage from the overall HHS budget?**

25. **Can you tell us how you plan to incorporate primary prevention into HHS' work addressing the opioid epidemic? How can we help communities to implement these interventions?**

Answer: We know that preventing substance use during youth is a key factor in preventing future substance use, especially problematic substance use in adulthood. Several NIDA-funded studies have found that universal, evidence-based prevention programs targeting youth such as

the Iowa Strengthening Families Program can reduce future nonmedical use of prescription opioids in high school and early adulthood.

In general, youth are doing the better than other age groups with respect to opioids. Rates of nonmedical use of prescription opioids among people 12-17 years old have been declining since 2002. In 2002, 7.6% of individuals 12-17 years old reported nonmedical use of prescription opioids in the past year compared to 4.7% in 2014. Similar, opioid-related mortality has remained stable among 12-17 years since 2002. In 2014, there were 115 opioid-related overdose deaths among 12-17 year olds compared to 101 in 2002.

It is critical that we focus our resources on where we can have the greatest impact. As you know, my plan for combatting opioid abuse and overdose is a coordinated, multi-faceted initiative that relies on education, prevention, and treatment strategies with the strongest evidence base, and the Department has been working diligently to develop and implement these strategies. The Department also agrees that prevention services are critical in addressing the opioid epidemic across the country. In addition to continuing support for ongoing work associated with Substance Abuse Prevention through SAMHSA's 20% set-aside for prevention within the Substance Abuse Prevention and Treatment Block Grant and through their $10 million Strategic Prevention Framework Rx, the FY 2017 Budget includes improvements to prescribing practices as a key area where we can focus our efforts to prevent opioid misuse. While actions to address prescription opioid abuse must target both prescribers and high-risk patients, prescribers are the gatekeepers for preventing inappropriate access. Therefore, HHS is focused on increasing investments in state-based prescription drug monitoring programs (PDMPs) and adoption of e-prescribing practices, disseminating guidelines for opioid prescribing, and training providers.

The FY 2017 President's Budget for the Centers for Disease Control and Prevention proposes a $10 million increase for Prescription Drug Overdose and Misuse Prevention, for a total of $80 million in discretionary resources, to support improved uptake of CDC's new "Guideline for Prescribing Opioids for Chronic Pain" among providers, and to provide ongoing support to all 50 states and D.C. through the Prescription Drug Overdose program. In addition, the Budget proposes $5 million in new discretionary funding for the Office of the National Coordinator for Health Information Technology to harmonize technical standards in support of PDMPs, improve clinical decision-making, and further the adoption of electronic prescribing of controlled substances. In addition, the SAMHSA State Targeted Response Cooperative Agreement program, a $920 million effort over two years, will enable states to develop holistic approaches to addressing the opioid crisis, including prevention.

26. There are multiple grant programs addressing prevention at the Department of Education, HHS and Justice. How is HHS coordinating with those departments to leverage resources?

Answer: We must work across HHS, with our partner agencies and other stakeholders, as well as with Congress to identify and dismantle barriers as well as leverage our resources in order to effectively implement these strategies. Coordination of HHS activities addressing opioid use disorders is being led by the Office of the Assistant Secretary for Planning and Evaluation. In addition, HHS continues to coordinate its efforts to address opioid addiction and overdose with

its federal agency partners through the Interagency Workgroup on Prescription Drug Abuse Prevention/Opioid Overdose Prevention led by the Office of National Drug Control Policy. The Department of Education and Justice are also members of this interagency group. An example of federal coordination taking place at this level is the $10 million FY 2017 President's Budget proposal to partner with the Department of Justice to implement a new Buprenorphine-Prescribing Authority demonstration to expand the types of providers who can prescribe Medication-Assisted Treatment.

The Honorable Eliot Engel

The President's proposed budget again includes reduced funding for graduate medical education. Specifically, the FY17 budget proposes a cut of $17.8 billion over ten years. While the budget does include a small investment to train more primary care doctors, this effort – though appreciated – is not a substitute for supporting teaching hospitals. With the country facing a doctor shortage, this is not the time to put funding for physician training on the chopping block.

My home state of New York has built a premier infrastructure for training doctors. In more than one-third of the 50 states, more than 10% of active physicians have been trained by New York institutions. If funding for graduate medical education is cut, top teaching hospitals in New York and across the U.S. may be forced to reduce the number of physicians they train. As a result, patient care nationwide would almost certainly suffer. The rationale for this provision is to "encourage workforce development through targeted and more accurate indirect medical education." While this is a worthwhile goal, $17.8 billion in cuts to teaching hospitals will jeopardize their ability to train future doctors, thus hindering workforce development. Medicare funding for doctor training must remain stable – the stability of our country's teaching hospitals and the educations of future physicians are too important to put these funds at risk.

1. **Can you describe how the Administration expects teaching hospitals to absorb cuts to GME, and how we can in turn ensure that doctor training does not suffer?**

Answer: HHS recognizes the importance of graduate medical education. Nonetheless, like any other category of Medicare spending, payments to teaching hospitals must be justified by incurred costs. This proposal in the President's Budget will help graduate medical education programs promote high quality primary care services that address relevant public health needs by allowing the Secretary to target funding to training activities specific to issues. HHS believes this proposal brings these payments closer to the appropriate level and provides incentives for promoting high-quality primary care. In addition, the Teaching Health Center Graduate Medical Education (THCGME) Program provides funding for residency training in primary care medicine and dentistry in community-based, ambulatory settings. The THCGME Program seeks to not only bolster the primary care workforce through support for new and expanded primary care and dental residency programs, but also improve the distribution of this workforce into needed areas through emphasis on underserved communities and populations. In addition to the $60 million in funding appropriated in MACRA, the FY 2017 Budget includes an additional $527 million over FYs 2018-2020 to support up to 876 residents.

I'd like to address an area in which, I feel, Medicare has missed an opportunity to adopt approaches that have been proven in the private sector to both save money and improve patient care: home infusion therapy.

Home infusion allows patients to receive vital treatment in a cost-effective, comfortable and clinically-beneficial setting. Home infusion is widely covered by commercial payers as a means of keeping patients out of institutions for infusion treatments. As a result, both patients and these payers have benefitted from fewer hospital-acquired infections, which HHS has devoted substantial resources to curb.

Congressman Pat Tiberi and I have introduced H.R. 605, the Medicare Home Infusion Site of Care Act, to give patients the ability to receive life-saving therapies in their homes and avoid forcing them into institutional settings. This would, in turn, avoid unnecessary costs to the Medicare program and, most importantly, to patients' quality of life.

2. **Can you speak to any issues that you foresee with respect to providing Medicare coverage for home infusion drugs and services? I would be pleased to work with you to mitigate any concerns you may have, and to afford patients an opportunity to receive this life-saving care in their homes as soon as possible.**

Answer: Thank you for raising this important issue. Coordinating care is a cornerstone of the work the Department is doing around delivery system reform. Our goal is to foster a health care system that leads in innovation, delivers the most affordable, highest quality medicines and results in healthier people. We are happy to continue to work with you and provide technical assistance on the legislation.

In December 2014, Congress appropriated $576 million to the Assistant Secretary for Preparedness and Response (ASPR) for Ebola response and preparedness activities. This amount was higher than had initially been requested by the Obama Administration, in part because Congress wanted hospitals – particularly those designated as Ebola treatment centers in high risk areas – to be reimbursed for their preparedness costs to the greatest extent possible.

Nearly 15 months later, $340 million of the appropriated amount still hasn't been allocated for designated treatment center preparedness. As a result, many centers will receive only a small fraction of their preparedness costs. Furthermore, the omnibus spending bill passed in late 2015 included language requesting that ASPR allocate a portion of that unspent Ebola funding to health care facilities that have incurred Ebola preparedness expenses. Even though Congress once more expressed its will on this matter, ASPR has not released the funding.

I am very concerned that the failure to release this funding will discourage facilities from stepping forward to be designated centers for treatment in the future. As you know, Congress will soon debate funding to address the Zika virus, and we will once again need our nation's health care providers to help protect us from this new threat. Hospitals are not required by law to undertake this very expensive public service function, but do so in response to specific needs and requests by the federal and state governments.

Can you please explain why such a small proportion of the dollars appropriated for Ebola response and preparedness activities has been allocated by ASPR? How does HHS plan to use the remainder of the allocation, if not use it to reimburse hospitals?

Answer: A total of $208 million of Ebola emergency funding appropriated to the Public Health and Social Services Emergency Fund was allocated to support the Hospital Preparedness Program to health care system preparedness and response to Ebola virus in the U.S. While the primary focus of the Hospital Preparedness Program Ebola funding is on preventing, preparing for, and responding to Ebola, as required by Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities. While HHS provides funds and provides guidance, ultimately decisions on the levels of funding for Ebola treatment centers are made by the program's 62 awardees, the health departments in all 50 states, the District of Columbia, Chicago, Los Angeles County, New York City, and all U.S. territories and freely associated states. Funding allocations for HPP's Ebola funds were based on a formula that accounted for population and Ebola risk. The hospital preparedness supplemental funding also provided significant resources to establish nine regional Ebola and other special pathogen treatment centers. These facilities have enhanced capabilities to ensure they are the leading providers of care and treatment for Ebola patients in the U.S. and have the capabilities needed to manage other high containment, Ebola-like infectious diseases in the future.

With the funding provided, States will be able to support treatment facilities, including academic health centers and other hospitals. States are also able to support a broad range of preparedness activities such as caring for clinical complex patients; maintaining enhanced readiness through increased training; increasing capacity to handle highly contaminated infectious waste; receiving and participating in training, peer review, and assessment of readiness to ensure adequate preparedness,; develop strategies to ensure health care worker readiness and safety; and integrate behavioral health considerations for patients and staff.

HHS is assessing the direction from Congress on hospital preparedness in the FY 2016 appropriations report and identifying the scope of current needs for building treatment capacity.

For over 10 years, HRSA has been overseeing UNOS work on a process to revise the organ donation system so that it is more needs-based than geography-based. Current liver distribution rules require donated livers from deceased people to be offered to the sickest person in that particular region, even if there are suitable recipients in other regions who are even sicker. Acknowledging these disparities, the UNOS Committee responsible for liver distribution reform is has been exploring alternative models for distribution.

As this process has labored on, stakeholders in New York and elsewhere are eagerly awaiting a resolution, especially the many patients who remain on the organ transplant wait list. While UNOS has been careful to thoughtfully deliberate the adoption and implementation of liver distribution reform, needless deaths continue to occur under the current policy. It is therefore essential that UNOS reach a timely conclusion on a policy to remedy the current inequity that leads to these unfortunate and unnecessary deaths.

3. **Can you provide information about the timeline for a decision, and an update on what progress HRSA and UNOS are making with these deliberations?**

Answer: Any change in the OPTN liver allocation policy must be consistent with the requirements and principles of the OPTN final rule, which articulates the goals to be achieved through OPTN organ allocation policies. These policies must, among other factors, be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements).

Consistent with OPTN processes and requirements for the development of changes to the liver allocation policy, the following recent steps have been taken with respect to the alternative approaches to liver allocation.

- The Liver and Intestinal Organ Transplantation Committee (Liver Committee) released a "Concept Paper" in June 2014 to describe geographic challenges in access to liver transplants and outline allocation concepts under consideration, as well as alternative approaches. The publication was followed by a 60-day public comment period;
- A public forum was held in September 2014, with over 400 people in attendance, to discuss the concept paper. Afterward, the OPTN convened subcommittees to address issues identified during the forum;
- A second forum was held in 2015 during which subcommittees presented recommendations being considered by the Liver Committee as it develops a final proposal for proposed changes to the liver allocation policy; and
- A Redistricting Subcommittee of the Liver Committee reviewed additional analyses of alternative approaches for liver allocation. This subcommittee is charged with developing implementation plans, and resource assessments for several options for redistricting, including the "concentric circles" option raised at the most recent forum. In April 2016, the subcommittee presented its recommendations to the full Liver Committee during its meeting in Chicago.
- The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, at its April 2016 meeting, agreed on a proposal to be shared with the public for input in order to improve liver distribution nationwide. The proposal, to be published for public comment in August 2016, is intended to increase consistency in medical urgency scores at transplant for candidates in various areas of the country.

<u>The Honorable Jan Schakowsky</u>

Calorie labeling on restaurant menus allow Americans to make informed food choices for themselves and their families when eating out. Yet, the national menu labeling law (Section 4205 of the Patient Protection and Affordable Care Act of 2010) has been delayed by six years since enactment. Most recently, a rider inserted in the FY2016 Omnibus Appropriations Act states:

SEC. 747. None of the funds made available by this Act may be used to implement, administer, or enforce the final rule entitled "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" published by the Food and Drug

Administration in the Federal Register on December 1, 15 2014 (79 Fed. Reg. 71156 et seq.) until the later of—
(1) December 1, 2016; or
(2) the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments in accordance with paragraphs (g)(1)(i), (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of section 10.115 of title 21, Code of Federal Regulations.

1. **Will you please confirm the impact of this rider if it delays the national menu labeling law even further by one year after the Food and Drug Administration finalizes its *Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)*?**

Answer: The impact of this provision would delay enforcement of the menu labeling final rule well into 2017 for covered establishments to provide calorie and other nutrition information to consumers. Considering that consumers eat 1/3 of their meals in such establishments, further delay in enforcing this rule will leave consumers without important nutrition information necessary to make more healthful food choices.

2. **When can we expect the Department to finalize this guidance so that Americans can benefit from this important law?**

Answer: The Agency considers finalizing the guidance a priority and expects to publish the final guidance in May of this year.

3. **Dr. Thomas Frieden, the CDC director, said, "The finding that nine of ten adults and children still consume too much salt is alarming. The evidence is clear: too much sodium in our foods leads to high blood pressure, a major risk factor for heart disease and stroke. Reducing sodium in manufactured and restaurant foods will give consumers more choice and save lives." When can we expect the Food and Drug Administration to issue its voluntary guidance to the food industry on sodium reduction?**

Answer: FDA is aware of the potential public health benefits associated with a reduction in sodium intake over time and continues to be highly interested in strategies that support this goal. We are working on developing draft voluntary guidelines for commercially prepared foods with the goal of gradually lowering excessive sodium in the U.S. food supply in a safe, achievable and sustainable way. We anticipate publishing the draft voluntary guidance in the spring of 2016.

The Honorable G. K. Butterfield

Secretary Burwell, although colorectal cancer death rates in the United States have declined by half since 1970, large geographic disparities persist. I happen to represent North Carolina's First Congressional District which has the alarming distinction of hosting one of the so-called colorectal cancer 'hot spots.' That means that death rates in my district are 9 percent higher than in other parts of the country for colorectal cancer-a preventable

cancer in many ways. We need help in my district. Unfortunately, North Carolina was not one of the grant awardees from the CDC's Colorectal Cancer Control Program (CRCCP). I know that the program has limited resources but I'd like to see CDC develop ways to help communities like mine that have an identified public health problem.

1. Do you have any plans to expand the CRCCP nationally?

Answer: In FY 2015, CDC began funding a new five-year cooperative agreement for the Colorectal Cancer Control Program (CRCCP). With available resources CDC was able to fund 30 grantees, including 23 states, 6 universities and 1 tribal organization. CDC does not currently have plans to expand the program.

2. How do you see the program moving forward?

Answer: Despite strong evidence to support colorectal cancer (CRC) screening, currently, only 65% of adults report being up-to-date with screening, with more than 22 million eligible adults who have not been screened. While the Affordable Care Act is helping to improve access to insurance coverage for CRC screening, many adults face other barriers which make it difficult for them to receive this effective preventive service. The goal of CDC's CRCCP is to increase population-level screening rates by implementing evidence-based interventions which affect broader health systems change and help to address these barriers.

CRCCP grantees are working to increase screening rates within a partner health system (federally qualified health center, hospital/clinic network, etc.), and defined geographical area or disparate population. Grantees must implement at least two of four Community Guide recommended interventions (provider assessment/feedback, provider reminders, client reminders, or reducing structural barriers); and may also use secondary strategies such as patient navigation. Grantees are establishing baseline screening rates in the health systems with which they partner and will measure the change in screening rates over the five year program to assess the health impact of their efforts.

To date, 226 clinics from a total of 78 health systems have been recruited for participation in the CRCCP. These clinics include nearly 441,000 patients ages 50-75 and nearly 2,000 primary care providers. The average baseline CRC screening rate for clinics is approximately 35%. Recruitment of partner health systems and their clinics will continue for the duration of the five-year grant period; therefore, we anticipate that program reach will expand considerably over time. A comprehensive evaluation of the program includes annual collection of CRC screening rates for every participating clinic so we can closely monitor our primary outcome, which is to increase screening. CDC anticipates that over the five-year program period, grantees will show increases in population-level CRC screening rates within the health systems they are collaborating with as a result of the evidence-based interventions they are executing.

Secretary Burwell, I am a cosponsor of bipartisan legislation H.R. 1220, the Removing Barriers to Colorectal Cancer Screening Act. This legislation simply fixes a glitch in Medicare that charges beneficiaries a 20 percent copay when a polyp is found and removed during a screening colonoscopy. A colonoscopy is an A-rated service because you have the

opportunity to actually gain the mortality benefit through the screening process by removing the cancerous polyp. The intent of the ACA was to encourage preventive health by providing screening services for free. This financial barrier in Medicare works to discourage beneficiaries from getting their colorectal screening. I was pleased to see the Administration support this legislation in the budget documents.

3. Short of legislative action what else can be done to address cost barriers in Medicare and private insurance?

Answer: As you noted, the President's Budget proposes to eliminate beneficiary coinsurance/copayments under Part B for screening colonoscopies that result in removal of a polyp or other diagnostic/therapeutic procedures. Under current law, Medicare beneficiaries do not have to pay the part B deductible or coinsurance/copayment when they have a screening colonoscopy. However, when a polyp is detected and removed during a screening colonoscopy or another procedure is performed, coinsurance/copayments are applicable. In that case, the service is considered to be a diagnostic or therapeutic procedure (e.g., colonoscopy with polypectomy) rather than a screening colonoscopy and patients are billed coinsurance and/or copayments. The Affordable Care Act provides that the Part B deductible is not applied in such cases, but does not waive the coinsurance/copayment. This proposal would address the inequity in beneficiary cost-sharing by waiving coinsurance and copayments on a scheduled screening colonoscopy even when the procedure actually furnished is considered to be a diagnostic/therapeutic one.

For private insurance, as you know, Section 2713 of the Public Health Service Act and its implementing regulations require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to cover, without the imposition of any cost-sharing, evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved. The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods may vary. This recommendation received an A grade. If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations.

HHS shares interpretative jurisdiction over this provision with the Departments of Labor and Treasury. Over the years, HHS, Labor and the Treasury (collectively, the Departments) have issued a series of FAQs to answer questions from stakeholders to help people understand the Affordable Care Act and benefit from it, as intended. The Departments recently issued FAQs on colonoscopies in particular.[21]

[21] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf

4. **It is my understanding that there is still a lack of clarity in both private insurance and Medicare around coverage for a colonoscopy that follows a positive FIT test. Right now, both seniors on Medicare and those with private insurance will be charged out of pocket for the follow-up test. Faced with the cost, it seems to me that they may skip the follow-up colonoscopy altogether. So, we've removed the ability to stop cancer before it starts. If you are going to pay for an initial screening tool like the FIT test and you find a problem, the follow-up screening of a colonoscopy should be covered. What is the rationale behind this strategy?**

5. **Is there a plan to clarify this issue in Medicare and private insurance?**

Answer: A colonoscopy furnished under the circumstance you described is covered by Medicare but would be considered a diagnostic colonoscopy, not a screening colonoscopy, for which cost-sharing is not waived under current law. We would be glad to work with the Congress on any proposals to address this scenario. As noted above, a colonoscopy furnished under this scenario is covered by Medicare but cost-sharing is not waived under current law. We would be glad to work with the Congress on any proposals to address this issue.

The Honorable Joseph Kennedy

1. **Madame Secretary, in light of President Obama's request for $1.8 billion in supplemental funding to address the ongoing Zika virus outbreak, can you tell us more about what mechanisms HHS currently has at its disposal to respond to emerging and re-emerging pandemic diseases like Ebola and the Zika virus? As these and other global health threats grab international attention and climate change allows vectors to spread to new territory, what steps can Congress take to strengthen HHS' ability to prevent the spread of disease, respond to outbreaks, and ensure the availability of treatments and vaccines?**

Answer: Today's world of increasing connectivity and mobility accelerates shared global health risks. New viral and bacterial pathogens continue to emerge and can quickly spread around the world. We do not know when or where the next threat will emerge from. Between March 2014 and now, we have tracked over 200 outbreaks in 145 countries—in addition to Ebola. Most of the world is still unprepared to prevent, detect and respond to infectious disease threats. Fewer than 1 in 3 countries report that they are fully prepared.

The Global Health Security Agenda (GHSA) was launched in February 2014 to advance global health security against natural and man-made infectious diseases. Global health security is the road map for countries to become compliant with the International Health Regulations (IHR) which means they will be better able to identify and respond to disease outbreaks in their own country—reducing the numbers of people who get sick and die and preventing diseases from spreading across borders.

With funding provided in the FY2015 Ebola emergency appropriation, HHS is working with other US government agencies to support 17 countries to develop and implement five-year plans to meet GHSA targets and comply with the IHR. 14 other countries and 1 region are also being supported to develop a five-year plan. Other countries in the G7 and countries like South Korea

are also supporting this work in additional countries. However, there are still many countries that have public health systems that are vulnerable to infectious disease threats. Until all countries are able to comply with IHR requirements, the whole world is at increased risk from infectious diseases.

Even in countries with well-developed public health systems, infectious diseases can still cause a public health crisis. This was the case in South Korea with the introduction of MERS, though South Korea was able to contain further spread of MERS. All countries, including the United States, need flexibility in order to be able to respond quickly to an emerging public health problem—before it becomes a full-blown international public health crisis.

2. **Additionally, it's my understanding that the FY2015 Ebola Emergency appropriations provided $597 million to CDC to establish and strengthen National Public Health Institutes and for other international preparedness activities. How have these funds been used in Latin America and what efforts are underway to utilize the National Public Health Institutes in the region for addressing the Zika outbreak?**

Answer: The FY2015 emergency appropriations provided $597 million to support national public health institutes and global health security. These funds are critical to meeting the United States commitment to the Global Health Security Agenda (GHSA) to support 30 countries to increase their ability to detect infectious disease outbreaks, respond to outbreaks effectively in order to prevent international transmission. HHS and its interagency partners identified 17 countries for initial implementation of GHSA based on an assessment of both public health vulnerability and readiness of the host country government to commit to achieving specific targets. Given the threat posed by Ebola at the time of the program launch, the initial focus was heavily weighted toward Africa. The 17 countries are: Bangladesh, Burkina Faso, Cameroon, Cote D'Ivoire, Ethiopia, India, Indonesia, Guinea, Kenya, Liberia, Mali, Pakistan, Senegal, Sierra Leone, Tanzania, Uganda and Vietnam. All of these countries have developed a five year plan to achieve GHSA targets, and have begun implementation of activities to strengthen their public health systems and develop their public health workforce in order to reduce their vulnerability to infectious disease threats. The US government is also working with 14 additional countries and 1 region to begin their GHSA planning process. These countries are: Cambodia, Democratic Republic of Congo, Republic of Georgia, Ghana, Haiti, Jordan, Kazakhstan, Laos, Malaysia, Mozambique, Peru, Rwanda, Thailand, Ukraine, and the Caribbean region.

In addition, three additional countries are currently supported by CDC with FY2015 Ebola emergency appropriations to develop or strengthen their national public health institutes. These countries are: Colombia, Guatemala, and Morocco. Having an empowered national-level public health institute with strong management, organizational and communication capacities, invested with the proper legal authorities, are key for a country's ability to sustain infectious disease prevention, detection and response capacities, as well as to carry out other essential public health services. Two regional organizations, the African CDC and the West African Health Organization, are also being supported.

HHS and the global community have been challenged to respond to two urgent public health threats in different parts of the world—Ebola in West Africa and Zika in the Americas. In

addition, MERS continues to raise public health concerns in the Middle East and beyond. Unfortunately, according the World Health Organization, 70% of the 194 countries that have ratified the International Health Regulations (IHR) have reported that they are unable to comply with the IHR requirements that keep the world safe from infectious diseases. GHSA is a critical tool to help increase global capacity to prevent, detect and respond to infectious disease but vulnerabilities remain.

3. How are HHS-implementing agencies partnering with researchers in the affected countries to develop improved tools for detecting, treating, and preventing Zika virus infections?

Answer: Various components of the Department are partnering with researchers abroad to better prevent, detect, and treat the Zika virus.

General Collaboration and Partnerships
ASPR is leading an HHS Zika Sample Sharing Working Group to identify domestic and international sources of Zika positive clinical specimens to support development and validation of diagnostics and medical countermeasures like vaccines. Through this effort, Zika-related material (virus specimens and diagnostic reagents) has been shared with a number of international partners to foster an environment for rapid global public health response to Zika. ASPR is working closely with CDC to implement a framework for sharing of samples among Global Health Security Initiative members (Canada, European Union, France, Germany, Italy, Japan, Mexico and UK). Access to a wider variety and larger quantity of live virus samples increases the U.S.'s ability to develop clinical diagnostic tools, vaccines, and other public health countermeasures.

CDC is providing clinical and zoonotic specimens to selected laboratories (academia, government, and private sector) to spur the development of diagnostics (lab-based and point-of-care), treatment regimens, and candidate vaccines. Already, we have had a notable success with the development of a next-generation molecular assay that simultaneously detects Zika virus and two others circulating in the region that can confound diagnosis and surveillance. This assay, the CDC Trioplex, has been approved by the FDA for clinical use under an Emergency Use Authorization.

Additionally, CDC is actively working through our established surveillance sites within the Global Disease Detection network (Central America, Africa, and Asia) to monitor and identify Zika cases, deploy current diagnostics and prepare for next-gen diagnostics, treatments, and vaccines in the pipeline. Another active area of collaboration and study are effective mosquito control strategies - a lynchpin of prevention. Finally we are partnering with USAID to conduct joint Zika response activities.

NIH released a Request for Applications for Zika-specific investigations through a process which allows for expedited review to ensure new research is initiated quickly to address the Zika epidemic. See http://grants.nih.gov/grants/guide/pa-files/PAR-16-106.html

Many HHS Operating and Staff Divisions, including OGA, NIH, CDC, FDA, ASPR, among others, are working closely and have participated in Zika coordination activities with WHO and

PAHO. NIH scientists have served as expert advisors and participants at PAHO and WHO convened meetings to help harmonize natural history study protocols and to identify research priorities. HHS is also providing direct technical assistance to PAHO, the WHO and affected countries and working with them to enable access to clinical samples and data to support diagnostic and vaccine development. As NIH-supported research activities proceed, NIH will closely coordinate these activities with PAHO and WHO, as appropriate.

A Selection of Country-Specific Collaboration and Partnerships

With regard to natural history, NIH is attempting to understand several key issues – the impact of Zika on pregnancy and congenital outcomes, the role of prior dengue exposure on the course of Zika infection, and the pathogenesis of Guillain-Barre syndrome. These studies include natural history research in multiple Caribbean, Central and South American sites. The largest project, co-sponsored by Fiocruz (Brazil's leading biomedical research organization), is the Zika in Infants and Pregnancy (ZIP) study, a multi-country, prospective cohort study of ~10,000 pregnant women at sites in Brazil, Colombia, Puerto Rico, Nicaragua and other locales.

FDA has been working with ANVISA, Brazil's national regulatory agency, to assist them in their efforts to expedite the development of diagnostic tests and vaccines for Zika virus.

NIH is supporting development of several vaccine candidates, and plans to begin clinical trials in endemic settings in early 2017. These activities build on existing collaborations with clinical trial sites and partners in the Caribbean and Brazil. Additional HHS-implementing agencies are providing technical and regulatory expertise to support the manufacturing infrastructure in Brazil at the Butantan Institute that facilitates in-country development and production of Zika vaccine candidate(s).

NIH is partnering with FIOCRUZ (a leading scientific institution for research and development in biomedical sciences in Brazil) on a major study focused on Zika in pregnancy.

CDC is providing on-the-ground support in Puerto Rico, Brazil, Guam, Colombia, American Samoa, the US Virgin islands, the Marshall Islands and Panama. This includes conducting studies to learn more about the link between Zika and microcephaly and GBS and collaborative surveillance and research.

In Colombia, NIH is conducting a study to look at the links between Zika virus infection and birth defects.

CDC in Mexico has been working collaboratively with the Secretariat of Health/Department of Epidemiology to analyze municipality level surveillance data on Zika, including case reports in the border states with the US. These reports are published weekly to the border health working group.

NIH/NIAID has just initiated a natural history study of Zika virus infection in Mexico, including assessment of the clinical spectrum of Zika virus disease, antibody responses, and rates of viremia.

Recently, OGA provided leadership for bilateral discussions on Zika with Brazil, Cuba and Argentina, including our collective research efforts. Internationally, HHS is strengthening diplomatic support for U.S. policies on mechanisms for data and sample sharing and fora to advance understanding of the Zika virus in the international scientific community.

4. **And finally, how do the rates of microcephaly in Brazil compare to the rates of microcephaly in other Latin American countries with ongoing Zika outbreaks? Are the rates in Brazil higher, and, if so, what are the suspected reasons for the higher rates?**

Answer: The rates of microcephaly in Brazil do appear to be higher than in other countries affected by the Zika virus outbreak. Some of this difference is attributable to phase of the outbreak in Brazil relative to that of other countries - the outbreak began earlier in Brazil, more women were infected early in their pregnancies and have since given birth and thus their babies can be properly evaluated. Other factors may be due to susceptibility to infection and more severe outcome in some populations as well as overestimates of microcephaly in some settings. Studies are underway in other countries (such as Colombia, Panama, Brazil) focusing on microcephaly and also Guillain-Barré syndrome that should provide answers later this summer.

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