

**PRESIDENT'S FISCAL YEAR 2017  
HEALTH CARE PROPOSALS**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON FINANCE**  
**UNITED STATES SENATE**  
ONE HUNDRED FOURTEENTH CONGRESS  
SECOND SESSION  
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FEBRUARY 11, 2016  
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**PRESIDENT'S FISCAL YEAR 2017  
HEALTH CARE PROPOSALS**

**WEDNESDAY, FEBRUARY 11, 2016**

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

The hearing was convened, pursuant to notice, at 10:05 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Crapo, Roberts, Thune, Burr, Isakson, Portman, Toomey, Coats, Scott, Wyden, Schumer, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Bennet, Casey, and Warner.

Also present: Republican Staff: Chris Armstrong, Deputy Chief Oversight Counsel; Brett Baker, Health Policy Advisor; Kimberly Brandt, Chief Health-care Investigative Counsel; Chris Campbell, Staff Director; Jay Khosla, Chief Health Counsel and Policy Director; Katie Meyer Simeon, Health Policy Advisor; Jeff Wrase, Chief Economist; and Jill Wright, Detailee. Democratic Staff: Laura Berntsen, Senior Advisor for Health and Human Services; Elizabeth Jurinka, Chief Health Advisor; Matt Kazan, Health Policy Advisor; and Joshua Sheinkman, Staff Director.

**OPENING STATEMENT OF HON. PAT ROBERTS,  
A U.S. SENATOR FROM KANSAS**

Senator ROBERTS [presiding]. The committee will come to order. It is going to be my distinct privilege to introduce Secretary Burwell.

It would appear that Senator Wyden, Senator Grassley, Senator Crapo, and the indomitable Senator Schumer are not here. They have conflicts, none intended, and I am going to ask unanimous consent that the statements by the distinguished Senator from Oregon and ranking member, Senator Wyden, and our distinguished chairman, Senator Hatch, be inserted in the record at this point. Without objection—

[The prepared statements of Chairman Hatch and Senator Wyden appear in the appendix.]

Senator ROBERTS. Our witness today is Health and Human Services Secretary Sylvia Mathews Burwell. Secretary Burwell has been leading the Department of Health and Human Services since June of 2014.

Ms. Burwell has a long history of public-sector service, including in her previous position serving as Director of the Office of Management and Budget under President Obama. In the Clinton ad-

ministration, Ms. Burwell served as the Deputy Director of OMB, the Deputy Chief of Staff to the President, Chief of Staff to the Treasury Secretary, and Staff Director at the National Economic Council. She has not served as the Secretary of Agriculture, however.

She also has extensive private-sector experience, including serving as the president of the Walmart Foundation and, before that, as the president of the Global Development Program at the Bill and Melinda Gates Foundation.

Ms. Burwell received her bachelor's degree from Harvard University and a second bachelor's degree from Oxford University, where she was a Rhodes Scholar.

Thank you, Madam Secretary, for being here today. We would invite you to please proceed with your 5-minute opening statement.

We have inserted the statements by the ranking member and the chairman for the record. We will proceed with questions following the Secretary's statement.

Please proceed.

**STATEMENT OF HON. SYLVIA MATHEWS BURWELL, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC**

Secretary BURWELL. Thank you, Senator Roberts, and thank you, members of the committee. I want to thank you for the opportunity to present the President's budget for the Department of Health and Human Services.

As many of you all know, I believe that we have common interests and share common ground. In the last legislative session, this committee embraced that view of bipartisanship and leadership when it took historic steps to pass the Medicare Access and CHIP Reauthorization Act of 2015. I want to just thank the committee for that leadership on what is a very important piece of legislation, for a number of reasons.

The budget before you today is the final budget for this administration and my final budget. The budget 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, accelerates our progress in scientific research and medical innovation, and expands and strengthens our health-care system. And it helps us continue to be responsible stewards of the taxpayers' dollars.

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

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 virus. The administration is requesting about \$1.8 billion in emergency funding, with \$1.48 billion of that for the Department of Health and Human Services. We appreciate Congress's consideration of this important and timely request as we implement the essential strategies to fight this virus.

I know that the rise in opioid misuse and abuse has also affected many Americans as well. Every day in America, 78 people die opioid-related deaths. 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 do not receive the treatment that they need. So this budget proposes \$780 million to try to close that gap.

Research shows that early intervention can set the course for a child's success, and that is why we propose extending and expanding the home visiting program to help even more families in need to support their child's growth.

While we invest in the safety and health of Americans today, we must also relentlessly push forward the frontiers of science and medicine. This budget invests in the Vice President's cancer initiative. This is a vital investment for our future. Each 1-percent drop in cancer deaths saves our economy approximately \$500 billion, not to mention the comfort and security it brings to families across the country.

Today, we are entering a new era in medical science. With proposed increases of \$107 million for a precision medicine initiative and \$45 million for the administration's brain initiative, we can continue that progress. But for Americans to benefit from these breakthroughs in medical science, we need to ensure that all Americans have access to quality, affordable care. The Affordable Care Act has helped us make historic progress. Today, more than 90 percent of Americans have health coverage—the first time in the Nation's history that this has been true.

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

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

With that, I would be happy to take your questions. Thank you.

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

Senator ROBERTS. Thank you very much for your statement, Madam Secretary.

You recently stated that you believe we have more work to do with the Affordable Care Act, but the marketplace is stable. I am going to take the opportunity to remind you that one of the five insurers offering coverage in the marketplace in my home State of

Kansas left the exchange this year, and that insurer provided coverage for nearly half of all Kansans last year.

When we hear stories like this, when we say we have assured stability, it becomes a problem. I think that data your own department released late last year showed that premiums for the benchmark plan will increase 16 percent this year in Kansas, and that is an increase that is causing great concern.

So, with insurers already pulling out of the marketplace, I am troubled that CMS is taking steps to increase government control of the plans available on the exchanges and ultimately reduce consumer choice through the new notice of benefit and payment parameters. The notice claims that an excessive number of health-care plan options make consumers less likely to make a selection that leaves them satisfied.

So my question is, does CMS believe there are too many plan choices available on the exchanges? I cannot imagine you would say anything else but “no.”

Secretary BURWELL. With regard to the question of the stability in the marketplace, in the marketplace this year, most of the folks who came into the marketplace, 9 out of 10 actually had an ability to be in a market where there are three or more issuers, and that is where we believe competition occurs. So that was the situation. As I have said and as you quoted me, I believe we continue to take steps to further stabilize and make sure the market stays stable. We are stable now with those numbers, but we need to take steps.

With regard to the payment notice, I think you know we are in the middle of that, and we will be completing that payment notice.

Our objectives today are not about limiting choices for the consumer, but instead, making it easier for the consumer to make choices, and a number of the steps that we took this year in open enrollment are about that.

We created tools. In the marketplace this year, you could actually search plans and understand if the providers that you were looking for were a part of that. The other part of what we did was create a tool called the “total cost” tool, and it is a tool that allows you to figure out your deductibles and premiums for the year.

So our objectives in our rulemaking, which we will complete, are to continue to promote stability in the market and to make sure that there is consumer choice, not to limit it.

Senator ROBERTS. I appreciate that Acting Administrator Slavitt recently announced the creation of a Rural Health Council—

Secretary BURWELL. Yes.

Senator ROBERTS [continuing]. Whose job will be to review all regulations the agency promulgates for their impact on rural providers. I know that you have not had time to get up to speed on all the details, but I would appreciate any more information you could provide to the committee after this hearing. I am very much interested in how you see this new effort functioning.

The distinguished Senator Franken is the co-chairman of the Rural Health Care Caucus. We would like to know how this new council will coordinate with or utilize the work already done by the HHS Rural Health Task Force and the HHS National Advisory Committee on Rural Health and Human Services. We have a lot of



folks interested, but there may be some duplication, and I hope we can pull that together.

Secretary BURWELL. With regard to the council, the council that Acting Administrator Slavitt has pulled together, I think, is a response to topics that we have discussed in this committee.

I think you know my personal interest in rural issues. So with any regulation that was coming through CMS to me, there were a series of questions about rural America that I would ask every time. I think what we are now doing is formalizing a process by which those analytics that I think are important for us to understand are taken into account, because I believe rural markets and sometimes urban markets in our country are different, and, as we consider our rulemaking, we need to consider both.

So it is formalizing a process that we have been doing informally over the past year in terms of that rulemaking. I think you hear that it is an issue of interest. We would like to work with the Congress in making sure we are considering the right things as we ask these questions about the impact on rural America.

Senator ROBERTS. I appreciate that. Thank you very much.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

Secretary Burwell, it is always good to see you, and thank you for all your work on the budget.

I want to go over a couple of things: one, the implementation of the basic health plan, which now some States have taken up. I want to get your commitment that you are going to implement those plans across America. My understanding with New York is, it is already targeting lower premiums and plans that are better drivers of driving down cost in the marketplace. So I definitely want to get your commitment on that.

Secretary BURWELL. Yes. I think you know, in the time that I have been here, we have engaged in a number of these, and now with New York and Minnesota in terms of the two places. But we look forward to other States coming forward with proposals that do a number of things. One, they have to meet the basics of making sure that the number of people who would have access would have access. They need to meet the requirements of the health benefits that are required already and in terms of deficit neutrality for the Federal Government. But at the same time, we know these plans are about access, but they are also about States that are doing delivery system reform and thinking of more efficient ways to provide quality care.

So we look forward to working with States as they come forward with their plans.

Senator CANTWELL. Well, I think it is very telling when you look at this model, because clearly we are talking about the lower-income population that was always hard to serve, in general, getting them on an affordable plan, maybe because their employer did not offer it or did not have market leverage.

So to look at New York, with low monthly premiums of only \$20, it is quite astounding to see that we can provide great coverage for a huge population and, as I have always been a fan, focus more on managed care, which drives down the cost as well. So I look forward to your commitment to working with other States on that.

As the administration also looks at alternative payment models to properly incentivize care providers, how are we making sure that we are moving ahead, particularly for low Medicare rate States like Washington that want to see the improvements and not to be penalized, but to be rewarded from that? So how are we making sure that we are transitioning off of fee-for-service and onto this payment model in a rapid fashion?

Secretary BURWELL. There are a number of things we are doing. I think you all know that last year, in January, we committed, as an administration and at HHS, that we would transfer by the end of 2016 30 percent of our payments in Medicare to payments based on value, not volume, and that by 2018, it would be 50 percent of the payments.

What we are doing is, we are on track to meet that goal for this year, which is important. It is important because we are a large portion of the dollars, but it is important because of the signal that it has sent the market in terms of other people coming to that space, whether that is private players or Medicaid, like the State of New York, where, in Medicaid, that happened.

Additionally, to your point of rewarding those who are making advances in quality and affordability, we also, with our Accountable Care Organizations, took the feedback that we have received, and, in the next round of those, we have put forward changes that hopefully will protect and reward those who are already leading in the space.

Senator CANTWELL. On graduate medical education, there is something that you guys have entailed on setting the standards for emerging needs in health care as it relates to medical education.

What are those standards going to entail?

Secretary BURWELL. What we are trying to do—and this is on the Medicare side—is, we do want to make sure that the moneys that are for graduate education in the Medicare space are targeted toward those who are serving that population, the Medicare population. In addition, we want to make sure that we are focusing on primary care, where we know we need more services, as well as the issue of specialties where we do not have enough people.

So what we are going to try to do is create standards that target the money and guide it to the places where (a) it serves the population it is supposed to in terms of Medicare, but (b) it is targeted to the places where we have shortages.

Senator CANTWELL. Right. I think the problem that we have that we really need to focus on is that, given a State criteria, you can be in Seattle and be well-served but be in Spokane and have a shortage. So we need to focus on the fact that, even within a State, you can have great geographic differences in what you are doing to serve graduate medical education. So it is a very big priority for us to have that graduate medical education in Spokane.

Then my colleague, I am sure, is going to ask you about Puerto Rico, but the bottom line is, our colleagues here have to understand that, while there is a cap on Medicaid rate expenses right now in Puerto Rico, if tens of thousands of people come to the United States, there is no cap on that. So we are just digging a deeper and deeper hole in our budget by not fixing the problem in Puerto Rico.

Thank you. I will let my colleague, when he gets to that, address it.

Senator ROBERTS. Senator Coats?

Senator COATS. As you know, CBO recently came out with an estimate that said that in 10 years, without addressing mandatory spending and other issues, the mandatory spending and interest will consume 99 percent of all Federal revenues. Obviously, that is unsustainable.

You and I have been together in rooms talking about budget issues when you were OMB Director. We were not able to reach an accommodation on going big, so I decided if we could not do that, I would go small. So every week, I would go down to the Senate floor and talk about waste, fraud, and abuse and how we can save taxpayers money and better use it.

One of the issues that I am going to be talking about actually today is the IG's report regarding improper payments through CMS. It is my understanding that the Inspector General listed 25 unimplemented recommendations for improvement in protecting taxpayers' dollars with CMS. CMS has said it wants to address this, but it is short on resources. This is kind of a catch-22, because there is an estimate that CMS could have saved \$1.76 billion if it had followed the recommendation of improving automated claims and a number of other things.

So my question here is, you are asking for more resources. I would just like to bring this to your attention. There are ways to free up money for absolutely necessary functions for CMS, and some of these recommendations or all of these recommendations, if they are implemented, can help with that process.

So I wanted to bring that to your attention. I would like to get your response to that in terms of the ability to go forward and get these recommendations implemented.

Secretary BURWELL. We agree, and I think you probably know the 7-to-1 statistic in terms of, for every \$1 invested, we believe we can save \$7, and that is the average over the most recent period of time. And last year, together with the Justice Department, we had the largest take-down we have had in the fraud area. It was over \$700 million in one take-down.

So it is a combination, I think, of things we can do, the technology portion of it. We do believe we need finances to change and do some of that automation. We have asked for those resources.

In terms of Acting Administrator Slavitt, who I think has taken on these issues, I think you may have even had an opportunity to speak with him about it. It is an issue that is on our regular dashboard of things we are talking about, because we believe—just, I think, as you articulated—fraud is a very important part that I think we can go at aggressively, with data, getting ahead of it instead of chasing it.

The other part that I think we need to consider is, within improper payments, there is fraud and then there is that whole category where people are not providing the right data and information. We have tightened the requirements in order to do things like requiring paperwork before payment so that we get in front of it. We find that we are seeing greater numbers of people not giving the right paperwork. So we are focused on that technical assistance

to providers to get the information to us, but that is also a place where the resources are important.

Senator COATS. Well, given your experience as OMB Director, I know that this is something right in your wheelhouse.

So, as Secretary of HHS and overseeing CMS, I think you are exactly the right person in the right place to get this done, and we wish you success in getting these things implemented here, because it can free up funds, necessary funds, for programs that may be waiting for those funds.

Secretary BURWELL. Absolutely, and that is why we are hopeful that our budget request—that particular part of the budget request—results in greater savings. The 7-to-1 number is what we have seen on the average of the last 3 years.

Senator COATS. Thank you.

Mr. Chairman, I have 40 seconds left, which I yield back in the interest of a vote coming up.

The CHAIRMAN. Well, you are just great to do that. Who is next? Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

I will only ask one question on this round, given colleagues being here. We are very pleased the Secretary is here. Secretary Burwell, in my view, gives public service a good name. We are glad that she is here.

The issue of opioid abuse is widespread across the country, and it is of particular concern to Oregon. I think colleagues know that I have opened an investigation into potential conflicts of interest between opioid manufacturers and the pain industry. The concern here is that the manufacturers may be trying to influence opioid prescribing practices, and we will have more to say on that in the days ahead.

Now, Oregon has been among the States with the highest non-medical use of prescription pain relievers. The CDC estimates that 1 in 15 people who take prescription pain killers for non-medical purposes are going to try heroin within 10 years. Nationally, health care providers write enough prescriptions for opioid pain relievers for every adult American to have a bottle of pills.

Many studies and experts have found that physicians are inadequately trained on pain management. This past week, I sent a letter to the CDC Director to offer my support for the CDC's draft Guideline for Prescribing Opioids for Chronic Pain, which will help prescribers have consistent evidence-based guidance for appropriate opioid prescribing.

So set aside, for purposes of this morning, Madam Secretary, this question of the investigation into potential conflicts of interest. We will talk more about that in the future. But for purposes of this morning, what does HHS plan to do to ensure that opioids are prescribed more appropriately, and what is the plan to reduce the number of people using prescription pain relievers for non-medical purposes?

Secretary BURWELL. When I came to HHS in June of 2014, this was one of the priorities that I chose as a Secretary, because I am from the State of West Virginia, where I think many of you know the problem is acute, as in neighboring States, but also all over the

country. I have visited in Colorado, Pennsylvania too—across the country.

So we put together a three-part strategy based on the evidence that we had seen to date in terms of the most important levers that the Federal Government and HHS have. It was three parts, with number one being the issue you just touched on, and that is prescribing. Prescribing is how this starts. It is how it starts in terms of the prescription medication.

As you reflected, so many people who do heroin, it is after they have done prescription drugs. In Colorado, I met a young woman who said after 3 months, heroin was cheaper, easier to get, and a better high. So we see that. And she had started with her wisdom teeth being pulled and taking the drugs.

So, first, prescribing practices, that is the work that CDC is doing.

Second, medication-assisted treatment, and this is the approach that I think there is broad bipartisan support for, and it is supported at the State level, with the Governors, with sheriffs, with everyone, in terms of making sure that we are getting the treatment for the people, because right now, in our State, across the country, we have so many people who are already addicted.

That is what the vast majority of the moneys that we have in this proposal, in our budget, do. It is important to note that is money that will go to States and communities. It will go through SAMHSA and it will go through HRSA, but the vast majority of those dollars are to get out so that we can build that capacity in States and communities to do medication-assisted treatment.

The third part of the strategy is naloxone, and, sadly, we do have a situation where many people overdose, and you all know the numbers. As I mentioned in my testimony, 78 people a day in the country are dying an opioid-related death. That overdose can be prevented from being a death by applying naloxone, sometimes called Narcan.

So part of the moneys are about making sure that we are able to help and support communities to get access to that drug, to their first responders, as well as, we recently saw organizations like CVS and Walgreens working to make this drug an over-the-counter drug in States.

Senator WYDEN. With so many other colleagues waiting to ask questions, Mr. Chairman, I will ask some others on future rounds.

The CHAIRMAN. Thank you, Senator.

Senator Thune is next.

Senator THUNE. Thank you, Mr. Chairman.

Madam Secretary, welcome; nice to have you here. I appreciate that I have been able to discuss some of these issues with you previously. But I want to raise some concerns we have had about the Great Plains Area Indian Health Service. The reports coming out of there have been unacceptable. Unfortunately, there has been a failure to deliver on the promises to fix health-care services in this area.

Reports of IHS's failings were issued in 2010, 2011, and 2013, and in 2014 I was informed that a contractor was in place to strengthen the link between external oversight and the development of effective patient care processes. Report after report, it cov-

ers the same issues. Yet, when it comes to fixing these issues, the administration seems to continuously fail.

So I would like to know from you what the administration has done in the past few years to engage with tribes in the Great Plains area to make meaningful reforms to the system and to ensure that patients receive the quality care that they deserve.

So, if you could, talk a little bit about that.

Secretary BURWELL. Yes. Thank you, Senator. I share your concerns in terms of the progress that has not been made that needs to be made.

There are a number of changes that we are making right now in terms of trying to get a different result from where we are. I think it was important, though, that when CMS said that we did not have safety and quality issues, that we acted upon that to protect the health and well-being of the folks. That still means they need access to quality and how do we get there.

First, in the region itself, we actually, I think you know, have changed the leadership in the region. In addition, we are supporting that by sending some of our Public Health Commission Corps officers who work on quality issues in to supplement the IHS folks on the ground.

In addition, at the Department itself, we are doing quality and management changes, because I think it is both about meeting the quality standards and management and cultures that we need to make some changes in. And we have hired a Deputy, Dorothy Dupree, who has come from the field to work on the quality issues, and brought in Mary Smith as another Deputy to work on the management issues.

In addition, I think you saw in the hearing which you were in—and I thank this committee for her hearing—I specifically asked the Acting Deputy, Dr. Mary Wakefield, to actually put together an interagency group within the Department of Health and Human Services, which met yesterday, to set specific goals of what we can achieve during our time.

Senator THUNE. Thank you. We will look forward to continuing to follow up on those issues.

I want to change gears for just a moment and ask about—and this is kind of more forward-looking, I hope—how we can make reforms at the IHS. I would like to follow up on at least an issue that I have addressed with the officials at IHS.

Late last year, I requested an update on when the administration would finalize a regulation that was initially published in December of 2014 which would expand Medicare-like rates for physician and non-hospital-based services under the Purchased and Referred Care program.

I understand from the budget proposal that this regulation is awaiting approval at OMB, and I am encouraged by what we are hearing about the progress, and I am interested in when you believe that this regulation will be posted. And, additionally, I would like to know how the administration plans to conduct its consultation with the nine tribes in South Dakota.

Secretary BURWELL. With regard to the specific regulation that you are speaking of, yes, it is at OMB under its review process, and that is generally a 90-day process.

The comments come back to us, and the question is how extensive those are in terms of the timing. But it is at a late stage of the regulatory process, and it is one that is a priority for us in terms of those that we have gotten to OMB.

So we are hopeful that soon we will get it out. I think it is also related to the issue that I think you know about, because your State and your Governor have been an important part, as has Alaska, of changing the way we do some other payment issues that are not a part of that regulation, but I think are important to the payment system and how we provide health care.

So we are working on the regulatory front, but we are also working on something that does not, I think you know, require the same process in terms of the payment. And I think you know we are changing some of the matching rates.

Senator THUNE. Right. I appreciate the effort there and would just encourage you to continue to push OMB to be able to move forward with the finalization of that regulation.

I have written you in the past too regarding one area of improvement, which is the electronic mechanisms used to exchange information in the claims and payment process, and in the Purchased and Referred Care program, claims are still being mailed back and forth. My understanding is, the administration is considering a move to electronic claim payments, and we would be interested in an update, if that is something that the administration believes is feasible.

Secretary BURWELL. With regard to the specifics of where that one is, I would like to get back to you on it. But the overall concept, I think you know, with the emphasis in our delivery system reform—one of the anchors of the strategy there—is electronic health benefits and data and information and the ability to move that more quickly so we improve quality and we improve affordability.

So it fits within that overall strategy of all that we are trying to do. Where it specifically is at this moment, I will need to get back to you on.

Senator THUNE. We appreciate that. Thank you.

My time is up. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Nelson?

Senator NELSON. Under the ACA, 17.6 million people now have health care. Louisiana is expected to expand Medicaid in their legislative session. That is another 400,000 people. That is 18 million.

The Republican Governor States that have refused to expand Medicaid and will eventually is another 4 million. So 18 million plus 4 million is 22 million—22 million people will have health care out of an eligible population of 34 million that did not have health care. That is two-thirds. To use the lexicon of today, that is a huge success. I do not think that that story is really understood, how successful the ACA is.

Now, if you wonder where I got the 34 million, I am taking 45 million, which was the population that did not have health care, and I am subtracting those who are here illegally, 11 million, to get 34 million—22 out of 34 million will have health care. That is a success.

I want you to chronicle that story.

Secretary BURWELL. I think when we think about the issue of the success, it is around affordability, access, and quality. And, as you appropriately reflect on the access point, as I mentioned in my opening testimony, we are now at a place where over 90 percent of Americans have insurance in the country, and that is a very big change from where we were.

For Medicaid, 14 million additional folks are in Medicaid from 2013 to now, and we know in the marketplace that 17.6 million, as well as other numbers in terms of that reduction.

The other thing that I think it is important to reflect is, when we have low unemployment, people have health insurance through that as well.

So all those things are coming together to put that downward pressure, but I do not think we can forget the other things, like preexisting conditions, and so many Americans know people who have had cancer, who have asthma, and that has been a very important change that I think many people think is very beneficial, as well as preventative care.

That gets a little bit to what Senator Cantwell said and some of the issues we have all discussed about downward pressure on price.

Senator NELSON. Puerto Rico, the mosquito that is in Puerto Rico that has spread a lot of dengue fever is the same mosquito that carries the zika virus. Now, fortunately, the zika virus produces a flu-like symptom that is relatively moderate. But where it is having these tragic results is on pregnant women with children who are deformed.

Puerto Rico needs help, and, lo and behold, if Puerto Rican pregnant women are being exposed and they have this tragic result of these defective births, that is going to be an additional expense upon the health-care system to take care of these babies. I know you put \$250 million in your budget to curb what is expected to be, in Puerto Rico, this outbreak of zika. Do you want to comment about this?

Secretary BURWELL. Yes. With regard to the zika virus, the concern that we have right now, and the plan that we have put in place, is about preventing further damage and focusing specifically on pregnant women. What we know is that, on the island of Puerto Rico, this mosquito is a very dominant presence. It is a mosquito that will sometimes bite four humans in one feeding and, therefore, it spreads the disease quickly.

So also, because 80 percent of the people actually are not symptomatic, you do not necessarily know if you have had it. So it is important to get resources to Puerto Rico in terms of pregnant women, taking care of and protecting them, and us doing mosquito control.

It is not just for Puerto Rico. Puerto Rico is the place where we expect that we will see the most cases, and we have had mosquito transmission already. But in the continental U.S., in States like Florida and Texas, we are also concerned, because this mosquito is prevalent as well, and we want to make sure that we are putting the resources against preventing as much spread as we can of the zika virus.

The CHAIRMAN. Senator Bennet?

Senator BENNET. Thank you, Mr. Chairman.



Thank you, Madam Secretary, for your public service and your leadership.

I want to continue along the lines that Senator Nelson was talking about, with respect to zika virus, and broaden the question a little bit. As you know, the CDC's Division of Vector-Borne Diseases in Fort Collins, CO has been on the frontline of studying and monitoring the issue of this disease for years.

The President, as you mentioned in your opening presentation, has proposed \$1.8 billion to respond to the zika virus. Can you give us more detail about how you propose to spend that money and what role the Division of Vector-Borne Diseases would play in responding to the virus?

Secretary BURWELL. We are very appreciative of the work that they have done to date. Because the issue of testing for zika is something that is occurring mainly with the CDC and there in Fort Collins, that is where a lot of the testing is occurring. We are trying to move the testing out to States so it will be more proximate to those in need.

That is a part of what that money is about, making sure that States will have the capacity to test, because for any woman who has gone to Mexico—and we know the estimates are about 450,000 pregnant women travel to these regions where zika is—if they come back infected, they will not necessarily know, because 80 percent of people do not know they have the disease.

So if you are pregnant and come back, you most likely will be tested, and we recommend you are tested if you have gone to this region. Therefore, a lot of the money is about making sure that the States are going to have that testing capability.

Senator BENNET. Thank you. I want to shift gears a little bit. Senator Grassley and I, along with Senators Nelson, Brown, and Portman, introduced the ACE Kids Act. Our bill now has 30 cosponsors. It would improve care for children with medically complex conditions like cancer, congenital heart disease, and Down syndrome. Approximately two-thirds of the 3 million children with medically complex conditions in the U.S. are covered by Medicaid. These children account for an estimated 6 percent of Medicaid enrollees and nearly 40 percent of Medicaid costs for kids.

Our bill would create a national framework of world-class providers and hospitals in the Medicaid program that would coordinate care across State lines on behalf of these children. I know HHS has worked within certain States to test these types of models. We hope to develop it nationally and work across State lines.

Senator Grassley and I are working with our Finance Committee cosponsors and Senators Hatch and Wyden to try to pass the bill.

I am bringing it to your attention because, as you know, operating Medicaid across State lines is not easy, the way it is designed, and we are going to need assistance from your team at CMS to pass the law this year.

Is this something that you would be willing to prioritize?

Secretary BURWELL. Yes. We want to work with the authority we have to do some of the things that we can do that are ideas and concepts, and we want to work with you on ensuring that we can do all the work that we can to make sure that these kinds of children are served.

Senator BENNET. Great. I appreciate that. I think we could do a much better job of providing better care at a lower cost if we could coordinate it. So thank you.

With that, Mr. Chairman, I will yield back, because I know there is a vote. Thank you.

The CHAIRMAN. Thank you. I appreciate it.

We are going to go to Senator Portman. I apologize to you, Madam Secretary; I will be back, but the bill on the floor is my bill, and I am going to have to at least go vote on it.

Senator Portman will take over, and then my staff will say who is next. If any Republican Senator is here, they can direct who is next.

Senator Portman?

Senator PORTMAN [presiding]. Thank you, Mr. Chairman. It is a privilege to have the gavel. I will not abuse it.

Thank you, Madam Secretary, for reaching out before this hearing and seeking my counsel. Of course, I had none for you, except to say that we have differences on this budget.

I agree with what Senator Bennet just said about the importance of our Kids Health Act, which is called the ACE Act, which will help, as he said, improve care, but also reduce costs. I would love to work with you on that.

We do have some differences on the big picture: \$3.3 trillion in new taxes. You and I have talked about some of these fiscal challenges we face that are not resolved in this budget.

But I want to talk about something that I like in the budget, and that is the work on opioid addiction. So prescription drug and heroin addiction is at epidemic levels in my State and around the country, and we are losing, as you indicate, lives every single day. We lost over 2,300 in Ohio in this last year alone.

We have, over the last 3 years, been working on legislation that is bipartisan and comprehensive. We have had over a dozen meetings up here with experts from around the country. We tried to bring in the best people to figure out how to get at this problem. You and I have talked about it, and you have reached out to me, and I appreciate that, over the last several years on this issue.

That legislation, called CARA, Comprehensive Addiction and Recovery Act, just passed the Judiciary Committee while you were testifying, and it passed, as I understand it, by a voice vote. In other words, it was unanimous. That does not happen around here.

So I am going to thank you for what is in the budget, because what you put in the budget is consistent with CARA and provides more funding specifically for treatment.

One of the things I like about your budget is, it also provides some funding to look at—and I am reading from your budget—“evaluating the effectiveness of treatment programs.” So it is research at the Federal level and best practices, because not all medication and treatment programs are equal. Some work better than others, and some that I have visited in Ohio have incredible results. Others, frankly, are struggling.

So I think that is important too, at the Federal level, to provide that. So I encourage you to continue to do that. I know you have a personal interest in this and a passion for it.

Senator Whitehouse is the other co-author of this, but we have a bipartisan group. We have over 120 groups from around the country that have now supported us on this, including the National Association of District Attorneys, the Attorneys Generals—I think 38 of them now endorse the bill—the groups who represent the people who work in the trenches every day in the States, they have endorsed it.

This is one that we can actually get done, and I know that the White House has said generally good things about the bill but has not been willing yet to say that they support it. I hope you will support it. I hope you will get behind it. We understand there has to be funding that goes along with it, and that is why I think the budget is a step in the right direction.

The funding that we got in at year-end will help, but we will need additional funding to be sure that the legislation, which is authorization, can actually be implemented in the proper way.

I wonder if you have any thoughts on CARA you could share with us today.

Secretary BURWELL. First, thank you for your leadership in this space. It is important to the progress that I think we can make in terms of a number of folks, and you certainly have been a strong leader. And I appreciate our conversations about these issues as well.

I think, as you said, it aligns with the strategy that I articulated earlier in this hearing, which the bill addresses. I think we want to continue to work, and I am hopeful. I think you know I just have 11 months, and I hope that we will start to see the results of our efforts, but it is going to take longer. But the idea is that we can put in as many as possible of the things that I think we need to do and that support for the medication-assisted treatment, as well as these prescriber issues that we are going to face when we get the new guidelines.

So we look forward to continuing to work with you on it. I am glad to hear about the vote. I, obviously, was here, so I did not know.

Senator PORTMAN. Thank you. We are encouraged by the vote and also by the amount of support we are getting from around the country on this. I think the administration weighing in more precisely on this legislation would help us to get it through the process without what often happens around here, which is political games. And we are going to see it. People will offer amendments to it to try to kill it. People will say this is about politics.

It has never been about politics. We have been working on this for years. We have kept it not just bipartisan, but nonpartisan. But we would love your help to get this to the President's desk, where I believe he would be very pleased to sign it to start this new strategy to be able to have the Federal Government play a more important role, a better partnership role, with State and local governments and nonprofits to address what is a crisis in our communities.

There is other legislation, as you know, that Senator Toomey and myself, Senator Brown, and others, have introduced. It is called the Stopping Medication Abuse and Protecting Seniors Act. This helps us to be able to save lives by reducing the likelihood that patients

in Medicare are doctor-shopping, getting prescriptions for pain medications from multiple doctors, multiple pharmacies.

We have cosponsors on both sides of the aisle. We know these programs work in the private plans. The CMS Administrator testified several weeks ago that Medicare is prohibited from using this important tool.

I know your budget touches on this, but I wonder if you could comment on that legislation and your view on this and whether we can also move that legislation forward to avoid some of this prescription drug abuse that is causing the problem.

Secretary BURWELL. As was commented by CMS, in terms of our ability to do it, I think you know, it would come statutorily. We see Medicaid programs in States doing it, as well as the private sector.

I think the one concern we just want to make sure of is that we do not make access too hard. Pain is an important issue in terms of the issuance. So I think we agree we can do a much better job, which I think is what the objective of the bill is, in terms of controlling this access to these drugs in terms of providers and pharmacies. We just want to make sure we do it in a way that does not inhibit access for those who actually need it.

Senator PORTMAN. Thank you, Madam Secretary. I look forward to working with you on that as well, because it does require a statutory change.

Thank you, Mr. Chairman.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman. We have rotating chairmanships today, so I am getting confused.

Madam Secretary, thank you for your service to our country. I think you do an outstanding job.

As you know, Congress passed the Autism CARES Act in August of 2014, which I wrote to continue the research, the intervention, the support programs that existed under the old-named Combating Autism Act. While the CARES Act contains requirements that HHS conduct research into key areas impacting the autism community, chief among them is a report focused on young adults and youth with autism who are transitioning out of school-based support services into the larger community.

According to the CDC data, one in 68 children nationally and, unfortunately, one in 45 in my home State of New Jersey is identified with autism spectrum disorder. Early diagnosis and interventions have come a long way to support these children, but, unfortunately, youth and adults do not have the same access to support and services after they leave the schools. So the happenstance of a date on the calendar changes their lives dramatically.

After the law's passage, I convened a roundtable discussion with key autism community leaders in New Jersey. This issue of aging out and transitioning to community-based services was something that was consistently mentioned as an area in dire need of attention, which is exactly why I mandated this report, which would provide Congress, the agencies, researchers, and providers with a comprehensive understanding of not only what services are currently available, but what we need to do to ensure that every individual with an autism spectrum disorder can succeed in adulthood.

Now, the report on young adults and transitioning youth is due to Congress this upcoming August, 2 years after the Autism CARES Act was signed into law. Can you provide us with an update on the progress of the report and confirm that it will be completed by the statutory deadline?

Secretary BURWELL. First, thank you for your leadership in this space, because it is important to helping us do the work that we do.

We are working on this report, and I will find out in terms of the specific question you are asking on August exactly and come back to you.

Senator MENENDEZ. I am concerned because I understand, and my understanding may be wrong, that this has not even been started. So, if that is the case, I do not know how we make the August deadline. But I hope I am wrong and you will give me better news than that. But if not, then I would like to give it a sense of urgency.

Now, I know many of my colleagues have talked about the opioid epidemic, and, of course, it deserves that attention. Last year, in New Jersey, heroin deaths in our State were up 160 percent since 2010, and we suffered more than 1,200 overdose-related deaths. So this is really an epidemic.

Now, I recently held a listening session with key addiction treatment stakeholders in New Jersey to address this growing crisis, and, to a person, the issue that came up most frequently—there were many, but the one that came up across the spectrum as the most substantial barrier to addiction treatment was the limitation on a provider's ability to conduct medication-assisted treatment.

As you may know, these limitations cap a provider's ability to treat, at most, 100 patients. Now, with the number of people seeking treatment far outpacing the number of providers who can help, it seems to me that this is an outdated limitation tying providers hands and limiting treatment to those who need it the most.

So I would certainly like to see a broader provider universe, but when something is an epidemic, you need to figure out that maybe an artificial cap set at some time past is now not appropriate for the moment.

So while I appreciate the administration's bold request for additional funds in this area—and I intend to be as vigorously supportive of it as I can—what can we do to increase the access to medication-assisted treatment, and what further efforts can the Department take under its current authorities?

Secretary BURWELL. I think that is specifically buprenorphine, that specific drug, in terms of the medication, and that specific type of medication-assisted treatment. Right now, we are actually in the middle of changing our regulations and proposals and using as much of our administrative authority as possible to change that.

So that is something that I would expect to happen this year. With buprenorphine, as Senator Portman indicated, it is a place where the questions of diversion of it and use are the things that we want to make sure of. I think we believe that we can expand those caps and move those numbers without creating that problem, but that is what we are working on right now, using our administrative authority.

I would also reflect that as part of the budget, in the budget, there is a proposal to actually expand the ability for trained people in correct settings—in other words, making sure that others beyond physicians might be able to use it, meeting certain criteria.

So there are two fronts we are working on. One is within the budget; the other is administrative action we are taking where we think we can get to this.

Senator MENENDEZ. I would appreciate it if your staff would keep us abreast of how that administrative function is moving.

Finally, I just want to mention, if I may, Mr. Chairman, I know my colleagues have brought it up, but I hope that your department will do everything you can to take the administrative steps that are possible within your wherewithal on the health-care crisis in Puerto Rico.

I listen to the stories from people on the island, and I listen to their families in New Jersey, and it is getting way out of hand. There are other issues that they have in terms of their finances, but this is an issue that is of increasing concern. I hope that you will see what administrative powers you have to help the people, the 3.5 million American citizens who just happen to live in Puerto Rico.

Secretary BURWELL. We are very focused in terms of the administrative actions we can take, and have taken a number of those in the Medicare space.

I think, as you know, the Medicaid space is where large dollars and large amounts of care are very important, and it is on unequal footing. I am sure this committee spent time yesterday with my colleague, Secretary Lew, on important legislation that needs to occur in this area.

But I would be remiss if I did not emphasize the importance of some of the help, and what we are trying to do is make sure that Americans in Puerto Rico have equitable care with regard to Medicaid in terms of those rates, and that is what the proposal is in the budget. At the same time, we will do everything we can from an administrative perspective.

I also think the issue that was just raised about zika is particularly important. When one thinks about the costs that Senator Nelson was mentioning, CDC estimates that for children who are born with some of these severe birth defects, depending on the severity, that the cost is \$1 million to \$10 million per child.

So making sure that we are doing everything we can right now to help and assist and support Puerto Rico in preventing cases of zika in pregnant women that could, in turn, lead to these additional issues, is a place that is a priority focus.

I think you probably heard—I have spoken to that in the past several days, in terms of the urgency of the need, of the financial assistance to it.

Senator MENENDEZ. I appreciate your answers. We are ready and willing to do whatever we can from this side of the Capitol to be helpful in your efforts there.

Secretary BURWELL. Thank you.

Senator MENENDEZ. Thank you, Mr. Chairman.

Senator ISAKSON [presiding]. Thank you, Senator Menendez.

Secretary Burwell, welcome.

Secretary BURWELL. Thank you.

Senator ISAKSON. Let me just say in public what I told you in private 2 days ago on the phone. I want to tell you how much I appreciate your accessibility, your willingness to work to solve problems, and I appreciate everything you have done for us in Georgia. Thank you very much.

You are on the Moonshot Task Force for cancer cures, is that not correct?

Secretary BURWELL. I am.

Senator ISAKSON. I have a homework assignment for you.

Secretary BURWELL. All right.

Senator ISAKSON. The Surgeon General, in 2014, said skin cancer was the fastest-growing killer of all cancers, and melanoma the fastest-growing of the skin cancers.

As one who has survived two melanomas in my life, I took that on as a call to action and started investigating what was happening at FDA and found out there was a 13-year backlog of ingredients that had been submitted to FDA for approval in sunscreen that had been delayed in terms of the processing of their approval. So we passed the Sunscreen Innovation Act out of the Health, Education, Labor, and Pensions Committee, passed it on the floor, passed it by the House, and got it signed by the President. Fourteen months later, none of those ingredients has been approved yet. Nothing has moved forward.

To quote the President, he has asked you to identify and address any unnecessary regulatory barriers and consider ways to expedite administrative reforms. Would you please make the first item on your agenda the Sunscreen Innovation Act and getting those backlogged sunscreen additives approved?

Secretary BURWELL. With regard to the issue, we have had time, and, since last year, I have spent time on this issue. One of the things in terms of those ingredients is, we actually need the data and information from the actual manufacturing companies.

I think you know we are working with them, being very clear about, here is what we would need to meet the standard of approval, and that is part of what the Act did, in terms of the new Act: making sure that we meet the standards.

The sunscreens, and I think everyone knows, now we put them on every day because we know what you said is a true thing. On our children, our 8- and our 6-year-old, every day in the summer, those sunscreens are going on. The question of what that sunscreen does in terms of absorption in the skin and whether it causes other issues, that is what we want to just make sure. We just want to get to a base level of safety.

We are being very clear. We heard you when you talked to us last year about this issue, and we are trying to work with the companies to be very clear about, this is the data we need. And for us, if they are saying that it was approved in another place, then can we just see the data, can we just see the analytics, to make sure that we know what we are putting on children is safe?

So this is one we will continue to work on. We want to make progress on it too. We are trying to work with industry to make sure that we are being clear, that we make it as simple as possible to get the information we need to make sure it is safe.

Senator ISAKSON. I will do a favor for you. If you will get me the information that I need to call them to tell them to expedite getting submitted to you, I will do that if—and I have just been handed this, so I take responsibility for the accuracy of this, but I have a great staff. [Laughter.]

It says FDA has moved the goalpost and is now requiring a new test that no one has ever heard of. So I will check on what that is if you will check on that too, and we can see if we can get the barrier removed, because I think it is important to get these done as fast as possible.

On the zika virus, I know Tom Frieden and I talked last week. I think the estimated request is \$1.48 billion; is that correct?

Secretary BURWELL. That is correct, \$1.48 billion for HHS.

Senator ISAKSON. In another hearing I was a part of, I heard there was money left in the Ebola fund that had not been spent yet, and somebody had suggested using some of that to go toward zika until we can get the bill through the Congress on zika.

That would be fine, but please do one thing for me. There were private hospitals that assisted the administration in responding to the Ebola crisis. They were told they would be reimbursed for their costs as they responded, so make sure they have all been reimbursed before you spend that on something else.

Secretary BURWELL. Yes, sir, Senator. One of the things I think we want to make sure of is that we finish the job on Ebola. That is a very important thing for us to do. We know that just this last week, a new case in Sierra Leone has occurred.

So even when we had declared it clean, we have a new case. And the good news is, they were swabbing dead bodies to continue watching for it, and that is how we found it. We were able to do the contact tracing and everything. So we need to make sure we finish the job on Ebola, including making sure we pay those communities, hospitals like Emory and others, that helped with this issue.

Senator ISAKSON. CDC did a marvelous job in responding to it, and the administration is great in what they did. I just want to make sure everybody who was going to get reimbursed gets reimbursed.

Lastly, one of the companies in my State is Equifax. Equifax is a provider, I think, to CMS to verify income and eligibility for Medicaid eligibility and things of that nature.

Make sure that you all are utilizing those people. They are not the only provider. I know we have a lot of things fall through the cracks, and things are paid that should not have been paid because people really were not eligible when they claimed they were.

I understand there is an underutilization of those verifications. If you would, follow up on that to make sure we are using the available resources, which are cost-free to us, to make sure that those eligible for Medicaid are, in fact, eligible and getting the benefits.

Thank you very much.

Secretary BURWELL. Thank you.

The CHAIRMAN. Senator Casey, I have not asked my questions yet, nor have I even greeted our distinguished Secretary. If I can just greet her, and then I will ask my questions after you.



Welcome.

Secretary BURWELL. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Sorry. The big bill on the floor is mine—

Secretary BURWELL. That is all right.

The CHAIRMAN [continuing]. And I have been running back and forth. I had a bill in the Judiciary Committee as well.

I just want to welcome you to the committee, and I am sorry it is belated. But I am very pleased with the hard work that you are doing. It is a tough job, and I think you are doing it in about as straightforward and good a way as I could expect.

So I just want to let you know that I am proud of you and want to keep working with you. So listen to our side too, and we may be able to get a lot done here if we do.

But we are happy to have you here. I will have some questions for you after Senator Casey.

Secretary BURWELL. Thank you.

Senator CASEY. Mr. Chairman, thank you very much.

Secretary Burwell, thank you for being here, and thanks for your stellar public service at a difficult time.

I have two questions, and I will get to them quickly, but I hate to pass up the opportunity to report some good news. We need that around here once in a while. Someone has to talk about good news.

Just some numbers. You do not have to respond, but I was struck by some of these. Between 2010 and 2014, 87,000 fewer patients died in hospitals due to hospital-acquired infections—that is a good number; there were 150,000 fewer readmissions, which is good for the individual and good for saving money.

But in the budget presentation, I was happy to see a lot of things, but I will just hit some highlights—and this will not be fair to every priority—but a couple of things.

Requiring coverage of the Early Periodic Screening, Diagnosis, and Treatment program for children's inpatient psychiatric treatment facilities; providing full Medicaid coverage for pregnant and post-partum beneficiaries; extending the Children's Health Insurance funding through 2019; and the new initiative or, I should say, the new dollars for an existing initiative, the Maternal, Infant, and Early Childhood Home Visiting program, a \$15-billion investment over 10 years. It is voluntary, and it is evidence-based home visiting, which is good for the new baby and good for the mom and the family.

So all that by way of good news, in addition to the 17.6 million, is it, newly covered by ACA since the enactment. So that is all good news.

On the bad news side, you have been asked, I know, several times about the opioid problem, a terribly significant problem in our State. We have the ranking now of Pennsylvania being third highest in heroin deaths. The Coroners Association—every one of our 67 counties has a coroner reporting on how people die, and that number has gone up from about 47 a few years ago to hundreds of deaths every year, and thousands if you look at it over several years.

So it is a huge issue and a huge problem. I know you have been working on it, and the administration's new initiative is welcome.

I guess one subset of this is, I have heard anecdotally that child welfare agencies are reporting an increase in foster care placements due to the heroin and prescription opioid abuse epidemic. How is HHS taking into account the needs of the child welfare population as it coordinates its response to this epidemic?

Secretary BURWELL. I think in a number of ways. One of the most important ways is actually making sure that the mother gets into coverage and health care before she has the baby, because this is also about the health of the baby and making sure that we do everything we can for an addicted mother.

Actually, in Colorado, I did visit one of the successful programs—so it is important to make sure that we have that coverage, the coverage that has occurred through the ACA in terms of people coming in through the marketplace. But in your own State, with the expansion of Medicaid, we believe we are going to reach more women.

So step one is making sure they have the coverage. Step two is making sure they are willing to come in.

I hope that the conversations we are all having publicly destigmatize women coming in, because that is the other problem that is a barrier. So you do not have health insurance, so you cannot pay for it, is a barrier; then, the question of, you are stigmatized if you come in.

So these are some of the issues that we are working on to make sure that we start at the beginning of the child's life, in terms of a healthy birth and a mother who feels connected to that child and is willing to care for it in an appropriate way.

Senator CASEY. I appreciate your work on this.

My last question is on the complex rehab accessories issue that came up at the end of the year, where we legislated. But now we are in a situation where for the first 6 months of the year, providers will face the same payment difficulties they would have faced if we had not passed legislation.

CMS, as you know better than I, performs these quarterly updates. We had some discussion with Dr. Wakefield when she was here, but I am just asking that you work with CMS to ensure that the congressionally mandated payment change for complex rehab accessories is included in the April update.

Secretary BURWELL. We will work to implement that as quickly as possible. I think you know this was at the end of the year, and I think Administrator Slavitt is planning on coming up and having a conversation directly with you about it.

Senator CASEY. Yes.

Secretary BURWELL. So we will follow up in that way.

Senator CASEY. Thank you very much. I appreciate your work.

The CHAIRMAN. Thank you, Senator Casey.

I think I will take time now to ask my questions, because I may have to leave again. I have so many things I am doing today that it is hard for me to keep up with it all.

But welcome, again, and I appreciate the work that you are doing down there. It is very meaningful and very difficult. It is almost an impossible agency to run. So you are doing well.

An area of great concern on the topic of executive overreach is the Medicare Part D program. There have been rumblings that the

President may issue an executive order that would allow the Federal Government to negotiate prescription drug prices in the Medicare Part D program.

Now, such an executive order would be in violation of the law, as the statute explicitly prohibits such interference in private negotiations. And despite this fact, I take the possibility of an executive order very seriously. I am a strong supporter of the biopharmaceutical industry as a source of innovation and intellectual property that produces life-saving drugs and therapies.

The Part D program gets these needed drugs to Medicare beneficiaries, and we need to keep the program as it was originally structured, because it works. Everybody knows that Part D is one of the most important things that really works. Beneficiaries have a choice of prescription drug plans. Private entities negotiate to keep costs down. Overall spending is significantly less than originally projected. Beneficiary satisfaction is very high. In fact, it has been a tremendous success.

Moreover, allowing the government to, quote, “negotiate” prices is not a new idea. Congress has considered this policy and has chosen against it. The President’s budget proposal states that it has no budgetary impact. The Congressional Budget Office does not see it as a big saver.

So having said all that, my question is, Secretary Burwell, is anyone at HHS working on or has HHS worked with the White House on an executive order that would allow the government to negotiate prices or on any other changes related to drug prices?

Secretary BURWELL. With regard to the issue of drug prices, I think you know we are focused on both sides of the issue of drugs. It is not just a crisis. It is about innovation, which is why we actually brought everyone in for a conversation about both of those issues at the end of last year so that we could hear from industry, as well as consumers, in terms of the issue.

As we think about it and the steps that we have taken, we are focused on both: that innovation as well as that affordability.

I think you know—and certainly Senator Portman raised the issue—of deficits and entitlement and mandatory spending, and we take that very seriously and are looking for the opportunities that we can find in terms of drug prices, because it is becoming an increasing percentage of our overall health costs. We saw great increases in 2014, the most that we have seen in many, many years, in terms of the drug prices. So that is why we are focused on the issue.

The steps that we have taken to date, though, include the session that we did, include closing the donut hole, which was a part of the ACA, which, at this point, has saved seniors \$20 billion, 10 million seniors. Then the third step that we have taken to date is on the issue of trying to provide transparency, because we do believe that puts downward pressure on prices, and we have created a Medicare—

The CHAIRMAN. Let me interrupt you. I am very concerned about this, because I think that they fouled it up on data exclusivity with regard to the TPP, the Trans-Pacific Partnership. And frankly, if you do not have a data exclusivity time of 12 years, which we negotiated—Senator Kennedy and I negotiated that, because we know

that we have to get enough data exclusivity time for the companies to recoup their costs.

On bio, in the TPP, where we can actually get cures, it takes about 15 years and \$2 billion, so you need some time to be able to recoup that money. With the 5 years that they have in that provision, the costs are going to be so high that everyone will be screaming, and the bio industry will go down the drain, and that is where we are going to find some cures that might really save health-care costs over the long run.

In the case of pharmaceuticals—I am sure if they get that 5-year figure in the TPP, they will try to do something similar with pharmaceuticals, which cost \$1 billion and take 15 years to develop. This would be problematic, as manufacturers need to recoup those funds in order to go on and create newer drugs.

So I am concerned about it, and I hope that you will weigh in, because we have to have some economic sense on these things or we will lose the whole pharmaceutical and certainly the whole bio industry because of what I consider to be a stupid provision in the TPP.

My time is up. I think Senator Cardin is next.

Senator CARDIN. Thank you, Mr. Chairman.

Secretary Burwell, thank you for your service. We very much appreciate your career service to the public.

We have talked earlier, but let me just point out that the extension of access to emergency psychiatric care, which was included in the omnibus—I authored it, along with Senators Toomey and Collins—is a logical extension of the program through September, but it allows you to extend it through 2019.

It is revenue-neutral. But we need the guidance, and I know you are working on it. It is very important, particularly for those from 18 to 64 years of age. So I would just urge you to stay focused on that. We think it is critically important for access to psychiatric care.

I also thank you for being willing to look at the pediatric oral health care issues. We provided coverage under the Affordable Care Act, but the OIG report indicates that far too many American children are not getting access to dental care. So we need to figure out a strategy to get beyond just coverage—make sure coverage is adequate and make sure that there is access to qualified dental services.

I want to follow up on the Psychiatric Care Act, but also to deal with the community mental health needs. This past week, I had a roundtable discussion at Sheppard Pratt in Baltimore with experts on mental health and addiction services.

We have talked about this several times in the committee: the need for greater community access to mental health and addiction services. What came out at this meeting was a couple of very interesting facts, but the number-one priority still is the reimbursement structure that does not take into consideration care managers.

So, if you are a hospital trying to deal with psychiatric care—someone comes in to your emergency room—do you really know how to triage that person into the most effective, least expensive care setting; do you have that capability? If you are a qualified health center, are you able to deal with walk-ins and referrals, and

do you have 24/7 capacity to do this? And the reimbursement structure is not terribly friendly toward those who understand that they must have those types of capacities in their facilities.

I know that you invited comment last July on how we could make the reimbursement structure more effective, and I know Congress has taken some actions in regard to programs in several States. Can you just update us as to how we are moving forward to encourage community-based models for integrated collaborative care for mental health services?

Secretary BURWELL. Section 223 allows for the implementation of an approach where we are trying to experiment both with different payment models and build on the backs of the behavioral health centers that are already in communities, as well as our Federally Qualified Health Centers, and that is a step that we took. Certainly, Senators Stabenow and Blunt and Ms. Matsui on the House side have been very engaged in this issue. We are ahead of our schedule with regard to implementation, as you reflected, in terms of doing the demonstrations.

In the budget that came up on Tuesday, we would like to extend those demonstrations so more of those who applied can start doing the types of things that you are talking about. So we are hopeful that our budget proposal is accepted, and I think Senator Stabenow and Senator Blunt are both supportive of actually even going beyond what we have in our budget.

Senator CARDIN. I strongly support that, strongly support it, and thank you. Thank you for doing that. That is very important. My colleagues have been incredible.

I would just suggest that we need system-wide changes in the reimbursement structure so that we can deal with mental health. I know you are looking at that, because it is part of, I believe, your July inquiry.

We should take what we have learned—we know that for every \$1 we spend in these settings, we are going to save \$6. Yet, the reimbursement structure does not allow creative ways of using care managers in communities that may not be part of this program. So I just urge us to think broader as to how we can make the system work for mental health, because historically it has not and today it is still not.

Secretary BURWELL. I think we are hopeful that we can get the examples and the models to scale in terms of the changes that we will do.

The other way that what you are talking about can happen is through our Accountable Care Organizations. And having visited some of those in New York and seeing the progress they make with integrated behavioral health care, we are funding those both through 223, as well as through our Accountable Care Organizations where we are creating models. We need to have the analytics.

Senator CARDIN. I am glad that Senator Stabenow showed up, because I know I have one of our real champions on this issue—

Secretary BURWELL. Yes.

Senator CARDIN. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Scott?

Senator SCOTT. Thank you, sir.

Good morning, Madam Secretary.

Secretary BURWELL. Good morning.

Senator SCOTT. It is good to see you again. Just a couple questions for you this morning. I happen to be the co-chair of the Prescription Drug Abuse Caucus. I know that there is a lot of funding throughout the budget for opioid abuse.

There was one account that was zeroed out. I assume the access to recovery account was zeroed out by the administration, and my assumption is that there are other resources in other parts of the budget, realizing the fact that more people are dying because of overdose than from auto accidents or gun violence.

Would you speak to that so that would help some of the folks I am hearing from in their concerns?

Secretary BURWELL. Yes. I think this gets to one of the topics we have talked a little bit about: making sure there is not overlap in programs and that we are reducing that. In the proposal and the money that we have asked for in the opioid space, there is specifically money around naloxone and Narcan, and even last year with existing funding, we have moved those moneys out.

We are trying to work on this on two fronts in terms of helping people with the overdose portion of this, and that is through our funding and helping communities, but we are also working with the private sector to make sure that it is taking steps to be able to access it. I think you probably know that in a number of States, we see pharmacies, like CVS and Walgreens, working with the State to pass regulations to make it over-the-counter so that that access can occur not just for first responders, but, sadly, sometimes family members need it too.

The other thing that we are doing across the Department in this space is, FDA has approved the first nasal naloxone, making it easier for regular people to be able to give it to their loved one if they need to, so they do not need to do a jab.

Senator SCOTT. Very good. Thank you. Next question for you: I know that you have spent some time in South Carolina, and we appreciate that—and you should come back more often. I am sure they would like to see you in Charleston.

In 2013, each State was provided with a CMS liaison to contact with questions and issues, and these were removed recently and replaced with a generic e-mail account, and it is causing some challenges in South Carolina. It seems to be nearly impossible, according to the Department of Insurance, for States like South Carolina to get quality answers, especially answers that are necessary from a timely perspective.

What I have been told by the DOI is that the respondent they are talking to many times does not list their name, just e-mail contacts, and it is signed basically from the FFM response team. When they do identify themselves, it almost never includes the individual's e-mail or contact information.

So the long story short is that it is—from the South Carolina DOI—very difficult to have an actual conversation via e-mail or by phone with a specific person that leads to an immediate response that is clear.

Secretary BURWELL. Two things. One, I will follow up on that. The responsiveness and customer service in this space is something that is important to our relationships with the DOI. I need to find

out exactly which part. Does it have to do with the FFM, the Federal market?

Senator SCOTT. Yes.

Secretary BURWELL. I will follow up in terms of that.

The other thing is, this does get to the issues of resources for CMS. I think you probably know that the question of funding for these things—in this particular type of service, we cannot use the fees. In our budget this year, fees that are coming in from the FFM will far exceed what we are asking for in appropriations, which is a good thing, and we are happy about it.

Senator SCOTT. Yes.

Secretary BURWELL. But there are certain services the fees cannot pay for, including some of these. So as you are reviewing the budget, if you will look at that—

But let me follow up specifically on, have we changed something and do we need to figure out how people know whom to contact? I hear very clearly that you need to be able to follow up with someone, is what I am hearing in your question.

Senator SCOTT. Exactly. Exactly. Someone as opposed to a department; with a specific person, they get a more immediate response.

I assume that in your budget there is some flexibility to shuffle some of the resources around.

Secretary BURWELL. We do and we have done so, but I am sure you probably know that the funding for CMS over the past few years has certainly been an issue that has been a challenge for us, and we are hopeful we are at a different place this year.

Senator SCOTT. Last question for you: I know you have already answered a couple questions about the challenges around the CO-OPs. The Federal Government has distributed about \$2.4 billion in loans to 23 CO-OPs around the country. However, recently, including in my home State of South Carolina, we have seen CO-OP closures, which will likely result in lost coverage, higher premiums, and perhaps even higher deductibles.

In my State alone, about 67,000 South Carolinians could lose their insurance. Sadly, South Carolina is not alone. As we have heard so far this morning, CO-OPs in 22 of the 23 States where they operate are suffering large losses, according to last year's results, and there are very few signs that these CO-OPs will actually be successful into the future.

What is your next step?

Secretary BURWELL. With regard to the CO-OPs, in terms of our next steps, the consumer is at the center of our strategy and our approach to making sure that we take care of those consumers. That is why a number of CO-OPs came out before open enrollment, and we will continue to monitor the situation with the States, which are the lead regulators, I think, as you know.

Having said that, most recently, one of the steps we have taken is clarity in our guidance so that the CO-OPs can actually seek a broader range of capital for them to have in-flows as they try to work through any issues they have.

The consumer is at the center. We support the States, and we continue to monitor this closely so that we understand if there are changes in the facts that they have given us.

Senator SCOTT. Thank you. My time is up, but thank you very much.

The CHAIRMAN. Thank you, Senator Scott.

Senator SCHUMER, you are next.

Senator SCHUMER. Thank you. First, let me thank you, Secretary Burwell. I think you are a superlative Secretary. I have seen a lot of them in the many years I have been around here, and nobody has a greater grip on what is going on, understands the policies, understands the practicalities, and is able to get things done. So kudos and accolades, at least from this Senator, and I know from many more.

So what I wanted to talk to you about is two things. One is the zika virus. I do not know if that has come up so far, but I apologize if it has. But your administration—our administration—has sent us \$1.8 billion in emergency supplemental requests for funding to address the zika virus.

We have a window here. We have time, because the mosquitoes that carry it, *Aedes aegypti* and even a related one that is in New York, the Asian tiger mosquito, are not going to come for several months yet. So we have time, and we are pretty good if we get a handle on intercepting mosquito-borne diseases—witness what we have done with yellow fever and malaria here in the United States.

So I am glad you have asked for these moneys, and, again, to our Republican colleagues, I am going to plead with them not to just talk the talk, but walk the walk. You cannot combat these crises, whether it is zika or opioids or mental health or security in our country, without a lean, effective government. The private sector is not going to fight zika, and cutting CDC, cutting all the agencies, FDA, makes no sense.

But what some are trying to do is say that we should not have any new moneys; we will use the moneys that were set aside for Ebola, which have not all been spent yet, to fight the zika virus, which seems to me like robbing Peter to pay Paul. Ebola, thank God, is not here now, but it could come back.

So would you please explain to me why we should not do that and rather have a new allocation of money for zika, what the moneys for Ebola are being used for, why they are still needed even though the Ebola crisis, for the moment, has subsided both here and in Africa?

Secretary BURWELL. With regard to our Ebola moneys, there are three main pots, and one, in the reports that we send to the Congress, is fully obligated, but I think as many of you know, much of the money, we are in the middle of negotiating contracts for and using.

The biggest pot of the money that is left from the Ebola, is about \$500 million, and that has to do with the global health security agenda. The Congress gave us that money, and we have committed to 17 countries to help and invest over a 5-year period, so we spend it wisely. Our moneys go down as their moneys go up. We are negotiating plans so that we have implementation. We are working on that together, and those moneys were set over 5 years to do this.

The reason that is so important in terms of, why would you take that money, is that one of the conversations we did not have this year was Middle East Respiratory Syndrome. Last year, we had



more cases outside of Saudi Arabia than we have ever had in history, but we did not talk about it because Korea was able to handle it.

Each year we have something. We have to get these countries ready. And actually, zika started in Africa, and we did not know. We do not know if they have microcephaly in Africa because there was no ability to provide a detection response.

Senator SCHUMER. So some of the money goes to stop Ebola from spreading to other countries—

Secretary BURWELL. That is another portion.

Senator SCHUMER [continuing]. And dealing with it in existing countries, because—

Secretary BURWELL. That is another portion.

Senator SCHUMER [continuing]. We all know it will come here if it is there.

Secretary BURWELL. That is another portion of the money, and we know that just recently, in Sierra Leone, a case came back. We were able to detect the case, Sierra Leoneans were, because they were still swabbing. We are still supporting them. So dead bodies they swab and test was how it was found. So it did not spread more.

So we need to get the job done in the three West African countries and continue our commitment to prevention of not just zika or Ebola, but MERS and other respiratory viruses.

Senator SCHUMER. Got it. And is not some of the money also to develop a vaccine or some kind of preventative measure?

Secretary BURWELL. That is the other piece of it, and BARDA and BioShield and our efforts there, together with the NIH, are moving the research.

Senator SCHUMER. So we would be robbing Peter to pay Paul. We would be making ourselves less safe against Ebola to make us safer with zika if we just did not put some new dollars into zika and used the Ebola money for that, and you think that would be a serious health mistake. Is that fair to say?

Secretary BURWELL. It would be a mistake.

Senator SCHUMER. Next, quickly, because I am running out of time here: Puerto Rico.

We have been talking about Puerto Rico and the dire situation. As you know, I have sponsored, along with many of my colleagues, some of whom are here—Senator Cantwell has played a leading role in this—legislation to deal with the problems of Puerto Rico, and we need bankruptcy as number one, and Senator Hatch has been trying to be very, very helpful on this, and we appreciate it.

But in addition to bankruptcy—in bankruptcy, no money should be a substitute for allowing a territory to declare bankruptcy. We need other moneys to help, and those would be additional.

My question is, how long do you estimate Puerto Rico's current Medicaid allotment will last, and what would happen if Congress fails to provide additional money to their Medicaid program or, as we have both proposed, to grant them State-like treatment?

Secretary BURWELL. We will continue to analyze the situation. We worry that things, in terms of that allotment or that cap on using it, could happen as soon as this year, and that is part of why we have the proposal that we currently have in the budget to make

sure that we treat Puerto Rico equitably in terms of how other Americans are treated with regard to Medicaid.

It is an important financial issue. It is an important health issue for the island.

Senator SCHUMER. Mr. Chairman, I thank you for that extra minute and appreciate your holding this hearing and always your courtesies.

The CHAIRMAN. Thank you, Senator Schumer.

Senator Carper is next. Senator Carper, could you wait just a second?

Senator CARPER. Sure.

The CHAIRMAN. Hold that time; put the time back up.

I have to leave. So let me just thank Secretary Burwell for being here, as well as all of our colleagues who have participated in this hearing. It is my hope that the issues that we have discussed here today can be addressed as we work to improve the Nation's health-care system and to ensure that taxpayer dollars are used efficiently and effectively. Now, we owe that to the dedicated taxpayers and citizens of this great country.

But I would also ask that any written questions for the record be submitted by Thursday, February 25, 2016. If we can do that and you can answer them as quickly as you can, we would appreciate it.

Sorry to interrupt you, but I wanted to do that.

Senator CARPER. Thank you.

Madam Secretary, welcome. It is great to see you, great to talk with you this week. Your dad and my mom spent some time in nursing home care, my mom for dementia, and I think your dad as well.

I shared with you the other day that on Monday, I visited Presbyterian Village Nursing Home, just outside of Dover, DE—lovely facility—and they are doing something I thought was very encouraging. They have stopped prescribing—I will call them antipsychotic medications. I am used to going in nursing homes and seeing particularly the dementia patients, they are drugged out. They do not know who they are, where they are, are not very responsive.

There are a lot of people in this nursing home in their 90s and even in their 100s. They have a fitness center there, they are doing yoga, but they do not take those medicines. They reported to me on the number of falls. The number of falls now as compared to what it used to be, it is dramatically reduced. I think they have currently, of their long-term residents, zero percent of them on antipsychotic drugs.

On a personal level, but really on a professional level, I just want to know if the Department of Health and Human Services, with everything else you are doing, if this is something that you are thinking about?

We have worked on this issue with respect to trying to stop or at least reduce the prescribing of these mind-altering drugs for foster kids. That has been an important issue. This is something for your grandparents or great-grandparents. I think they are on to something at Westminster Village.

Any thoughts?

Secretary BURWELL. I think it aligns very much with what we are trying to do to get an educated, empowered, engaged consumer at the center of their care. And when we pay people for actually the outcome instead of paying for fee-for-service and the transaction, that is, I think, when we get to that.

That is when, in a place like that, on a regular basis, there is a meeting of the caregivers with the family to have the conversations about these things, to talk about them so you can reduce those medications. So I think it is all part of the delivery system reform that we are doing and the shifting of the payment system in Medicare.

I think the other place where we will be pushing on this kind of specific issue is as we try, through our Innovation Center, to do our experiments in home-based care, which Senator Wyden certainly has spent a lot of time promoting.

It is a lot about payment incentive as well. Certainly, opioids are a separate category, but the type of drugs you are talking about, I think have a lot to do with how we pay physicians to care for people and how we pay providers to care for people. It is about the quality of their care, defining that and defining that the outcome is value, not volume, not how many pills you prescribe, not how much they are taking, but what the situation is for the individual.

Senator CARPER. Good. Thank you. For us, this one is personal. So I very much appreciate what you just said.

During the last Congress, I worked with Dr. Coburn and with you and some of your colleagues in the administration on issues including improper payments and something called the PRIME Act, which dealt with preventing and reducing improper Medicare and Medicaid expenditures. Over the last two Congresses, we passed bits and pieces, but we have now enacted, I think, the entire PRIME Act, which is just a wonderful thing, I believe.

I am going to ask you, for the record, to respond to me about the implementation of the new law, which has been implemented in pieces, and how we are doing in this effort to curb waste and fraud, but not here at this forum; we just do not have time.

I would ask, though, that on the reducing opioid and pain killer additions, as I understand it, the folks who are, in some cases, physician assistants, nurse practitioners, are able to prescribe medication for opioid addiction to help increase the number of health-care providers who could help us address this epidemic.

Could you just talk about—I think there is a pilot, and I may be confused on this, but I think there is a pilot program that would focus on this area, allowing them, not throughout the country to prescribe medicines for opioid addiction, but to do it on a pilot.

The question is, is that something we ought to do on a pilot or is it something that we should allow them to do nationwide? Do we need the pilot, I guess is my question?

Secretary BURWELL. With regard to the issue of medication-assisted treatment and broadening the number of prescribers that can do it, we actually have a proposal in our budget that would allow broadening.

I think there are two separate issues. There is the issue of broader medication-assisted treatment, and there are different categories of it. One particular issue is buprenorphine, which is a drug that

has limits and caps. Right now we are in the middle of reviewing that and using our administrative authorities to raise those caps. That drug, distinct from some others—there are concerns that it may have greater diversion. So we want to make sure that, as we are creating access to it, we do it in ways so that we do not have diversion.

So I think there are two different categories as we think about when we scale things. Where we have the evidence that we are not going to create an unintended consequence, we move more quickly and more broadly. In the cases where we need some more evidence to make sure that there are reasonable questions being asked, we would do that in smaller settings.

Senator CARPER. Thanks. Thanks for your leadership. It is great to see you. Thanks.

Senator WYDEN [presiding]. Senator Stabenow?

Senator STABENOW. Thank you very much.

Secretary Burwell, obviously we thank you for all your wonderful leadership. I do want to follow up on behavioral health, mental health, and substance abuse. But before doing that, I want to thank you for all of the efforts of your department and the administration in helping us with the incredible public health emergency in Flint.

The person you have put on the ground, Dr. Nicole Lurie, is really tremendous, and so is the work that is going on there. I know you will be going next week to Flint. So we appreciate your personal attention.

As you know, we have a community of 100,000 people who, through no fault of their own, have seen their water system poisoned and basically, in many parts of it, destroyed because of a lack of corrosion treatment before switching to the poor quality Flint River water, and up to 9,000 of those are children under the age of 6 who are now exposed. Some of the houses have lead levels as high as a toxic waste dump. So this is extremely serious. We are still hopeful. We have had difficulty coming together and getting bipartisan support here to help rebuild the pipes and so on, but we are still working and still hopeful we will be able to come together and do something. But thank you for your help.

I do want to talk about, as you know, another passion of mine we spent a lot of time on, and that is implementing what Senator Blunt and I were able to get passed in the new law to create the structure so that we are not just funding mental health and substance abuse services from grants that ebb and flow up and down, but implementing a structural change in payments that recognizes when a behavioral health specialist, a psychiatrist, psychologist, social worker, does work that meets quality standards, that they should be reimbursed like we reimburse other health professionals under a Federally Qualified Health Center.

We have known actually since President Kennedy passed the Community Mental Health Act over 50 years ago, that we needed a structure in place so that we were providing comprehensive health care in the community. That is really the final gap: mental health parity.

So, as you know, under the direction of legislation passed by the Congress, we now have qualified community behavioral health clin-

ics and definitions of what quality is, like we do for FQHCs, Federally Qualified Health Centers.

The question is, how do we get that available in every community in every State? So the Congress was willing to provide enough funding for eight States, with planning grants for States interested to see if they could meet those qualifications in order to apply to be one of the eight States, under your direction and SAMHSA and all of the wonderful folks who have been involved in your whole team: HHS, CMS, everyone.

You have the program ready to go, and 24 States have gotten planning grants. Twenty-four Governors, 24 States have said, "We want to do this." We are planning how we meet those quality standards, and we currently only can accommodate eight States, even though to do anything else we want to do—opioids, mental health, and so on—it all comes back in the end to having community services, so people are not going to jail or the emergency room at the hospital. They are getting the service in the community.

So first, I noticed that in the President's budget, you expand the number of States from the eight we are talking about to 14. There are 24 States that are getting ready to go.

I wonder if you might speak to what is our joint effort, Senator Blunt and I, a bipartisan effort to actually allow every State that is working to be ready to go, to have the opportunity to provide the resources so that we really have mental health and substance abuse services in the community.

Secretary BURWELL. Thank you for your leadership in this space, Senator. You know, you and I have spent time, Senator Blunt and I have spent time, through your leadership, moving forward on that establishment of the quality standards and then the implementation, because it is about the infrastructure to implement, and that is why it is so important in these communities across the country that lack access. So many communities across our Nation actually lack basic access to psychologists, psychiatrists, or other behavioral health professionals, and we do have an infrastructure in place.

So now what we need to do is take those quality standards and make sure we pay, and that is what I think we believe that the eight demonstrations that we are doing are going to do. So we believe it is taking that step, and our budget is proposing that we do more, because we think that is the right thing to do, to build on this, to get that transitioned to where we finally treat behavioral health issues on par.

It is not just about saying we are going to do it, it is about having providers to do it and quality measures to pay for. So this is the direction we are pushing hard in. I think you know we are meeting our statutory deadlines in terms of some of this work, because we believe in it strongly.

Senator STABENOW. Yes. And I want to just take another minute to thank you for doing that, because you are working hard to meet those standards, and you have proposed expanding that.

We want to take it to every State that is interested and, frankly, listen to the sheriffs across the country who are tired of having people in jail who ought to be receiving mental health or substance abuse services, or hospital administrators who are treating people.

I will never forget talking to the Cook County Sheriff, whose director of his jail is a psychiatrist. And when we ask why, it is because over a third of the people in his jail need psychiatric help.

So, under the quality standards that we have now put in place, 24-hour emergency psychiatric help would be required as part of this quality certification, and hopefully Congress this year will decide to give the 24 States who have stepped forward the opportunity to put services in place.

Secretary BURWELL. We look forward to working with you on it.

Senator WYDEN. Senator Warner?

Senator WARNER. Thank you, Mr. Chairman.

Thank you, Secretary Burwell. Thank you for your responsiveness. If I can get my questions out quickly, you may be done for the day. I have a three-piece statement. One, a thank you; secondly, a concern; and third, a question, and I will try to make sure I give you time to respond.

On the thank you, an issue that we have talked about a number of times is the Gabriella Miller Kids First Act, which deals with pediatric cancer and celebrates the life story of an extraordinary young woman from Leesburg, VA, who passed, but advocated for research in pediatric cancer. I was very glad to see that it was fully funded in the President's budget proposal. I know we had to work through some things to get that done, and I am grateful for that.

I was also glad that the President's Cancer Moonshot included elements targeted at pediatric cancer, since pediatric cancer is so different from adult cancer. So thank you for that.

On the concern issue—and this is just to put it on your radar screen; we are working with CMS—we know that due to budgetary constraints, a number of the community-based care transition programs that initially folks thought might last for 5 years have been cut to 4 years.

We have a successful program in Virginia under the aegis of Bay Aging that does this coordinated transition care. Unfortunately, they were cut back without being able to make the full transition to sustainability.

We are working with CMS, and this is a concern, but I am not asking you to do a one-off here. We are working with CMS; they have been cooperative. But when we see successful programs that can and should make the transition to economic viability—I think we have one here—I, again, would just appreciate the collaboration and cooperation from CMS to try to make this a successful program and make this transition.

Finally, a subject, again, that we have talked about at times, and it is one I think, candidly, that the American public is ahead of most of our elected officials on, and that is around care planning and end-of-life issues. I think that we still remain the only industrial nation in the world that has not had this kind of adult conversation about care planning, about trying to make sure that issues around end-of-life are dealt with respectfully, recognizing that this is not about limiting choices, but it is about expanding choices.

I was pleased to see that CMS introduced a payment form for physicians to have those kind of conversations about advanced di-

rectives and POLST\* and the other legal entities that come out of those conversations. Those conversations should include family members, loved ones, religious advisors.

Senator Isakson and I have been working on this for some time, and we are gaining broader-based bipartisan support, and there is not a member of the Senate whom I have talked to who does not have a personal story. Mine was that my mom had Alzheimer's for 11 years, 9 years of which she did not speak, and I was a relatively well-informed citizen, yet we did not have all those conversations before it was too late.

We are working on it. I guess I would just like to assure you of our commitment that we will continue to work with your staff on the care planning codes, how we look at more wraparound services. We are trying to work to make sure that these types of advanced directives can actually travel across State lines, and I know this is something Senator Wyden has been engaged and involved in, as well. When mom or dad or aunts and uncles move, we need to make sure that those documents travel with them, built into their EMR.

I guess I would just like your comments in this space and, again, acknowledging that I think, for the most part, elected officials have to move beyond kind of some of the horrific language that may have been used 6 or 7 years ago. This is a part of everyone's life, and it needs to be dealt with with respect and dealt with appropriately. My hope is with the Care Planning Act, we actually may get this done.

So, Secretary Burwell, if you would like to make a couple of comments on that—

Secretary BURWELL. First, thank you for your leadership, because your leadership and Senator Isakson's and others', it helped to create this space where we could go forward and make the changes that we have made in terms of paying, and we think that is an incredibly important first step.

But we know it is a first step, and now the question is, how do you implement this so this is useful to the people and meets the goals and objectives that I know we share?

So we are going to continue to work in that space. We welcome the comments. We welcome continuing to work with you on this issue. We did this because we believe it is an important change and a change that is about quality of care for people across this country and their families. So we take seriously the next steps that we need to do, and we look forward to working with you on that. I think being able to pay makes a very big difference.

Senator WARNER. And I would simply say, Senator Wyden, not only being able to pay but to have that conversation, and also to recognize that people's wishes ought to be respected.

It is, again, I know, an issue that we have talked about, and you have been a leader on this for many years. But my sense is, on the good side, that this is an issue where the American people are, candidly, ahead of their elected officials, and there is not a single member in this body who, if you sit down and have an honest conversation with them, has not had some experience either with a

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\*Physician Orders for Life-Sustaining Treatment form.

family member or friend. And it just breaks your heart sometimes when you see—I recall one Virginian who had to go twice, as a daughter, to make sure that her mother's wishes at 102 of not being resuscitated when she had chosen not to be were honored.

I, again, appreciate the Secretary's sensitivity on this issue. It is a hard issue to talk about, but it is one that I think, in America, we need to address. And it is not about limiting choices, it is about expanding choices.

Thank you.

Senator WYDEN. Thank you, Senator Warner.

It is striking. I was going to talk to Secretary Burwell just for a few minutes about the future, and how appropriate it is that Senator Warner, who, along with Senator Isakson, has really been in the vanguard of laying out some new policies to expand choices for end-of-life care, raised this issue.

One of the areas I am very proud of took years, and is now—as a result of the Secretary's good work—a demonstration finally put in place called Medicare Care Choices. So for the first time, older people participating in this demo do not have to give up the prospect of curative care in order to receive their hospice benefit. I have been hearing about that since the days when I had a full head of hair and rugged good looks and was director of the Gray Panthers.

Senator WARNER. Mr. Chairman, was that back in the early part of the 20th century? [Laughter.]

Senator WYDEN. It is impossible to calculate. But the point is, what Senator Warner has been talking about is creating more choices. This is not about Washington, DC producing another Federal cookie-cutter program where you are going to have to do A, B, C, and D. What Senator Warner is talking about is, the centerpiece of end-of-life care should be about empowering patients and their families, and it is high time.

Senator Warner, you and I and Senator Isakson have been prosecuting this case, and I am very appreciative of it. Medicare Care Choices starts us down the path, but Senator Warner is absolutely right about several of the next steps, and I am with you.

Secretary Burwell, one of the assessments I would make as we wrap up is that, because of the good work that you have been doing, you and your colleagues, America is not going to turn back the clock. America is not going to turn back the clock on the Affordable Care Act.

You have talked about the increased enrollment. I am particularly pleased that you are making this point that the heart of the ACA, right at the center of it, is making sure that people do not get discriminated against for preexisting conditions.

I always thought that as long as you allowed that, which was the history of American health care for just eons, you basically had health care in America for the healthy and the wealthy, because if you had a preexisting condition and you were wealthy, you could pay for it. If you did not have one at all, you were in clover.

So you all have, I think, now made it clear that the Affordable Care Act is not going to be repealed. We are not going to go back to the days when you could beat the stuffing out of people who had a preexisting condition, and I think it is appropriate to talk about the future.



So I am going to spend just a couple of minutes doing that. First, Newt Gingrich and Tom Daschle wrote an op-ed piece here a few days ago. I do not think you see that happen every single day: the past Republican Speaker, the past Democratic Leader writing an op-ed piece, and they said, let us have a bigger role for the States, let us have a bigger role for the States in the Affordable Care Act.

They had a variety of ideas: pulling the Governors together to look at approaches, making sure that the various funding sources were more integrated. I guess in the lingo of your agency, those are funding streams, but to me, it is taking the various funds and trying to find a way to coordinate them.

What do you think about that? What are our opportunities for—and, as I ask the question, I want to be clear, this is not talking about anybody trying to duck the coverage requirements and the consumer protections and the law. This is about whether people across the political spectrum can figure out how to test various approaches at the State level.

What are the possibilities?

Secretary BURWELL. I think that there are possibilities across a number of different places, in terms of where the authorities lie for us to work with States to do the things that they want.

We actually earlier spoke with Senator Cantwell about the basic health program and the steps that New York took in terms of how they wanted to approach that. And as you mentioned at the end, one of the things I think that is fundamental and so important is that there is a basic baseline with regard to what the benefits need to look like in terms of making sure that the access that has been gained is not lost and that we are also watching the finances in terms of the Federal Government.

So when we think about that, there are ways, like the basic health plan, where progress has been made, and there are different alternatives and approaches to that.

Also, I would just highlight that the Governor of Alabama this week announced that he is working with us and has come to closure on a waiver that will do regional care organizations, like Accountable Care Organizations. He has created an approach in his State that is innovative and is working toward the kind of care that we were just talking about at end-of-life: an educated, empowered, and engaged consumer at the center of their care throughout their entire life, and those are the kinds of things we want to work with.

The constraints, in terms of where the boundaries are, have to do with affordability and access. With regard to 1332, we have put out guidelines that articulate the standards that have been met. We have not put further constraints on because we want to hear innovative ideas.

Senator WYDEN. The second question I would just like to touch on is a committee project. I am very appreciative of Chairman Hatch's interest in this, and he knows that I have been interested in this for years.

Medicare of 2016 is not the Medicare of 1965. The Medicare of 1965 was, people stayed in hospitals a lot longer, and if you hurt your ankle and it was not a really serious injury, it was Part B of

Medicare. If it was really serious, you were in a hospital for a few days.

That is not Medicare today. Medicare today is cancer, diabetes, heart disease, strokes. That is most of the spending. And we now have a task force, which, fortunately, is led by Senator Isakson and Senator Warner, with their interest in these issues, and it is really stunning what you come up with when you look at this.

After seniors, particularly in areas where you do not have Medicare Advantage, get that free physical—thank you, Affordable Care Act—so often their care or kind of the non-system that exists just sort of leads them off the rails, and they end up in a hospital emergency room and when they are about to be discharged, nobody even knows who to send a record to, because the care is so fragmented and splintered.

You, in putting together the HHS budget, obviously, have taken a look at this whole question of chronic illness. What do you think is ahead there?

Secretary BURWELL. I think as you are reflecting, with chronic care, both in terms of quality and in terms of costs, we know that about 80 percent of our total health care costs come in those chronic situations, whether that is diabetes, heart disease, other things. So both from a quality-of-life perspective and a cost perspective, taking these issues on is important.

I think the other thing is, as we think through the strategic approach that then guides all the tools and levers that we have from a policy and payment perspective, at the center of that is more integrated care.

We need to change the way that we deliver care in the country, and we are on a pathway to do that, whether that is in prevention, as you highlighted, the importance of the preventative care services that are required without additional cost through the Affordable Care Act, or making sure that you have a primary care home, where that person is responsible for making sure that the pieces and parts of your care are connected in a way that serves you.

I think that connects to a point we discussed earlier, which is making sure that we are paying for value, not volume. So we are paying for the outcome of your health care, and whether that is that prevention up front or when you do have something, making sure we get the outcome you want, connecting those things together. And that is why the payment system is a very important part of the tools we have at hand to drive this change, in terms of care that is more integrated and focused on the individual with them engaged as part of that care, in terms of the choices we were discussing at the end of life, but well before then, in terms of your everyday care.

Senator WYDEN. I can tell you that, of course, the popular wisdom is that this is an election year and nothing is going to get done and the like, but I have been very appreciative of Chairman Hatch's interest in this, and he is telling us we are supposed to pull out all the stops to pull together a bipartisan bill to set what I think are reasonable principles we ought to work around.

So buckle up for that one. We are going to push very hard to advance that this year.

Let me turn briefly to some questions with respect to some of the other issues that are within your jurisdiction.

First, I want to make sure that we formally acknowledge the improvements to the TANF program, the improvements that you all have made. TANF, of course, again, outside of Washington, is public assistance. I think we have made some real progress, most recently in the tax bill in December with respect to the Earned Income Tax Credit. That is a very substantial victory.

We have more to do to help struggling parents find work, and I think you all have some promising proposals. So that is as much a reflection on your good work as a question.

With respect to foster care, I thought that—and I just heard about it from the staff—Senator Casey made a very good point with respect to the new spike in foster care, and certainly a factor in that is the opioid epidemic.

Chairman Hatch and I have spent the better part of the last year working on a proposal called Family First that would allow States to use their foster care dollars on programs that we know to be effective—drug treatment or mental health—and help prevent the need for foster care by keeping families together.

I think the premise is that these types of programs not only save money for the overall system, but they also improve the health and well-being of vulnerable youngsters.

Now, you all have a similar proposal, as I understand it, perhaps not with the same role for substance abuse treatment programs but as a foster care prevention tool.

Now, you pointed out there is certainly a role here for Medicaid, and that is important. Chairman Hatch and I feel strongly that child welfare foster care dollars can also be used more efficiently in this space, and I would be interested in whether you share that view.

Secretary BURWELL. I think you know that we do share the view of trying to make sure we are doing the things so that children can stay in their home setting as much as possible, as long as that is safe and appropriate—there are ways to encourage that—and many of our proposals do that.

So we welcome the opportunity to talk about what are the key ways that you do that in terms of supporting a parent or parents so that they are able to care for that child appropriately and then the question of where the funding stream is. We welcome that conversation.

Senator WYDEN. We started the vote on a bill that is in this committee's jurisdiction, the Trade Enforcement Act, and I am just going to leave you with one last thought.

We are going to be relying on your counsel and your expertise a whole lot during this remaining year, and what I have always sensed about your agency and handling the responsibilities there is that doing your job well is a contact sport.

I admit that I went to school on a basketball scholarship, so that is kind of my world, but I see you constantly reaching out to legislators, to State officials, to the advocates, and these are people who often do not have the power and clout. I just want you to know I really appreciate that, because I think you are kind of writing a sort of manual for how you ought to do this job at this incredibly

important agency, which is sort of the people's agency for kids and seniors and the disabled.

I wish there was more time to get into some additional issues, but we are going to come back to you on some big questions, because I know you and I have talked briefly about the 18-month investigation that Senator Grassley and I did into the hepatitis C drugs. There is a piece out this morning that indicates that the States are rationing hepatitis C drugs, that they cannot afford to take care of people, and, by the way, when you ration hepatitis C drugs, people get sicker and sicker and have these very serious liver illnesses, which cost even more money.

So we are having problems today handling just a small percentage of those who have hepatitis C, and we are likely to end up with bigger expenses as a result of care being rationed.

I think, and it is a question we are going to start examining here, we are on the cusp in the United States of having a policy that says we are going to have spectacular cures for illnesses—and the hepatitis C drugs are cures, talking about Sovaldi and Harvoni—and we are going to have spectacular cures I suspect for diabetes, a variety of cancers, and the like. The question will be, will Americans be able to afford to get those cures, and that is going to certainly be a debate that would not be for the fainthearted.

So I am really glad that we are going to get to have you for close to an additional year, and I so appreciate particularly the way you constantly come back to pulling people together. You do not get this job done well and come up with policies that pick up bipartisan support by osmosis. You get it done because you are constantly reaching out to people and saying, "Look." Bipartisanship is not about accepting each other's bad ideas. Bipartisanship is about taking good ideas, and I think you handle that very well.

I think Chairman Hatch indicated we have some colleagues who may ask additional questions for the record.

With that, the Finance Committee is adjourned.

[Whereupon, at 12:10 p.m., the hearing was concluded.]

## A P P E N D I X

### ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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PREPARED STATEMENT OF HON. SYLVIA MATHEWS BURWELL, SECRETARY,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Hatch, Ranking Member Wyden, 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 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 3 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 at 52 centers in Utah and 216 centers in Oregon. 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 10 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.

#### HEALTH CARE 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 Health Care 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 2-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 crit-

ical 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 2-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 Antibiotic-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 5 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 as well as 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, 100,000 of which are refugees, consistent with the Administration’s commitment to admitting at least 100,000 refugees in FY 2017.

HHS is legally required to provide care and custody to all unaccompanied children apprehended by immigration authorities until they are released to an appropriate sponsor to care for them while their immigration cases are processed. Based upon the recent increase in unaccompanied children apprehended at the Southwest border, ACF is taking prudent steps to add temporary capacity so that we are adequately prepared. To ensure that HHS can provide care for all 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 re-



sources only if the caseload exceeds levels that could be supported with available funding.

#### 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.

The Administration's investment in Head Start services has more than doubled access for infants and toddlers over the course of the Administration, and significant investments have been made to strengthen the quality of services that Head Start provides. The FY 2017 Budget provides a total of \$9.6 billion for the Head Start program, which includes the resources necessary to maintain this expansion of services. In addition, the Budget builds on the investments made in FY 2016 to expand the number of children attending Head Start programs that offer a full school day and year program, which is proven to be more effective than programs of shorter duration and helps meet the needs of working parents. In collaboration with the Department of Education, the Budget includes \$350 million for Preschool Development Grants to support states in building and expanding high-quality preschool systems.

The President's Budget continues the historic proposal to provide \$82 billion over 10 years in additional mandatory funds for child care to ensure that all low- and moderate-income working families with young children have access to high-quality child care. This proposal will increase the number of children served to a total of 2.6 million by 2026 and raise the quality of care children receive. In addition, the FY 2017 Budget includes almost \$3.0 billion in discretionary child care funding, an increase of about \$200 million, to support states, tribes, and territories as they implement the new health, safety, and quality requirements of the bipartisan child care reauthorization, and to create pilots that will test and evaluate strategies for addressing the child care needs of working families in rural areas and families working non-traditional hours.

*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.

#### 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.

#### 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 10 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.

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 QUESTIONS SUBMITTED FOR THE RECORD TO HON. SYLVIA MATHEWS BURWELL

## QUESTIONS SUBMITTED BY HON. ORRIN G. HATCH

## PROGRAM INTEGRITY

*Question.* In a recent response to this committee's inquiries into the recovery audit program, CMS indicated they were shifting the focus of the recovery audit program. The new focus will be on providers who have high error rates. With \$60 billion misspent last year alone, it seems that you would want your auditors to recover monies wherever they are in jeopardy. That certainly was what the Tax Relief and Health Care Act of 2006 envisioned. I would like to know how recovery auditing works in the commercial sector and why we are not applying those practices to the Medicare recovery auditors as TRHCA envisioned.

*Answer.* Senator, I know that you and this committee care deeply about program integrity. I agree that good stewardship of taxpayer dollars is important, and that is why I consider it a top priority as Secretary. From FY 2010–2014, RACs returned \$7.1 billion to the Medicare Trust Funds. The Medicare Fee-for-Service Recovery Audit Program is a valuable tool, and we believe ongoing enhancements to the program can allow CMS to use Recovery Auditors to more effectively recover and address improper payments by focusing on the highest risk providers. At the same time, these enhancements will increase transparency, improve provider fairness, and lead to better provider and Recovery Auditor communication. The Recovery Auditing Program uses techniques similar to commercial sector recovery auditing principles, such as using data analysis to identify improperly paid claims, requesting medical documentation to help identify possible improper payments, affording debtors a dispute or appeals process, and recovery/collection processes payments. In addition, also similar to commercial sector recovery auditing, Recovery Auditors must pay back contingency fees for review determinations that are overturned on appeal and are paid on a contingency fee basis. As part of the procurement for the next Recovery Auditor contractors, CMS performed several rounds of market research and found that requirements vary among commercial sector recovery auditors.

CMS balances its responsibility to protect the Medicare Trust Funds with its responsibility to protect providers from inappropriate claim denials that impede access to patient care. To that end, CMS has established controls over our contractors' performance, such as approving all audit topics prior to widespread review, and independent validation of claim reviews to determine contractor accuracy.

*Question.* I'd also like to know how you intend to define what a high error rate is; is it 10%? We already have an error rate for the Medicare program that is over 12% and it is costing us \$60 billion every year in waste. How you will identify providers with high error rates and why do you think having recovery auditors review these error prone providers is appropriate rather than some of the other actions and tools Congress has given you?

*Answer.* CMS plans to adjust a provider's additional documentation request (ADR) limit by comparing a provider's own claim denial rate to CMS' national target improper payment rate. A provider's claim denial rate will be calculated by the number of claims found by the Recovery Auditor to be improperly paid, divided by the number of claims reviewed by the Recovery Auditor during a particular time period. This will allow for broader reviews of claims in these areas, and for CMS to better target reviews of providers that pose the greatest risk to the Medicare program. Additionally, in those cases where CMS specifically directs the Recovery Auditors to review a specific topic or provider, the ADR limit will not apply.

CMS is continuously working to improve collaboration between auditing contractors to promote accurate and efficient auditing of Medicare claims while reducing provider burden and ensuring beneficiary access to health care/health services. CMS

is planning to share the details on this new, risk-based approach to adjusting ADR limits soon.

*Question.* If recovery auditors are severely limited in the number of claims they are allowed to review for inpatients claims, what other areas has CMS approved them to review? What are CMS's plans for broadening the types of improper payments that can be reviewed and targeted for recovery?

*Answer.* During the time period that patient status reviews were statutorily prohibited, CMS has continued to allow the review of inpatient claims for issues not related to the inpatient/outpatient status of the patient, such as to determine if the claim was coded correctly. Additionally, during this time, CMS approved a number of audit topics for various provider types, such as Skilled Nursing Facilities, Outpatient Hospitals, Physicians, Hospice providers, and Durable Medical Equipment suppliers. Recovery Auditors have almost 700 different review topics available for their review.

*Question.* What is the timeline CMS expects to adhere to in terms of finalizing the procurement for the next round of Recovery Audit contracts?

*Answer.* CMS is actively engaged in the procurement process for the next round of Recovery Auditor contracts and expects to award the new contracts this summer.

#### RISK ADJUSTMENT

*Question.* The former CMS actuary, Rick Foster, recently wrote a paper indicating that the risk adjustment mechanism in the exchanges disincentivizes the enrollment of young and healthy individuals. That doesn't seem to bode well for the program. What are you doing to address this? We also hear regularly that the Medicare Advantage risk adjustment system does not adequately recognize certain conditions prevalent in the Medicare population. Shouldn't there be a close assessment of these risk adjustment programs to ensure they are well supported by medical evidence and promote coordinated care?

*Answer.* The risk adjustment program is important to protect against potential effects of adverse selection inside the Marketplaces. It protects consumers' access to a range of robust coverage options by reducing the incentive for insurance companies to seek to insure only healthy individuals. This year, 3 million people ages 18 to 34 were signed up for coverage nationwide. The overall percentage of plan selections for those ages remains stable.

As the Marketplace continues to mature, we are working to further refine the risk adjustment model. For example, in the 2017 Notice of Benefit and Payment Parameters Proposed Rule, published in December 2015, we sought comment on a proposal to recalibrate the risk adjustment model to incorporate preventive services into the simulation of plan liability for the 2017 benefit year. We expect that the incorporation of preventive services will increase the risk scores of plans with healthier enrollees and more accurately compensate risk adjustment covered plans with enrollees who use preventive services. We have also taken a number of steps to strengthen the risk adjustment program more broadly speaking.

CMS decides whether to include a condition category in the model after balancing several considerations, including each category's ability to predict costs for Medicare Parts A and B benefits, whether the diagnostic classifications measure disease burden, and whether diagnosis codes that are subject to discretionary or inappropriate coding should be excluded. Although not all conditions are included in the CMS-HCC model, the model still predicts beneficiaries' expected costs for all A and B benefits, including costs associated with chronic and mental health conditions. Given the goal of managed care organizations, we expect plans will appropriately manage chronic conditions and mental health conditions for their beneficiaries, irrespective of model refinements.

We also take very seriously the concerns raised by stakeholders that the Medicare Advantage risk adjustment model may disproportionately affect specific populations, particularly dual eligible beneficiaries. In response to feedback about the accuracy of the Medicare Advantage CMS-HCC risk adjustment model for predicting costs of dual eligible beneficiaries, in 2015 CMS undertook an evaluation to assess how well the model performs for these beneficiaries. In October 2015 CMS invited public comment on Proposed Changes to the CMS-HCC Risk Adjustment Model for Payment Year 2017.

## SPECIAL ENROLLMENT PERIODS

*Question.* CMS has taken action to reduce the number of qualifying events that allow an individual to use a Special Enrollment Period for coverage, but there are still nearly 30 qualifying events while Medicare only has five. Does CMS plan to take further steps to reduce the number of qualifying events that allow for a Special Enrollment Period?

*Answer.* Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. On January 19 CMS announced several changes<sup>1</sup> including:

- Clarifying the definitions of SEPs to ensure the rules are clear to everyone,
- Reviewing all SEPs and eliminating those that are no longer necessary, such as:
  - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy;
  - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents;
  - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit;
  - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays;
  - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options;
  - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and
- Providing stronger enforcement so that SEPs serve their intended purpose and do not create unintended loopholes.

We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.

## CHRONIC CARE

*Question.* Secretary Burwell, as you know, CMS has taken steps to improve care and outcomes for Medicare beneficiaries with multiple complex chronic conditions. Alzheimer's disease is a progressive, fatal condition affecting an estimated 5.1 million American seniors. Medicare beneficiaries with Alzheimer's and other dementias pose a unique challenge in terms of utilization and spending to the Medicare program. Seventy-four percent of seniors with Alzheimer's disease have at least one additional chronic condition such as hypertension, heart disease and diabetes. High rates of co-morbidity among seniors with Alzheimer's and other dementias are helping to drive the rapidly rising cost of care for this population. Alzheimer's disease complicates the ability for individuals and families to manage these other chronic conditions, resulting in 3 times as many hospitalizations and higher rates of Medicare spending than beneficiaries who do not have dementia. Additionally, estimates show that about 1-in-5 Medicare dollars will be spent on someone with Alzheimer's disease or other dementia in 2015, a total Medicare spend of about \$113 billion. Absent the development of an effective treatment or cure, this number is expected to grow to around \$589 billion by 2050 (not adjusted for inflation), representing a significant threat to the Medicare program. Until a cure is found, we must work together to improve care for Medicare beneficiaries and their families facing this devastating disease.

Responding to the growing threat that Alzheimer's and other dementias poses to Medicare spending, the Senate Finance Committee's Bipartisan Working Group on Chronic Care recognizes that more time is needed by clinicians to discuss the diagnosis of serious or life-threatening illnesses, like Alzheimer's disease, with their patients. As a result, the Working Group has proposed a one-time visit code in Medicare for beneficiaries who have received a diagnosis of Alzheimer's or another dementia to allow for a discussion about the disease and its progression, existing

<sup>1</sup>[https://www.regtap.info/uploads/library/ENR\\_RetiredSEPs\\_011916\\_v1\\_5CR\\_011916.pdf](https://www.regtap.info/uploads/library/ENR_RetiredSEPs_011916_v1_5CR_011916.pdf).

treatment options, and the availability of other resources that would reduce risks to the beneficiary and promote disease self-management. In light of this proposal, as well as the *National Plan to Address Alzheimer's Disease's Goal 2: Enhance Care Quality and Efficiency*, can you help us to identify and address gaps in care planning for those beneficiaries with Alzheimer's disease and other dementias to ensure they (and their families and caregivers) are receiving appropriate and comprehensive care planning services following a diagnosis?

Answer. HHS has made extensive investments to address the challenges of Alzheimer's disease and related dementias (ADRD). The President's FY17 Budget proposes a total funding level of \$4.7 billion for these diseases, including an increase of \$275.5 million over FY16 enacted levels, the majority of which is Medicare spending. The Budget continues the Department's commitment to support effective research, education, and outreach, as well as patient, family and caregiver services.

I would like to thank you and your colleagues for your leadership on this issue and continued support of the National Alzheimer's Project Act (NAPA). NAPA offers an important opportunity to build on and leverage HHS programs and other Federal efforts to help change the trajectory of ADRD. In coordination with other Federal partners, HHS is working to carry out NAPA's charges to address gaps and improve coordination between HHS agencies on issues such as research and services, acceleration and development of ADRD treatments, improvement in early diagnosis and coordination of care, including care planning, reduction of ethnic and racial disparities in rates of ADRD, and coordination with international partners.

Although finding a cure for ADRD is an important part of our NAPA work, over the past year the discussion at NAPA Advisory Council (Council) meetings has gradually evolved from a sole focus on increasing the research budget toward the topics of care and services for individuals who have dementia and support for their family caregivers. Among the Council's new initiatives is planning a Care and Support for Dementia Summit, which is intended to provide an overview of care and services issues, existing care models, and the future of care.

The expansion in the Council's focus is consistent with HHS agencies' progress in improving services for people with dementia and their caregivers. Work includes programs by HRSA to educate physicians and providers about how to talk to families about dementia diagnoses and long-term care options. The Administration for Community Living has funded dementia-capable and evidence-based service systems for people in the community with dementia and their family caregivers, including improving the Aging Network, which provides caregivers with resource materials and support programs. Additionally, NIH has ramped up funding for research—its investments grew 25% between FY11 and FY14.

Through a Chronic Care Management Services code, effective on January 1, 2015, Medicare will pay separately under the Medicare Physician Fee Schedule for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions by qualifying practices. This provides payment for at least 20 minutes of clinical staff time provided during a month for patients with the following requirements: multiple chronic conditions expected to last at least 12 months, or until the death of the patient; and chronic conditions which place the patient at significant risk of death and/or decline. It requires the establishment, implementation, revision, or monitoring of a comprehensive care plan. Alzheimer's disease and related dementias are among the chronic conditions listed that would fall under the Chronic Care Management Services.

#### FAILED CO-OPS

*Question.* What steps is CMS taking to ensure stakeholders are made whole and consumers held harmless from incurred costs of failed CO-OPs? How many total consumers are impacted through the failed CO-OPs? What percentage of the total exchange enrollment has been impacted through the closures? What is the impact of the CO-OP closures on the wider market including insurers, providers, and agents/brokers?

Answer. The primary focus of all our efforts is to ensure that CO-OPs are meeting the needs of their consumers. CMS continues to help CO-OPs identify and correct issues and improve their insurance plans.

Each of the consumers in the CO-OPs that closed at the end of 2015 maintained coverage until the end of the year, and nearly three-quarters<sup>2</sup> of the CO-OP Mar-

<sup>2</sup>Does not include consumers who enrolled in new plans outside the Marketplace.

ketplace consumers have continued their coverage in a new plan in 2016. Affected CO-OP enrollees had access to a special enrollment period, and are able to shop for 2016 coverage on the Marketplace until February 28, 2016. In all cases, CMS is focused on making sure consumers continue to receive medical services.

The CO-OP program is only one part of the Affordable Care Act's overall approach to encourage competition and to give consumers a variety of affordable coverage choices. Whether consumers are getting coverage from a CO-OP, another issuer, or Medicaid, millions of Americans who were previously uninsured now have access to affordable, high quality health care coverage. As several of the Affordable Care Act's coverage provisions took effect, an estimated 17.6 million Americans gained coverage through the third quarter of 2015. In the years since the passage of the Affordable Care Act, we have seen increased competition among health plans and more choices for consumers.<sup>3</sup> During the third Marketplace Open Enrollment, 9 out of 10 returning customers were able to choose from 3 or more issuers for 2016 coverage, up from 7 in 10 in 2014.<sup>4</sup>

*Question.* What steps will CMS take to recoup losses from CO-OPs that appear unlikely to repay their loans? Who will be responsible for loan repayment once a CO-OP ceases operations? How much money has been lost?

*Answer.* We take our obligation to taxpayers very seriously. The U.S. Department of Justice is responsible for collecting any debts owed the U.S. Government. While it is too early to tell how much money can be recovered, we are working in close collaboration with the Department of Justice and will use all available tools to recover money from these companies.

The 12 CO-OPs currently winding down received \$1.24 billion in total loan funding; \$1.05 billion of that was awarded before coverage began on January 1, 2014.

*Question.* In the NBPP for 2017 CMS repeats their proposal for individuals to opt for automatic reenrollment into a different issuer if the costs are lower. What steps would CMS take to ensure individuals are not auto reenrolled into a CO-OP that is no longer selling due to enrollment caps or closure?

*Answer.* All Marketplace plans available to consumers for plan year 2016 were certified for sale on the Marketplace prior to the start of Open Enrollment on November 1, 2015. As you may recall, announcements that CO-OPs were winding down were also made before the start of Open Enrollment, so those CO-OP plans were never certified, and were not available, for sale on *HealthCare.gov* for 2016. Because the auto re-enrollment process takes place after the start of Open Enrollment, consumers could not be auto re-enrolled into a closed CO-OP. State Departments of Insurance, as the primary regulators of insurance, may authorize a freeze on new enrollment for any issuer, including CO-OPs, however, such a freeze does not impact members continuing with the plan. Consumers enrolled in a CO-OP who did not make an active plan selection for 2016 were auto re-enrolled into their plan for the 2016 plan year.

*Question.* How many CO-OPs are participating in the OPM Multi-State Plan Program and how many States do they cover?

*Answer.* The CO-OP operating in Connecticut, HealthyCT, is the only CO-OP participating in the OPM Multi-State Plan Program for the 2016 coverage year.

#### EXISTING CO-OPS

*Question.* What is CMS doing to make sure CO-OPs are priced adequately? Is CMS reviewing how many months of operating capital the remaining CO-OPs have available to determine if they will remain solvent for the entire calendar year of 2016? Does CMS expect any CO-OPs to close in 2016 during the benefit year? Since closing CO-OPs during the benefit year is disruptive to consumers because they will need to select new coverage, possibly restart their deductible or find a new doctor, what oversight metrics is CMS using and how is CMS coordinating with States ensure no other CO-OPs will close during the benefit year? What are DOIs doing to address issues before problems occur? How do HHS and the DOI validate financial stability?

<sup>3</sup> [www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html](http://www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html).

<sup>4</sup> [www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html](http://www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html).

Answer. CMS has obligations to operate as a proper steward of the taxpayer dollars issued through the loan program and to administer the CO-OP Program for the benefit of consumers. Since awarding both start-up and solvency loans, CMS has been closely monitoring and evaluating the CO-OPs to assess performance and compliance, and has engaged regularly with State Departments of Insurance (DOIs), which are the primary regulators of insurance issuers in the States. As the primary regulators of insurance, States retain responsibility for regulating CO-OPs, analyzing and actuarially certifying rates and surplus levels.

CMS uses a stringent oversight process. All CO-OPs are subject to standardized, ongoing reporting to CMS and interactions with CMS that include weekly, biweekly, or monthly calls to monitor goals and challenges; periodic on-site visits; performance and financial auditing; and monthly, quarterly, semi-annual, and annual reporting obligations. During site visits, CMS reviews management structure and staffing, financial status, business strategy, the policies and procedures of the CO-OP, marketing and sales information, and operations, including vendor management and oversight. CMS also reviews whether a CO-OP is meeting their obligations for medical management and member relations. CMS also collaborates with State Departments of Insurance (DOIs) concerning each CO-OP loan recipient.

CMS also monitors the CO-OPs' overall financial condition using several factors of the Federal Deposit Insurance Corporation's Uniform Financial Institutions Rating System. CO-OPs have monthly, semi-annual, and annual reporting requirements, including financial statements, balance sheets, income statements, statements of cash flow, and enrollment statistics. Last year, CMS increased the data and financial reporting requirements for CO-OPs. Each CO-OP is required to provide a semi-annual statement of its compliance with all relevant State licensure requirements, and, if necessary, an explanation of any deficiencies, warnings, additional oversight, or any other adverse action or determination by DOIs received by the CO-OP. If the CO-OP is experiencing compliance issues with State regulators, the CO-OP is required to describe the steps being taken to resolve those issues. CMS meets monthly with the State insurance regulators regarding each CO-OP. This additional financial data has helped CMS to identify underperforming CO-OPs, providing CMS the opportunity to work with the CO-OPs and DOIs to help correct issues.

Finally, CMS can terminate its loan agreement with a CO-OP if it determines that the CO-OP is no longer viable, sustainable, or serving the interests of the community. CMS works closely with DOIs and shares information to assist in their assessments of CO-OPs. If a loan agreement is terminated, CMS works with the State DOI and the CO-OP board to wind down operations in an orderly way to mitigate impact to the consumer.

While CO-OPs are primarily responsible for their own success, CMS will continue to help them identify and correct issues and make improvements. CMS is committed to continuing its work with the CO-OPs offering coverage this year to facilitate progress and expand into new markets when appropriate. CMS has also clarified our policies on important topics<sup>5</sup> and is exploring what changes could be made to help CO-OPs diversify their boards and grow and raise capital, while still preserving the fundamentally member-run nature of the CO-OP program.

*Question.* How much funding remains within CMS that has been allocated but not drawn down by CO-OPs? What happens to funds that are returned to CMS?

Answer. As of December 31, 2015 \$2.378 billion had been disbursed of a total \$2.459 billion. Any funds paid back by the CO-OPs or recouped by the Department of Justice are returned to the Treasury.

#### HEALTH REIMBURSEMENT ARRANGEMENTS

*Question.* Historically, many small business owners reimburse employees for medical care and services through Health Reimbursement Arrangements (HRAs). However, due to a Department of Treasury regulation, since July 1, 2015, these businesses, which are voluntarily providing financial assistance to help employees pay for health care through an HRA, are now subject to a \$100 per day, per employee fine—totaling \$36,500 per employee annually, up to \$500,000 total. This is 18 times more than the \$2,000 employer mandate penalty for not providing any coverage.

<sup>5</sup> <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf>.



These small businesses are trying to help their workers—but the Internal Revenue Service says they should be fined for doing so.

The Small Business Healthcare Relief Act (S. 1697) is a bipartisan, common-sense bill before my committee that would allow small businesses with less than 50 employees to continue to provide employees with an HRA without being subject to outrageous IRS fines. Small businesses should be allowed to do the right thing: Help employees pay for health insurance and medical expenses without being subject to excessive financial punishment.

I don't understand how this administration can claim they want to make health care more accessible and affordable and yet impose a \$36,500 per employee penalty on an employer that wants to help their employees afford coverage. While I will continue to work with my colleagues to advance this legislation, you could make legislation unnecessary by rescinding this outrageous IRS ruling.

- Why is the IRS punishing employers who are simply trying to offer assistance to their employees?
- What kind of impact do you think the IRS ruling on HRAs is having on employers and employees?
  1. Are employers dropping HSAs as a benefit?
  2. What types of cost increases are employees seeing as a result of the ruling?

Answer. We are willing to work with Congress on any proposal that improves access, affordability, quality, and health of the economy. Because this proposal could have substantial revenue effects, it does not meet this test without including an offset. I would defer you to my colleagues at the Department of Treasury for specifics around their regulations.

#### EMPLOYER REPORTING REQUIREMENTS

*Question.* The ACA reporting requirements compel employers to report significant amounts of data detailing information about employees, their health plans and who had access to employer sponsored insurance to the IRS after the end of each year. This information will be used to levy the individual mandate penalties. It will also be used to levy penalties on low incomeworkers who were erroneously granted an advanced premium tax credit by the Exchanges when the employee had an existing offer of employer sponsored insurance.

Unfortunately, because employers are reporting information on the availability of employer sponsored insurance up to 17 months after the exchange granted the erroneous advanced premium tax credit, these lower income employees could be left with a shocking tax bill over a year and a half later.

When will the IRS notify individuals of their potential tax liability and wouldn't it help low income individuals and improve tax administration if the administration used up-to-date information about the availability of employer sponsored insurance at the time individuals were applying for tax credits rather than 17 months later?

Answer. As you know, applicable large employers (ALEs) must report to the IRS information about the health care coverage, if any, they offered to full-time employees. ALEs are also required to furnish a statement to each full-time employee that includes the same information provided to the IRS. The IRS will use this information to administer the employer shared responsibility provisions and the premium tax credit, and individuals who purchased health insurance coverage through the Marketplace may use this information to verify their eligibility for employer-sponsored coverage. Like other information reporting, this information is provided after the conclusion of the year, reflecting that coverage and other related information may change over the course of the year.

Advance payments of the premium tax credit (APTC) are payments during the year to an individual's insurance provider that pays for part or all of the premiums for a qualified health plan covering the individual and his or her family. APTC eligibility is based on the Marketplace's estimate of the premium tax credit the individual will be able to take on his or her tax return. If APTC is paid for an individual or a member of his or her family, the individual must reconcile (or compare) the APTC with the premium tax credit at the time that the individual files his or her tax return. If the APTC is more than the premium tax credit, the individual must repay the excess APTC, which occurs as part of the individual's tax filing process. However, the amount that an individual is required to repay may be limited based on the individual's household income and filing status. Individuals calculate the

amounts they are owed or owe a result of reconciliation themselves on their tax returns.

Several tools are used to help determine whether an individual enrolling in Marketplace coverage is eligible for employer-sponsored coverage. First, CMS has provided an employer coverage tool to enable consumers to get information about employer coverage to which they have access, available at: <https://www.healthcare.gov/downloads/employer-coverage-tool.pdf>.

In addition, starting in 2016, the FFM will notify certain employers whose employees enrolled in Marketplace coverage with APTC because the employee attested that he or she was neither enrolled in employer sponsored coverage nor eligible for employer coverage that is affordable and meets the minimum value standard. The FFM will send notices to employers if the employee received APTC for at least one month in 2016 and if the FFM has a complete address for the employer. Employers receiving this notice may appeal the Marketplace's eligibility determination.

We will continue to work with consumers so that they understand the eligibility requirements for coverage and financial assistance. I would refer you to my colleagues in the Department of Treasury for further specifics around the premium tax credit reconciliation process and the employer reporting requirements.

#### ACA SOCIAL SECURITY NUMBER REPORTING

*Question.* The ACA reporting requirements require employers to report dozens of new data elements to the IRS, including private information such as dependent and spouse social security numbers.

In an era where even the Federal Government's most private personal data has been breached, how can you ensure employers and Americans that their private information will be safe guarded?

*Answer.* At HHS, we vigilantly monitor, test, and strengthen our systems against cyberattacks, in order to prevent, detect and respond to any potential vulnerabilities. We are continually updating physical and cybersecurity controls for our systems, including High Value Assets, defined as systems, facilities, data and datasets deemed of particular interest to potential adversaries, at all of our Divisions. HHS has in place teams that constantly work to identify potential issues and risks, share best practices and lessons learned, and focus on cybersecurity policy and monitoring, training and awareness.

HHS Computer Security Incident Response Center (CSIRC) scans against new indicators of compromise—the unique fingerprints of an incident—immediately upon receipt and notifies all operating divisions within 24 hours. HHS has multiple layers of cybersecurity, including:

- Required use of a hardware-based Personal Identity Verification (PIV) cards or alternative forms of strong authentication; this requirement is one of the most significant steps that can be taken to reduce the risk of adversaries penetrating networks and systems.
- Continuing to work on ensuring employees use strong authentication to access HHS networks and have access to only those resources that are required for their job function.
- Through the Trusted Internet Connection (TIC) initiative, HHS reduced its number of Internet connections from approximately 150 to 3. This allows us to better deploy cutting edge tools to detect and block Internet-based attacks while minimizing the potential network entrance points that could be exploited.

HHS also continues to enhance training and awareness activities to better educate HHS employees on threats such as phishing.

In addition, the HHS Office for Civil Rights (OCR) administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules, which require covered health care entities (health plans, health care clearinghouses, and most health care providers) and their business associates to protect the privacy and security of individuals' health information and establish individual rights with respect to that information. Covered entities—including components of certain Federal entities that are health care providers and/or health plans—and business associates must implement reasonable and appropriate administrative, physical, and technical safeguards to protect the information they maintain from unauthorized uses and disclosures. In the case of a breach, covered entities are obligated to notify affected individuals, HHS, and in certain cases the media, of the breach. Importantly, entities can avoid

breaches and the attendant breach notification requirements by implementing appropriate protections.

OCR opens investigations based on individual complaints and certain breach reports as well as information about potential noncompliance obtained by other means, such as through media reports. All HIPAA covered entities and their business associates, including those that may be Federal entities, could be subject to civil money penalties for noncompliance with the HIPAA Rules. Moreover, OCR refers complaints and breach reports that implicate the criminal provisions of HIPAA to the Department of Justice (DOJ), as DOJ has criminal jurisdiction under HIPAA. DOJ determines whether or not to pursue any potential criminal violations of HIPAA.

I defer to IRS and Treasury for more information about their systems.

#### ACA TAX CREDIT NOTICES

*Question.* Obamacare requires HHS to send a notice to an employer when an employee is deemed eligible for an advanced premium tax credit. These notices are important because they allow employers to warn employees that they may be subject to a surprising tax bill when the employer has already offered the employee health coverage.

Would a more up-to-date and substantiated data base help decrease the number of erroneous advanced premium tax credit determinations?

Employers expected to receive notices beginning in 2015. What date will you begin sending employers notices so they can help their low income workers avoid unexpected tax penalties?

Answer. HHS has previously discussed the challenges in building a new database for checking employer sponsored coverage information—while we do support reducing reporting burden by consolidating and streamlining reporting, if feasible, building the functionality required to collect and retain information regarding employer-sponsored insurance coverage will be time and resource-intensive. Starting in 2016, the FFM will notify certain employers whose employees enrolled in Marketplace coverage with APTC because the employee attested that he or she was neither enrolled in employer sponsored coverage nor eligible for employer coverage that is affordable and meets the minimum value standard. The FFM will send notices to employers if the employee received APTC for at least one month in 2016 and if the FFM has a complete address for the employer. The IRS will independently determine any liability for the employer shared responsibility payment without regard to whether the Marketplace issued a notice. We will continue to work with consumers so that they understand the eligibility requirements for coverage and financial assistance. I would refer you to my colleagues in the Department of Treasury for more specifics around the employer reporting requirements.

#### PACE PLANS

*Question.* The Program of All-Inclusive Care for the Elderly (or PACE) has a proven track record of providing the highest quality of care to some of our most vulnerable seniors—those who need a nursing home level of care but wish to continue living in the community. In Medicare, Medicaid and the private sector, health care delivery and payment systems are seeing significant and accelerating change. Yet the PACE, which pioneered so many of the features we now seek to build into our health care system, is being constrained by regulations that are almost a decade old.

What is the administration doing to update those regulations and provide more flexibility to PACE so that our seniors can have greater access to its gold-standard, proven and replicable model of integrated, community-based and person-centered care?

Answer. I share your support for the PACE program, and CMS is taking steps to modernize and streamline PACE enrollment and services.

PACE has proven successful in keeping frail elderly individuals in the community, and we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more States, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS has received numerous suggestions from PACE organiza-

tions, beneficiaries, members of Congress, and other stakeholders and looks forward to continuing to work with all stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services.

*Question.* Recently, Congress gave the Department authority to develop pilots for extending the PACE model to new populations. How is the administration proceeding in the development of those pilots and when can we expect CMS to announce the opportunity to participate in a pilot?

*Answer.* The PACE Innovation Act of 2015 expands the Department's authority to allow waivers in order to conduct demonstration projects that involve PACE. We are excited about these new opportunities, and CMS is developing options for moving forward.

The 2016 President's Budget includes a legislative proposal to create a pilot demonstration to test whether the PACE program can effectively serve a younger (55 and under) population without increasing costs. This proposal was removed from the 2017 President's Budget because the recently passed PACE Innovation Act grants HHS the authority to test this expansion and other PACE models under the CMS Innovation Center authority.

CMS is actively working with stakeholder and advocacy groups to determine how the PACE comprehensive care approach can be expanded to reach a broader population. We will keep your staff apprised of the status of the pilot.

*Question.* Currently Medicare beneficiaries who enroll in the Program of All-Inclusive Care for the Elderly (or PACE) do not have the option to keep the Part D plan of their choice. For many, this is a disincentive to enroll in PACE. What steps would CMS require to allow Medicare beneficiaries to have a choice in the Part D plan they enroll in if they choose to enroll in PACE?

*Answer.* Beneficiaries who join a PACE program get Part D-covered drugs and all other necessary medication from the PACE program. Similarly, in most cases, beneficiaries who choose to join a Medicare Advantage Plan that includes prescription drug coverage must take the drug coverage that comes with the Medicare health plan if it's offered. While we believe coordination between medical and drug benefits under the current system is beneficial, we would be happy to provide technical assistance on any proposals you may have in this area.

#### WORLD HEALTH ORGANIZATION MILK MARKETING RULES

*Question.* I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk consumed by young children. My understanding is this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the U.S. dairy industry that need to be further examined.

Will you commit to working with this committee and all impacted stakeholders to halt this process until these implications are fully understood?

*Answer.* At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,<sup>6</sup> and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first 3 years of life, a critical window for health and nutrition outcomes.

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 February 1–29, 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products

<sup>6</sup>As presented in report EB138/8: Maternal, infant and young child nutrition. Available at [http://apps.who.int/gb/ebwha/pdf\\_files/EB138/B138\\_8-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf) (accessed March 14, 2016).

consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to 3 years of age.

HHS is working with other relevant Federal agencies to prepare a technical comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

#### PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE

*Question.* The bipartisan Medicare Access and CHIP Reauthorization Act of 2015 established the “Physician-Focused Payment Model Technical Advisory Committee” to consider alternative payment models proposed by stakeholders. The Technical Advisory Committee is to evaluate the proposed models against criteria established by the Secretary through notice and comment rulemaking. The Technical Advisory Committee is to then make comments and recommendations to the Secretary as to the extent the proposed models meet the criteria. The Secretary is required to provide a detailed response to those recommendations that is made public on the CMS website. While nothing in the statute requires the Secretary to implement alternative payment models recommended by this Technical Advisory Committee, the committee is meant to expand the Secretary’s ability to evaluate models. Some stakeholders are interpreting comments by CMS officials pointing out that the statute does not require the agency to implement Technical Advisory Committee recommended-models as a lack of interest in the committee’s deliberations. How do you envision that HHS and CMS will use the Technical Advisory Committee to maximize its utility?

*Answer.* CMS looks forward to receiving recommendations for new physician-focused payment models from the Physician-Focused Payment Model Technical Advisory Committee (the PTAC). We will need robust stakeholder engagement with the PTAC, including physicians and other clinicians, to suggest well designed, robust alternative payment models, including eligible alternative payment models under MACRA. Although the statute does not require CMS to test models that are recommended by the PTAC, CMS will give serious consideration to proposed physician-focused payment models recommended by the PTAC. The PTAC serves an important advisory role in the implementation of alternative payment models.

In addition, section 1115A of the Social Security Act authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. Under this authority, the Innovation Center is able to pursue new physician-focused payment models, including ones that could incorporate the recommendations of the PTAC. We believe such models hold great promise for achieving better care, smarter spending, and healthier people.

#### CONTINUOUS GLUCOSE MONITORS

*Question.* In your comments regarding the administration’s budget, you mentioned that the department is working to give Americans the tools to lead healthy and productive lives. While that is a laudable goal, I point out that there are tools on the market right now that would help Americans greatly but yet are inaccessible due to Medicare’s lack of coverage. I am speaking in particular about continuous glucose monitors. Approved by FDA more than 10 years ago, these devices are covered by more than 95% of all private plans yet Medicare still does not cover them for beneficiaries with insulin-dependent diabetes. I ask that you work with CMS to find a way to resolve this issue so that our seniors, who stand to benefit the most from this important technology, have access and can continue to lead healthy and productive lives.

*Answer.* Thank you for raising this question. Providing Americans the tools to live healthy lives is a shared goal of ours. However, for items and services to be covered by Medicare, the law requires that they must be eligible for coverage under a defined benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and meet all applicable statutory and regulatory requirements. The Medicare statute provides coverage for broad categories of benefits, including durable medical equipment (DME). For a device to qualify as DME, it must, among other requirements, be primarily and customarily used to serve a medical purpose. “Precautionary” equipment, however, has long been considered nonmedical in nature, and therefore is not covered as DME. Consistent with current guidance,

including from the FDA and continuous glucose monitor (CGM) manufacturers, CGMs are not intended to replace a patient or beneficiary's traditional blood glucose monitoring via fingerstick, test strip, and glucometer. Consequently, the functionality of a CGM—at least at this time in the device's development—is precautionary. A CGM is used to indicate when a fingerstick and glucose meter reading may be necessary, so that a beneficiary can, after getting an accurate reading, make a therapeutic decision; while the CGM supplements that process, it does not replace it.

PUERTO RICO

*Question.* Secretary Burwell, the President's budget calls for roughly \$30 billion in additional Medicaid funding for Puerto Rico. You, along with Secretary Lew and NEC Director Zients, sent a letter last year to Congress with a somewhat presumptuous reminder to us about our responsibilities, and identified that additional health funding should be provided in a "fiscally responsible manner." I have two questions about the funding called for in the President's budget.

First, given that I have been asking the administration how much Medicare funding you'd like for Puerto Rico and how you'd propose to pay for it, why have you not provided a direct and complete answer to date?

*Answer.* HHS is committed to continuing our work to strengthen Puerto Rico's health care system and improve health outcomes on the island using available administrative authorities. With regard to the Medicare program specifically, HHS has explored several changes to expand resources for health care providers and ensure beneficiary access to care on the island.

- *Provide a More Robust Accounting for Low Income Patients and Uncompensated Care*—The FY17 Budget proposes to give the Secretary authority to adjust Medicare's disproportionate share (DSH) payments to better account for the higher costs of low income patients in Puerto Rico. Both DSH and uncompensated care payments depend, in part, on patients being eligible for Supplemental Security Income (SSI) which Puerto Ricans do not receive. As indicated in the FY 2016 Inpatient Prospective Payment System (IPPS) final rule, HHS expects to further address the distribution of uncompensated care payments to Puerto Rico in the 2017 rulemaking process.
- *Increasing Payment Rates for Hospitals in Puerto Rico*—HHS is moving forward with accelerated implementation of new legislation passed by Congress at the end of last year that aligns the formula to pay hospitals in Puerto Rico with the formula used in the 50 States, increasing hospital payment rates in the Commonwealth by approximately 5 percent.

More detail on additional administrative actions will be made available as part of ongoing rulemaking activity.

That said, the single most impactful step we can take is reforming Puerto Rico's Medicaid program. As part of the President's FY17 Budget, the administration detailed its proposal to improve health care outcomes in Puerto Rico and prevent hundreds of thousands of Americans from losing access to health care. The proposal would lift the Federal cap on Medicaid funding to Puerto Rico and other U.S. territories, raise the Federal Medicaid rate from 55 percent to 83 percent over time as territories strengthen and modernize their Medicaid programs, and expand eligibility to 100 percent of the Federal poverty level over time. These reforms are integral to the administration's broader roadmap to financial stability for Puerto Rico.

A true solution for the 3.5 million Americans living in Puerto Rico, including reforms to strengthen Puerto Rico's Medicaid program, would require legislation. We are happy to work with you as you develop legislative proposals.

*Question.* And, second, if you were to put the administration's \$30 billion of Medicaid funding increase in stand-alone legislation, please offer specific ways in which you propose to fund it in a "fiscally responsible manner."

*Answer.* The President's budget includes a package of HHS legislative proposals that on net saves \$242 billion over 10 years, and our initiative to strengthen Medicaid in the territories must be viewed in that context. Specifically, the budget proposal provides additional resources to territory Medicaid programs in a fiscally responsible manner by requiring improved financial management and program integrity capacity and full mandatory benefits to receive full Federal financial support. We believe that these reforms are integral to the administration's broader roadmap to financial stability for Puerto Rico.

We are happy to work with you as you develop legislative proposals.

MEDICARE PART D PROGRAM

*Question.* An area of great concern on the topic of executive overreach is the Medicare Part D program.

There have been rumblings that the President may issue an executive order that would allow the Federal Government to negotiate prescription drug prices in the Medicare Part D program. Such an executive order would be in violation of the law as the statute explicitly prohibits such interference in private negotiations.

Despite this fact, I take the possibility of an executive order very seriously. I am a strong supporter of the biopharmaceutical industry as a source of innovation and intellectual property that produces life-saving drugs. The Part D program gets these needed drugs to Medicare beneficiaries. We need to keep the program as it was originally structured because it works. Beneficiaries have choice of prescription drug plans. Private entities negotiate to keep costs down. Overall spending is significantly less than originally projected. Beneficiary satisfaction is very high.

Moreover, allowing the government to “negotiate” prices is not a new idea. Congress has considered this policy and chosen against it. The President’s budget proposal States that it has no budgetary impact. The Congressional Budget Office doesn’t see it as a big saver.

So, having said all that, my question is: Secretary Burwell, is anyone at HHS working with, or has HHS worked with, the White House on an executive order that would allow the government to negotiate prices or on any other changes related to drug prices?

*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.<sup>7</sup> 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 FY 2017 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.

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QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

*Question.* Chairman Hatch and I wrote to CMS in June 2015 about an issue with Obamacare. The concern was in regards to the inaccuracy of advance premium tax credit (APTC) payments made to Qualified Health Plans (QHP).

In December 2015, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that CMS was making payments on behalf of people who may not have qualified to receive them.

It appears that CMS is not obtaining payment data on an enrollee-by-enrollee basis when making APTC payments. In addition, CMS is not providing APTC payment data to the IRS during the course of the year.

The lack of controls in place at CMS and the lack of communication with the IRS to track payments made to individuals is concerning because billions of taxpayer dollars are at stake.

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<sup>7</sup> <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/>.

When HHS OIG issued the December report, CMS was using an “interim plan” to manage the flow of information between the QHPs and CMS. CMS claimed that the interim plan would only be used until January 2016 when CMS would require all issuers to use a new automated computerized system for payment based on enrollee-by-enrollee tracking. In addition, HHS OIG recommended that CMS share more APTC payment data with the IRS in order to allow IRS to “verify the data reported on each individual’s Form 1095-A.”

Do you know if CMS has launched the new automated policy-based payment process that will track APTC payments on an enrollee-by-enrollee basis? If not, please explain the delay.

If the new payment process has been launched, how many QHP issuers are using it? How many are not using it?

Answer. In January 2016, CMS launched an automated payment approach, called policy-based payments, in determining an issuer’s advance payment using enrollment and payment data in the Federally-Facilitated Marketplace (FFM). This system calculates and tracks APTC on an enrollee-by-enrollee basis. As of December 2015, 93 percent of enrollees were enrolled with an issuer deemed ready to transition to policy-based payments.

*Question.* If you have not launched the new automated system, have you implemented new policies and procedures to calculate and verify APTC payments that are independent of the attestations and assurances of QHP issuers? If not, why not?

If so, please provide an explanation and any supporting documentation of these new policies.

Answer. As stated above, CMS launched the policy-based payment system in January 2016.

*Question.* Do you believe that HHS OIG’s recommendation with respect to sharing APTC data with the IRS is unreasonable? If so, please explain.

Do you plan on implementing HHS OIG’s recommendation to share APTC data with the IRS for it to have the chance to independently verify this information? If not, why not?

If so, how will you communicate this information to the IRS?

Answer. Treasury regulations require each Marketplace to provide information to the IRS on a monthly basis about who is enrolled and the amount of APTC paid on the enrollees’ behalf. Pursuant to these regulations, CMS provides this information regarding the Federal Facilitated Marketplace, and each State-based Marketplace provided this information about its own enrollees. This information is provided to the IRS securely through the Data Services Hub, which CMS maintains.

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#### QUESTIONS SUBMITTED BY HON. JOHN THUNE

*Question.* I meet with members of South Dakota’s nine tribes frequently and one of the main issues they have with the Indian Health Service (IHS) and the Federal Government at-large pertains to the lack of meaningful consultation by the Federal Government with the tribe. Please provide me with a copy of the IHS’s policy for conducting consultation with tribal governments.

If there is no official policy, please explain why and whether the IHS will create one within the next 6 months.

Answer. IHS is committed to engaging with Tribal Governments and to transparency in the consultation process. Consistent with that commitment, our policy for conducting tribal consultation is publicly available at: [https://www.ihs.gov/IHM/index.cfm?module=dsp\\_ihm\\_circ\\_main&circ=ihm\\_circ\\_0601](https://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_circ_main&circ=ihm_circ_0601).

*Question.* In 2010, the Senate Committee on Indian Affairs released a report regarding the then-Aberdeen Area IHS office and detailed many issues regarding IHS interference with its employees speaking with members of Congress and members of tribal government. Often times, we hear stories of IHS employees being told that they are unable to speak directly to members of Congress or members of tribal government. During a recent hearing, the Director of the IHS indicated that there is a process in place to facilitate these conversations. As you know, 5 U.S.C. §7211 prohibits interference with a Federal employee’s communication with members of Congress.



Please provide this committee with a copy of the policy in place regarding the facilitation of employee communication with Congress.

Additionally, please provide an explanation from the Office of General Counsel regarding how this complies with 5 U.S.C. § 7211.

Answer. Consistent with 5 U.S.C. § 7211, IHS policies and procedures do not prevent or prohibit any individual employee from providing information to Congress. IHS is committed to ensuring that the Congress receives timely, complete, and accurate information regarding IHS. Consistent with that commitment, and like most agencies, IHS routes requests from Congress through the IHS Congressional and Legislative Affairs Staff (CLAS) and/or the Office of the HHS Assistant Secretary for Legislation (ASL). The role of IHS legislative staff—like legislative staff at other agencies—is to facilitate and coordinate responses, which may require input from different parts of IHS Headquarters, IHS Area Offices, or Service Units, and to ensure that the Congress receives timely, complete, and accurate information.

*Question.* Please detail, by fiscal year, the amount of carry over funding for each fiscal year from 2010 to 2015.

Answer. See attached table titled “Indian Health Service No-Year Balance Authority.”

*Question.* Do these funds return to IHS headquarters or are they retained at the regional offices?

Answer. At the end of each fiscal year, unobligated balances in no-year, or “x,” accounts are carried over to the next fiscal year. These carried over funds remain at the applicable organizational level that received or collected the funding. Third party collections are an example of no-year funds that are carried over from year to year and remain available to the organizational level that collected the funds.

*Question.* Is there a policy in place for how this carry over funding is to be utilized in future fiscal years? If yes, please provide the committee with a copy of that policy.

Answer. The use of carryover funds is directed by the relevant appropriations bills—no-year funds continue to be used for the purposes for which they were appropriated—and other authorizing legislation (*e.g.*, the Social Security Act, IHCA, etc.). In particular, the IHCA states that health care service payments under the Social Security Act, from the VA, and from third party providers are credited to the account of the program that provided the services and must be used to maintain accreditation and compliance with CMS conditions and requirements for participation.

*Question.* Of the total amount of IHS Equal Employee Opportunity (EEO) complaints filed, how many result in mediation?

Answer. From FY 2010 through FY 2015, of the total number of EEO complaints filed, 30 (2%) resulted in mediation, a method of Alternative Disputes Resolution (ADR).

*Question.* Following mediation, is the complaint noted within the employee record?

Answer. Information related to EEO complaints is not made a part of the official employee file to assure the confidentiality of the EEO process. EEO case information is to be safeguarded and the confidentiality maintained of those who participate in the EEO process to avoid having an adverse effect on the EEO process, as well as lead to the distinct possibility of giving rise to a claim of retaliation. IHS notes in the EEO Complaint File that ADR was conducted, and also notes the results of the ADR. If the parties reach an agreement, then the case is closed and entered into the Diversity Management/Equal Employment Opportunity (DM/EEO) database as a Settlement Agreement.

*Question.* Anecdotally, I have been informed that many of these mediations result in a settlement in which the complainant signs a nondisclosure agreement. Please provide the committee with any information regarding mediations that have resulted in these nondisclosure agreements.

Answer. All Settlement Agreements entered into between the Complainant and IHS are private and confidential and not subject to disclosure. Specific portions of the confidential Agreement may be made available to the parties responsible for implementation of specific terms of the Agreement.

*Question.* Please provide the committee with the most recent data available regarding the amount of Federal funds used to reach a settlement agreement following an EEO complaint.

*Answer.* The amount of Federal funds used to resolve informal and formal complaints is provided in the following table.

FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
\$313,991.00	\$433,372.59	\$396,748.20	\$880,225.46	\$888,448.00	\$385,300.15

*Question.* Please provide the committee data regarding any and all moving expenses reimbursed by IHS to employees that are relocated subsequent to an EEO complaint.

*Answer.* From FY 2010 through FY 2015, the total amount of moving expenses reimbursed by IHS to employees was \$27,537.

*Question.* Which funding sources within the GPA IHS are used for mediation settlements?

*Answer.* The Department of Justice Judgment Fund (Fund) is the initial funding source. However, the amount paid by the Fund must be reimbursed by the Indian Health Service (IHS). IHS recovers the funds from the specific Area where the Complainant was employed (*i.e.*, where the EEO complaint was filed). Specific funding sources include private insurance collections, Hospitals and Clinics, Alcohol and Substance Abuse, and Facilities Support.

*Question.* Please provide data (*most recent* available) and information for the following questions related to performance-based awards/bonuses and recruitment incentives paid to employees by the IHS:

*Answer.* All responses are based on CY 2015 recruitment incentive data and bonus award data paid in CY 2015 for the 2014 employee performance year. The attached document provides guidance on awards. Bonus awards are allocated by the Department and are subject to collective bargaining and Federal performance management policy and regulation.

*Question.* How many IHS employees received performance-based awards/bonuses?

Of the total, how many members of the Senior Executive Service (SES) of the IHS received such awards/bonuses?

Of the total, how many employees within the Great Plains Area (GPA) IHS received such awards/bonuses?

Of the total, how many SES members within the GPA IHS received such awards/bonuses?

*Answer.* For the CY 2014 employee performance based evaluation period, a total of 4,441 IHS employees received performance-based awards. Of this total,

- Twelve SES members in IHS received such awards.
- Four hundred eighty three employees in the GPA IHS received such awards.
- No SES members within the GPA IHS received any awards.

*Question.* What is the average amount of a performance-based award/bonuses paid to (i) IHS employees, (ii) SES members, (iii) employees within the GPA IHS, and (iv) SES members within the GPA IHS?

*Answer.* For the CY 2014 employee performance based evaluation period, the average performance-based awards paid to IHS employees was \$1,028.

For the CY 2014 employee performance based evaluation period, the average performance-based awards paid to SES members (their evaluation period is FY) in IHS was \$9,159.

For the CY 2014 employee performance based evaluation period, the average amount of a performance-based awards paid to employees within the GPA IHS was \$1,000.

For the CY 2014 employee performance based evaluation period, no SES members in the GPA IHS received any performance-based awards.

*Question.* What is the total amount of appropriated funds allocated to performance-based awards/bonuses within IHS?

What is the total amount of appropriated funds allocated to such bonuses for SES members?

What is the total amount of appropriated funds allocated to such bonuses for employees within the GPA IHS?

What is the total amount of appropriated funds allocated to such bonuses for SES members within the GPA IHS?

Answer. The total amount of appropriated funds allocated for CY 2014 employee performance based awards within IHS was \$8,228,261.

The total amount of appropriated funds allocated to such performance-based awards for SES members was \$143,900.

The total amount of appropriated funds allocated to such performance-based awards for employees within the GPA IHS was \$1,255,291 for awards.

The total amount of appropriated funds allocated to such performance-based awards for SES members within the GPA IHS was \$7,600, however, these funds were not awarded.

*Question.* Which funding sources within the GPA IHS are used for employee bonuses?

Answer. The GPA IHS employee bonuses are funded by either the Hospitals and Clinics or Direct Operations appropriations lines depending on which account is used to pay the employee's salary.

*Question.* To what extent does IHS use authority (e.g., 5 U.S.C. § 5753) to provide recruitment incentives to employees?

Answer. IHS uses this authority to the maximum extent possible. It is critical for recruiting clinicians to IHS sites in isolated and remote locations.

*Question.* Please describe (and provide relevant documents on) the policies on recruitment incentives for (i) employees and (ii) members of the SES at IHS.

Answer. IHS follows the Recruitment, Retention, and Relocation policy located in the Indian Health Manual for the payment of recruitment incentives for all employees, including SES positions. This policy may be found at [https://www.ihs.gov/ihtm/index.cfm?module=dsp\\_ihm\\_pc\\_p7c8](https://www.ihs.gov/ihtm/index.cfm?module=dsp_ihm_pc_p7c8).

*Question.* How many IHS employees received a recruitment incentive?

Of the total, how many members of the SES received a recruitment incentive?

Of the total, how many employees within the GPA IHS received a recruitment incentive?

Of the total, how many SES members within the GPA IHS received a recruitment incentive?

Answer. For CY 2014, 258 IHS employees received a recruitment incentive.

For CY 2014, no (0) SES employees (their performance period is on the FY) received a recruitment incentive.

For CY 2014, 25 employees within the Great Plains Area (GPA) Indian Health Service (IHS) received a recruitment incentive.

For CY 2014, no (0) SES employee within the GPA IHS received a recruitment incentive.

*Question.* What is the average amount of a recruitment incentive paid to (i) IHS employees, (ii) SES members, (iii) employees within the GPA IHS, and (iv) SES members within the GPA IHS?

Answer. The average recruitment incentive paid to IHS employees was \$11,169.

No recruitment incentives were paid to SES members.

The average recruitment incentive paid to employees within the GPA IHS was \$12,190.

No recruitment incentives were paid to SES members within the GPA IHS.

*Question.* If recruitment incentives have not been paid within the last 3 years to (i) IHS employees, (ii) SES members, (iii) employees within the GPA IHS, and (iv) SES members within the GPA IHS, please provide a detailed explanation as to the reasons why not.

Answer. Recruitment incentives were not paid within the last 3 years to SES members of IHS nor to SES members within the GPA IHS because IHS did not hire anyone from outside the Federal Government and IHS has been able to fill its positions within the basic salary rates for members of the SES.

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QUESTIONS SUBMITTED BY HON. JOHNNY ISAKSON

*Question.* CBER, or the Center for Biologics Research and Evaluation, has issued a series of Untitled Letters related to product classification of tissue products. FDA's Regulatory Procedures Manual explains that an Untitled Letter "cites violations that do not meet the threshold of regulatory significance for a Warning Letter. Therefore, the format and content of an Untitled Letter should clearly distinguish it from a Warning Letter." Unfortunately, several of these recent CBER Untitled Letters are not distinguishable at all from Warning Letters. Because CBER posts these documents on its website and they are read exactly like Warning letters, these Untitled Letters have caused great disruptions and uncertainty for industry including damage to companies.

Why has FDA begun issuing Untitled Letters rather than trying to have a dialogue with the company first about the product classification?

Answer. HHS is committed to minimizing disruption and uncertainty for industry while balancing safety concerns for consumers. In this vein, FDA's Untitled Letters often serve as the initial communication with regulated industry concerning regulatory violations. But, FDA also uses other means to communicate and resolve questions with manufacturers.

One example of these communications is the Center for Biologics Evaluation and Research's (CBER) Tissue Reference Group (TRG), which assists stakeholders on questions regarding human cell tissues and cellular and tissue based products (HCT/Ps). The purpose of the TRG is to provide a single reference point for product specific questions received by FDA concerning jurisdiction and applicable regulation of HCT/Ps. FDA has publically posted information on how manufacturers can submit inquiries to the TRG and publically discloses information related to TRG recommendations on the CBER website.

If FDA issued an Untitled Letter subsequent to an establishment inspection, the FDA investigator may have already informally discussed the situation, though the investigators are not required to do so. In determining whether to issue an Untitled Letter, FDA officials generally consider whether evidence shows that a firm, product, and/or individual is in violation of the law or regulations. Such evidence may have been obtained during a routine or directed inspection, or other means of surveillance, such as Internet website surveillance.

FDA issues Untitled Letters to serve as correspondence with regulated industry for violations that do not rise to the threshold of a warning letter, but which do merit mention. Untitled Letters are not limited to potential product classification issues but are generally a mechanism to communicate and to provide notice of a violation. These letters ordinarily provide the factual basis regarding the violation and serve to communicate the concern without committing FDA to enforcement action if the violation is not corrected.

*Question.* Why is FDA insistent that such letters must be posted on their website?

Answer. FDA has Center-specific policies as to whether to post Untitled Letters, except to the extent that it overlaps with FDA's approach to proactive posting under the Freedom of Information Act (FOIA). We are committed to minimizing disruption and uncertainty for industry while balancing safety concerns for consumers.

FDA's posting approach under FOIA requires the posting of any FDA record subject to the FOIA, such as an Untitled Letter if:

- FDA has received three or more FOIA requests for a copy of the record, or
- If the matter is of significant public interest and we expect to receive multiple FOIA requests for it.

This approach is consistent with Federal law, guidelines from the Department Justice, President Obama's January 21, 2009 FOIA Memorandum, and Attorney General Holder's March 19, 2009 Memorandum.

*Question.* In light of the above, are you willing to review your process for Untitled Letters, especially as it relates to product reclassifications, and examine ways to make issuance of these letters fairer, more effective and more consistent?

*Answer.* FDA is currently reviewing processes for issuing and posting Untitled Letters for FDA and each of the Centers. Specifically, it is reviewing ways that Agency and Center policies could be made more accessible and transparent. We will keep your staff informed as this process progresses.

*Question.* What are some procedural protections the agency might consider in this space?

*Answer.* FDA believes in transparency and consistency in its procedures. Although FDA recognizes that some stakeholders want greater uniformity in practices related to posting Untitled Letters, our product centers need to maintain some specific procedures to address the particulars of the products they regulate, taking into account available Center resources. Currently, a group with representatives from each of the product centers in FDA is collecting and analyzing the policies and looking for common practices to examine ways to create consistent policy here while allowing flexibility where needed for each Center or program.

*Question.* The American Association of Tissue Banks (AATB) made CBER aware on numerous occasions that it was preparing a homologous use guidance proposal for FDA's consideration. That AATB proposal was to be discussed at the AATB-FDA liaison meeting on October 29, 2015. Given the exchange of agendas and meeting materials in the weeks leading up to the meeting, the agency was well aware of this scheduled discussion. However, around 5 PM on October 28th, FDA posted its own homologous use draft guidance. This had the effect of rendering any substantive conversation about the AATB guidance impossible, as the subject matter was now part of an open docket which FDA cannot discuss while the comment period remains open.

Why did FDA choose to release this guidance just hours before the scheduled discussion with AATB, which limited the ability to have a meaningful discussion?

Will FDA evaluate AATB's proposed guidance document during the comment period?

In what area is there alignment between the AATB proposed guidance and FDA's draft guidance?

*Answer.* Thank you for your question. The guidance was released as soon as it was ready for release. FDA was receptive to the comments from the American Association of Tissue Banks (AATB) regarding the proposed guidance and looks forward to AATB's contributions through written comments on the guidance and at the upcoming public meeting.

As always, FDA will evaluate all comments regarding this guidance that are received, including AATB's proposed guidance, which FDA encouraged AATB to submit to the docket.

Both AATB's and FDA's documents share the goal of developing better clarity to help facilitate the development of HCT/Ps. FDA will carefully review the AATB proposal, as well as other comments received. In addition, FDA is having an open public hearing in 2016. Information on the hearing, including date, location and registration information, will be made available on FDA's website and will be published in the Federal Register.

*Question.* Trauma remains the leading cause of death under age 45. You received a comment letter that proposed to test and model, at least on a short-term basis, establishing three HCPCS codes specifically for trauma: (1) trauma high severity potentially life threatening; (2) trauma high severity life threatening; and (3) trauma critical care. This methodology would fold in the existing G0390 code for trauma team activation.

Has CMS modeled this proposal or does CMS have plans to do so and share publicly?

*Answer.* We appreciate the importance of ensuring that individuals have access to quality trauma care. The Center for Medicare and Medicaid Innovation (Innovation Center), as authorized by section 1115A of the Social Security Act, tests innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. The Innovation Center is always open to

new ideas for testing models. We would be happy to learn more about the trauma proposal.

*Question.* (Submitted jointly for Senators Isakson and Warner) The Medicare program appears to be missing opportunities to adopt approaches that have been proven in the private sector to both save money and promote community-based care. A good example of this is home infusion therapy, which is widely covered by commercial payers as a means of keeping patients out of institutions for their infusion treatments. Home infusion therapy, as opposed to some other sites of care, allows patients the opportunity to receive treatment in a more cost effective, convenient and clinically beneficial setting. Private payers also have reaped the benefits of reducing hospital acquired infections, which HHS has devoted substantial resources to curb. We have introduced the Medicare Home Infusion Site of Care Act of 2015 to address the lack of coverage for home infusion. This year we are working with CMS to address logistical and operational issues to ensure that the legislation can be implemented effectively and efficiently.

We ask for your agency's continued cooperation and support on this legislation for Medicare coverage of infusion treatments in the home.

*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.

*Question.* I understand that appropriated funding has not been adequately directed toward providers for preparedness at levels that Academic Health Centers (AHCs) feel are clinically necessary. Further, I understand that the Zika virus falls into the preparedness bucket, which the Federal Government has been underfunding.

Can you tell me specifically how this will be addressed/corrected?

How do we redirect funding already appropriated to address the emerging Zika virus public health emergency?

*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, 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.

In order to respond to the Zika virus both domestically and internationally, the administration has requested \$1.9 billion in FY 2016 emergency supplemental funding. This supplemental includes a requested \$1.5 billion to support domestic and international activities across HHS. This funding would support immediate response activities to prevent the spread of, prepare for and respond to Zika virus transmission; fortify domestic public health systems to prevent, detect, and respond to Zika virus transmission; speed research, development, and procurement of vaccine,

therapeutics, and diagnostics; provide emergency assistance to States and the U.S. territories to combat the virus; provide additional Federal Medicaid funding in Puerto Rico and the other U.S. territories for health services for pregnant women at risk of infection or diagnosed with Zika virus, and for children with microcephaly, and for other health care costs; and enhance the ability of Zika-affected countries to better combat mosquitoes, control transmission, and support affected populations. In addition, the supplemental Zika funds would allow HHS to complete the ongoing work being supported.

*Question.* I understand FDA is now requiring that manufacturers of over-the-counter sunscreen products perform a Maximum Use Trial (MUsT) in order to gain product approval. It is also my understanding that MUsT has never been required for sunscreen products in the past.

*Answer.* FDA is committed to preventing and treating skin cancer, and is implementing the Sunscreen Innovation Act (SIA) with the goal of providing consumers with access to sunscreen products that are safe and effective. The combination of a large increase in the amount and frequency of sunscreen usage, together with advances in scientific understanding and safety evaluation methods, has given rise to the need for additional data to support FDA's determination that an over-the-counter (OTC) sunscreen active ingredient is generally recognized as safe and effective for use in OTC sunscreen products.

FDA is recommending that sponsors of currently pending and future sunscreen active ingredients reviewed under the pathway provided by the SIA perform a human absorption study/maximal usage trial (MUsT) as part of the safety data submitted to show that an active ingredient is generally recognized as safe and effective (GRASE) for use in nonprescription sunscreen products and can be included in the OTC sunscreen monograph. Once FDA has determined that a given ingredient is GRASE on the basis of a MUsT and other safety and efficacy data, we do not expect that additional MUsT studies would be necessary for OTC products formulated using that ingredient and otherwise complying with monograph conditions.

The purpose of the MUsT is to evaluate whether and the extent to which a topically applied active ingredient is absorbed into the body. This is a critical safety consideration for nonprescription sunscreens because they are intended for chronic use, *i.e.*, they are applied regularly over a large portion of the body whenever consumers are exposed to the sun throughout their lifetimes. The information from a MUsT can help identify potential safety concerns and help determine whether an adequate safety margin exists for an active sunscreen ingredient to be included in the OTC sunscreen monograph.

The FDA has required a MUsT for the new drug applications (NDA) approval of a nonprescription sunscreen product containing ecamsule, performed according to the science as understood at the time the NDA was approved in 2006. The MUsT approach is consistent with how consumers use these products, and also with FDA's review of both nonprescription and prescription topical drugs intended for chronic use. In particular, it is the same approach FDA proposed in December 2013 for safety testing of OTC consumer antiseptic washes marketed under the OTC monograph system, and in May 2015 for OTC health care antiseptics marketed under the OTC drug monograph system. MUsT data also have been relied on since the mid-1990s to support FDA's clinical pharmacology/bioavailability assessment approval of new drug applications (NDAs) for chronic-use topical products.

*Question.* Please detail the requirements that need to be met in the MUsT Test.

*Answer.* FDA's current thinking about the conduct and evaluation of sunscreen MUsTs is described in draft guidance and proposed sunscreen orders issued in 2015 by requirement of the Sunscreen Innovation Act (SIA). Copies of the draft guidance and proposed sunscreen orders can be found at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm434843.htm>.

*Question.* What is it that companies must show in the MUsT test that cannot be shown in existing data collected by sunscreen manufactures?

*Answer.* Even though the protective action of sunscreen products takes place on the surface of the skin, current evidence suggests that at least some sunscreen active ingredients may be absorbed through the skin into the body, making it important to complete studies to determine whether, and to what extent, absorption occurs. If more than a minimal amount of absorption is observed, additional studies may be needed to determine whether there is a risk of long-term health effects that would offset the sun protection benefits of sunscreen products using that ingredient.

This is particularly important because we recognize that sunscreens are used very broadly by the whole population, even on children as young as 6 months of age and in pregnant and lactating women.

The existing data collected by the sunscreen manufacturers does not adequately assess the extent of absorption in humans and thus enable an accounting of human systemic exposure for risk assessment.

FDA has evaluated the existing data and communicated recommendations for additional studies for eight sunscreen active ingredients through proposed sunscreen orders under the SIA. In addition, FDA met with all sponsors of these ingredients who requested a meeting to discuss the studies necessary to support a GRASE determination for their specific ingredients, including the importance of a MUsT and the limitations of alternative approaches proposed to date. The data submitted as of February 11, 2016, do not provide sufficient information for FDA to evaluate whether and the extent to which an ingredient is absorbed into the body.

*Question.* Making the MUsT Test a pre-requisite for approval of a sunscreen ingredient through the TEA process means delays in consumer access to products already available all over the world to protect against skin cancer. How does HHS plan to address the risk-benefit balance between additional testing of products already in use against the need for more tools to protect against the growing public health threat of skin cancer, the most common form of concern in the world?

*Answer.* Given the recognized public health benefits of sunscreen use, the FDA is committed to finding ways to facilitate the marketing of sunscreen products that include additional OTC sunscreen active ingredients. To do so, the FDA must balance the public health benefits of access to a broader range of sunscreen active ingredients against the importance of providing an adequate margin of safety for products, such as sunscreens, that are marketed for regular use. Although sunscreens are regulated as cosmetics in the European Union and elsewhere, in the U.S., they are classified as drugs because they are intended to decrease the risk of sunburn. Sunscreens marketed under the OTC monograph system that meet certain final formulation efficacy requirements are permitted to be labeled for use to decrease the risks of skin cancer and early skin aging caused by the sun when used as directed with other sun protection measures. Drug products marketed to American consumers must satisfy safety and effectiveness requirements that Congress established under the Federal Food, Drug, and Cosmetic Act.

FDA's data requests are in line with the safety data the agency currently seeks for topical drugs in general under both new drug reviews and the OTC monograph process. Understanding whether and to what extent a drug is absorbed into the body is a key element in the benefit-risk determination for all drugs, including those administered via the topical route. Of note, MUsT studies are not long-term clinical trials; for most ingredients, it is expected that the duration of the MUsT will be only a few days, depending on the metabolism of the particular drug. With respect to the extent of delay potentially created by the recommendation to conduct a MUsT, based on prior experience with other topical drug products FDA believes that the approximate time needed for a sponsor to conduct a MUsT and submit a completed report is less than 6 months, a timeframe shorter than that which has already elapsed since manufacturers received FDA's recommendations. We also note that, although the SIA imposes strict time frames for FDA's review of safety and efficacy data, it does not address the timing of data submissions by active ingredient sponsors or other interested parties. As a result, the timing of FDA's final GRASE determinations for pending and future sunscreen active ingredients will largely be determined by how quickly sponsors are able to provide the data necessary to support a finding that a sunscreen containing a particular active ingredient would be GRASE.

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QUESTIONS SUBMITTED BY HON. PATRICK J. TOOMEY

OPIOID ABUSE

*Question.* In its FY 2017 budget request, HHS seeks authority from Congress to authorize Medicare prescription drug plans to "lock in" beneficiaries who are abusing prescription opioids to a single provider and pharmacy. Senators Brown, Portman and I have introduced the bipartisan Stopping Medication Abuse and Protecting Seniors Act to give CMS this authority. It would affect only a small number of beneficiaries—less than 1 percent—who have a record of frequenting multiple



prescribers to obtain excessively high, unsafe amounts of prescription painkillers. This legislation will help to address a growing problem in my State.

The intention of our bipartisan legislation is to stop fraudulent diversion and help improve the quality of care for those who are addicted. It also allows the at-risk beneficiary to select a pharmacy they would like to use. Beneficiaries are “locked in,” not out, from a pharmacy. As you may know, this “lock-in” approach is successfully utilized by nearly all State Medicaid programs and commercial insurers. It has reduced fraud and improved care. For example, those in Oklahoma’s “lock in” programs used fewer narcotics and saw declines in emergency department visits.

When a pharmacy is unable to fulfill a Medicare prescription, a Part D plan sponsor can make a “point of sale” edit to allow the beneficiary to use another pharmacy. Such would be the case in the rare circumstance that a beneficiary could not access narcotics from their preferred pharmacy under S. 1913.

At your appearance, you referenced the need to ensure beneficiaries with legitimate pain medication needs maintain access to controlled substances. Were you speaking about the broader issue of pharmacies that have imposed their own restrictions on opioid dispensing in order to mitigate possible attention from law enforcement, and if so, does HHS plan to take any action in this area?

Answer. First, I would like to thank you and Senator Brown for your leadership on this issue. As you note, this proposal is included in our budget and we would be happy to work with you on it. HHS is working with many partners, including pharmacies, to address the problem of opioid overdose, death, and dependence. When HHS developed its Opioid Initiative, we were keenly aware of the necessity to balance the needs of patients living with pain with the public health goals of reducing opioid overdose, death, and dependence. Chronic pain impacts the lives of millions of Americans and we must support evidenced-based treatment of pain. However, there has been an over-reliance on prescription opioid pain medications and this has resulted in alarming increases in prescription drug overdose, death, and dependence. We know that certain patients do benefit from these powerful medications, so our efforts to reduce opioid overdose must not create barriers for them.

There are many reasons for our over-reliance on prescription opioids but one is the lack of provider education and clinical tools to help guide safe and appropriate opioid prescribing. Our Initiative at HHS is making investments to provide clinicians with the education and tools they need to make informed prescribing and treatment decisions. This is a critical first step in driving down the opioid problem and ensuring that patients living with pain receive the most effective and appropriate care.

The 2016 CDC Guidelines for Opioid Prescribing for Chronic Pain, currently under development, is one example of the tools we are developing for providers. These guidelines, which are targeted for primary care providers treating chronic pain in adults outside end of life care, aim to improve pain management and safety for patients and provide clinicians with factors to consider when determining the appropriate treatment for their patient, which includes the use of prescription opioids. They will provide clinicians with important information that can facilitate safer treatment and maximize the benefits their patients receive from their pain treatment regimen.

To address the issue of pain more broadly, HHS is also in the process of developing a National Pain Strategy that outlines priorities for population level research on pain, enhancing provider education on pain and its management, improving patient access to evidence-based multidisciplinary pain prevention and care approaches, and implementing payment incentives that provide for quality pain care.

Pharmacies are also important partners in our efforts, particularly around training and education as well as naloxone access. In October 2015, the President announced Federal, State, local and private sector efforts aimed at addressing the prescription drug abuse and heroin epidemic. This announcement included commitments from pharmacy chains and several pharmacy organizations:

- The **American Pharmacists Association**, with an outreach capability of more than 250,000 individuals, will educate pharmacists, student pharmacists, and stakeholders through a new Resource Center on opioid use, misuse, and abuse.

- The **American Society of Health-System Pharmacists** will provide training and resources to 40,000 pharmacists, student pharmacists, and pharmacy technicians.
- The **National Association of Boards of Pharmacy** will enhance access to prescription drug monitoring program data for thousands more physicians and pharmacists in Arizona, Delaware, Kentucky, and North Dakota in 2016.
- **CVS Health** will allow CVS/pharmacy to dispense naloxone without patients needing to present an individual prescription pursuant to a standing order from a physician or collaborative practice agreement in an additional 20 States in 2016 and will launch a new drug abuse prevention program called Pharmacists Teach, where its pharmacists will make 2,500 presentations in high school health classes.
- **Rite Aid** will train 6,000 pharmacists on naloxone use over the next 12 months, and expand their naloxone dispensing program to additional States.
- The **National Association of Chain Drug Stores** will continue to educate their 125 chain member companies (40,000 pharmacies with 175,000 pharmacists) about opioid overdose and naloxone.
- The **National Community Pharmacists Association**, representing 23,000 pharmacies with over 62,000 pharmacists, will be distributing inserts to community pharmacists that highlight safe drug disposal and naloxone.

It should also be noted that HHS continues to work closely with the White House Office of National Drug Control Policy, as well as our colleagues at the Department of Justice to ensure a coordinated Federal response that best leverages our resources to effectively implement strategies that reduce the impact of opioid use disorders and overdose.

#### THE 25 PERCENT RULE

*Question.* In 2013, Congress enacted a new set of criteria for patients receiving care at long-term acute care hospitals. Congress also continued to prohibit CMS from adopting a 2007 regulation that would require LTCHs to rely upon at least four feeder hospitals who would be discharging or transferring patients. This is known as the 25% rule. Congress was concerned that many LTCHs would be unable to comply given that their communities do not have four major hospitals. Thus, LTCHs, especially in Pennsylvania, would be forced to close and critically ill seniors would be without high-quality post-acute care. As you may know, the statutory prohibition on the 25 percent rule expires in July.

In a congressionally directed report on LTCH payment policy from July 2015, CMS stated that “given the significant payment changes to the LTCH PPS . . . we believe it would be advantageous to analyze the impact of the implementation of a revised payment system including the introduction of site neutral payment rates to the LTCH PPS prior to considering further extensions (or modifications of the extensions) of the suspension of the 25 percent policy.” In this context, the operative policy is the 50 percent rule enacted by Congress since the 25 percent rule has not been in effect since 2007.

Furthermore, CMS goes on to state that any extensions or modifications would be dependent on analyzing admissions data under the revised payment system (*i.e.*, site neutral).

Given CMS’s reasonable view of the change in the LTCH sector, and the establishment of site-neutral, criteria-based reimbursement for LTCHs, why would CMS choose to implement a regulation that has been dormant for nearly a decade?

I’ve introduced legislation along with Senator Michael Bennet to maintain the existing 50 percent rule for two more years, giving CMS the time needed to evaluate admissions data in the current LTCH environment. Our bill is the Preserving Patient Access to Post-Acute Hospital Care Act (S. 2108). I would welcome technical assistance from HHS-CMS on our legislation as Congress and the Executive Branch consider whether the 25 percent rule is even necessary given the new patient criteria requirements.

Answer. Being from West Virginia, rural health is a priority for me as Secretary. HHS remains dedicated to improving access to quality health care for rural Americans.

As you know, the new clinical criteria for long-term care hospitals (LTCHs) just took effect in fiscal year 2016. In considering the potential policy proposals, CMS recognized that there is a current statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the statute that is

scheduled to expire in FY 2016. The 25-percent threshold payment adjustment policy was implemented based on analyses of Medicare discharge data that indicated that patterns of patient shifting appeared to be occurring more for provider financial advantage than for patient benefit. In order to discourage such activity, a payment adjustment was applied to LTCH discharges of patients who were admitted to the LTCH from the same referring hospital in excess of an applicable percentage threshold CMS believes that the site neutral payment rate will not address these patient shifting concerns unless the 25-percent threshold payment adjustment is applied to site neutral payment rate cases in the same manner as it is applied to LTCH PPS standard Federal payment rate cases.

The policy also provides for special treatment of rural, urban single, and Metropolitan Statistical Area (MSA)-dominant hospitals. In the case of an LTCH that is located in a rural area, the applicable threshold is set at 50 percent instead of 25 percent. For an LTCH that admits Medicare patients from the only other hospital in the MSA or from a MSA-dominant hospital, the payment threshold can vary between 25 percent and 50 percent, and would be equal to the percentage of total Medicare discharges in the MSA from the MSA-dominant hospital during the LTCH's cost reporting period.

It is too early to know whether these criteria will accomplish the goals of the new payment system. We need some experience under the new system first before we revisit the 25 percent rule. CMS believes it is prudent to maintain these policies as they currently exist while the agency gains experience and finalizes its proposal to apply the 25-percent threshold policy to site neutral payment rate cases. In the event that policy modifications are warranted, CMS would address them through future rulemaking.

We are happy to work with you and provide technical assistance on the legislation.

#### FEDERAL EXCHANGE

*Question.* CMS stated in its Notice of Benefit and Payment Parameters for 2017 that user fee collections will not be sufficient to cover Exchange operations in 2017, and was seeking an OMB waiver so CMS could use other monies to finance the Exchange. In the FY17 budget request, HHS estimated the need for \$535 million in appropriations to help operate the Exchange.

Please provide any advisory opinions, memorandums, or communication from the CMS Office of General Counsel about the use of user fees for exchange operations versus Secretarial activities that could not be covered by user fees.

*Answer.* Eligibility for user fees is determined under Office of Management and Budget (OMB) Circular A-25R and must "cover all Federal activities that convey special benefits to recipients beyond those accruing to the general public." The preamble to the Notice of Benefit and Payment Parameters explains how Marketplace user fee policy complies with this guidance, and this language is reviewed and cleared by HHS OGC as part of the regular regulatory review process. The \$535 million requested in the President's budget funds the cost of conducting activities that cannot be funded by the user fee. These activities provide services to all Marketplaces and SHOPS whether they are operated by the State or CMS, and therefore do not meet the "special benefit" test. Activities that are not eligible to be funded through user fees include: payment of financial assistance to issuers, eligibility verification services provided through the Data Services Hub (DSH), quality reporting, and some eligibility appeals. CMS regularly reviews allocable activities that provide support to both eligible and non-eligible activities to ensure all eligible activities are appropriately funded via the user fee. CMS, however, will always require some amount of discretionary appropriated budget authority to conduct non-eligible activities.

*Question.* In Medicare, Medicaid and the private sector, health care delivery and payment systems are witnessing significant and accelerating change. Yet the Program of All-Inclusive Care for the Elderly (or PACE), which pioneered so many of the features we now seek to build into our health care system, is being constrained by regulations that are almost a decade old. What is the administration doing to update those regulations and provide more flexibility to PACE so that seniors can have greater access to this model of integrated, community-based and person-centered care?

*Answer.* I share your support for the PACE program and CMS is taking steps to modernize and streamline PACE enrollment and services.

PACE has proven successful in keeping frail elderly individuals in the community, and we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more States, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS has received numerous suggestions from PACE organizations, beneficiaries, members of Congress, and other stakeholders and looks forward to working with all stakeholders throughout the rulemaking process.

CMS is dedicated to continuing exploring new opportunities and ideas to further strengthen PACE programs and services.

*Question.* Recently, Congress enacted S. 1362 authored by Senator Carper and me. Our legislation gave the Department authority to develop pilot programs for extending the PACE model to new populations so additional frail individuals can live in the comfort of their home and receive the care they need instead of having to be transferred to a nursing home setting. How is the administration proceeding in the development of those pilots and when can we expect CMS to announce the opportunity to participate in a pilot?

*Answer.* First, I would like to thank you and Senator Carper for your leadership on this issue. The recently enacted PACE Innovation Act of 2015 expands the Department's authority to allow waivers in order to conduct demonstration projects that involve PACE. We are excited about these new opportunities, and CMS is developing options for moving forward.

The 2016 President's budget includes a legislative proposal to create a pilot demonstration to test whether the PACE program can effectively serve a younger (55 and under) population without increasing costs. This proposal was removed from the 2017 President's budget because your recently passed legislation grants HHS the authority to test this expansion and other PACE models under the CMS Innovation Center authority.

CMS is actively working with stakeholder and advocacy groups to determine how the PACE comprehensive care approach can be combined with community care models and expanded to reach a broader population. We will keep your staff informed as this work proceeds.

#### FDA OPIOID ER/LA REMS

*Question.* The FDA has an Extended Release/Long-Acting Opioid Risk Evaluation and Mitigation Strategy. In implementing the REMS, FDA set a goal of having one-quarter of 320,000 prescribers being trained under the medical education requirements of the REMS by March 2015. Within 4 years' time, 60% of prescribers were to be trained. Did FDA hit its goal for March 2015, and how many prescribers have completed the training today?

*Answer.* We are making significant strides in our efforts to reduce opioid dependence, overdose, and death, but more needs to be done. The President's FY17 budget continues to expand the fight against opioid abuse, misuse, and overdose with significant investments in interventions that will make the most impact. The budget includes a \$10 million increase, for a total of \$77 million, 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 DC through the Prescription Drug Overdose Prevention to States program, as well as \$5 million to harmonize technical standards in support of Prescription Drug Monitoring Programs, improve clinical decision-making, and further the adoption of electronic prescribing of controlled substances.

Regarding your specific question, as of February 28, 2015 the number of ER/LA opioid analgesic prescribers trained at this milestone was 37,512, which is slightly less than half the 80,000 prescriber training goal with 2 years. FDA subsequently received updated information on these numbers, which shows a total of 38,370 ER/LA prescribers trained as of May 28, 2015. Of note, over 100,000 healthcare professionals completed the CE training; but cannot be counted towards the training goal due to either not prescribing an ER/LA opioid analgesic in the past 12 months or not being DEA registered.

We intend to share these results with a joint public meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug

Products Advisory Committee to assess its impact on preventing the misuse and abuse of opioids. The agency will training and expansion of the REMS program to include immediate-release opioids. For more information on the upcoming advisory committee meeting, please see the Federal Register notice at: <https://federalregister.gov/a/2016-05573>.

#### GDUFA

*Question.* Until enactment of the Generic Drug User Fee Act, FDA's facilities database lacked accurate information on facilities involved in the manufacture of drugs. Today, over 4,220 facilities supporting generic drug applications have annually self-identified improving FDA's visibility into the global drug supply chain. As a result we know that China is now the world's largest supplier of Active Pharmaceutical Ingredients (API) and also has the largest number of foreign, FDA-registered drug manufacturing facilities, about 700, followed by India.

Of over 4,000 facilities registered through GDUFA program, how many have been inspected within last 3 years?

*Answer.* Ensuring safety in these facilities is a priority for the FDA. The chart below is the total number of *all* human drug inspections, both domestic and foreign (excludes State Contract and State Partnership Inspections), conducted by FDA investigators for Fiscal Years 2013–2015:

#### FDA Human Drug Inspections \*

Fiscal Year (FY)	Domestic Inspections	Foreign Inspections
FY 2013	1,851	827
FY 2014	1,869	993
FY 2015	1,775	1,072

\*This data was generated on 12/10/2015 and excludes State Contract and State Partnership Inspections.

**NOTE:** The ORA database for drug inspection counts is not coded to separate out GDUFA inspections from other drug firm inspections.

*Question.* More than 900 new employees in the office of Generic Drugs have been hired since GDUFA began. Of these new hires, how many inspectors are assigned to foreign and domestic drug manufacturing facilities?

*Answer.* Field investigators are actually within the Office of Regulatory Affairs (ORA) rather than the Office of Generic Drugs (OGD). One-hundred forty people have been hired in ORA under the Generic Drug User Fee Act (GDUFA) from 2013–2015 with 80 hired as field investigators to perform both foreign and domestic drug inspections.

#### QUESTIONS SUBMITTED BY HON. PAT ROBERTS

*Question.* In 2011, the president issued an Executive Order directing each agency to periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome. During these reviews, what were some of the regulations that, according to public comments, were most burdensome?

*Answer.* The Department of Health and Human Services has made significant progress in its retrospective review activities since President Obama's January 2011 Executive Order 13563 on Improving Regulation and Regulatory Review. In the Executive Order, the President recognized the importance of a streamlined, effective, efficient regulatory framework to achieve economic growth, increased investment, job creation, and competition. HHS is committed to identifying and reviewing existing regulations in order to eliminate those that are obsolete, unnecessary, burdensome, or counterproductive or to modify others to increase their effectiveness, efficiency, and flexibility.

The Executive Order calls not for a single exercise, but for "periodic review of existing significant regulations," with close reference to empirical evidence. It explicitly states that "retrospective analyses, including supporting data, should be released online wherever possible." Consistent with the commitment to periodic review and to public participation, HHS continues to assess its existing significant regulations. Since the President's Executive Order on Improving Regulation and Regu-

latory Review, HHS has made significant progress in its retrospective review activities.

Since January 2012, HHS has posted biannual progress updates on its retrospective review initiatives; for instance, in the July 2014 update, HHS highlighted the completion of a series of rules from the Centers for Medicare and Medicaid Services (CMS) to reform existing regulations to reduce unnecessary costs and increase flexibility for health care providers. This final rule reduced the burden of outmoded Medicare rules concerning numerous daily practices in hospitals, thereby increasing the ability of health care entities to focus resources on providing high-quality patient care.

It is estimated that the overall national cost savings created by this rule is between approximately \$230 million to \$830 million per year annualized before 2019. Additionally, HHS invites the public to suggest additional items for retrospective review (for reasons including regulatory burden) at [www.hhs.gov/retrospectivereview](http://www.hhs.gov/retrospectivereview).

*Question.* In 2014, a CMS spokesperson said that regarding the Affordable Care Act's risk corridor's program, "the policy, modeled on the risk corridor provision in Part D was estimated to be budget neutral, and we intend to implement it as designed." However, since then, HHS has said that they will "explore other sources of funding for risk corridors payments." Given the shortfall of about \$2.5 billion shortfall for 2014, what "other sources of funding" was this statement referring to or is HHS considering?

*Answer.* As noted in previous guidance, additional risk corridors payments for program year 2014 will be paid out of 2015 risk corridors collections, and if necessary, 2016 collections. Since this is a 3 year program, we will not know how collections compare to payments for the program until the end of FY 2017, when the data from all 3 years of the program can be analyzed and verified. In the event of a shortfall over the life of the 3-year Risk Corridors program, the agency will work with Congress to provide necessary funds for outstanding payment.

*Question.* HHS's National Vaccine Program Office (NVPO) recently finalized the National Adult Immunization Plan (NAIP). What steps does your department plan to take in the short-term and long-term to advance and monitor progress in NAIP implementation through both Federal and non-Federal stakeholders?

*Answer.* The National Adult Immunization Plan (NAIP) is a 5-year strategic plan developed through the HHS National Vaccine Program Office (NVPO) to address the goals of (1) strengthening the adult immunization infrastructure; (2) improving access to adult vaccines; (3) increasing community demand for adult immunizations; and (4) fostering innovation in adult vaccine development and vaccination-related technologies. As a national plan, it will require engagement from a wide range of Federal and non-Federal stakeholders to achieve these goals. The plan emphasizes collaboration and prioritization of efforts that will have the greatest impact. The NAIP is intended to facilitate coordinated action by Federal and non-Federal partners to protect public health through vaccination of adults, and includes indicators to draw attention to and track progress against core goals, such as adult vaccination coverage and percentage of adults over 18 who are vaccinated against various diseases.

In developing the Plan, NVPO sought input from the adult immunization community, particularly regarding their role in reaching the Plan's goals and objectives. Looking forward, NVPO is developing an accompanying implementation plan, planned for release in 2017. This implementation plan will outline a set of concrete actions that can be taken by different stakeholders to support plan objectives and goals.

NVPO, in partnership with other Federal agencies, will regularly track and annually summarize progress on achieving the goals and indicators in the NAIP and present them to the Assistant Secretary for Health and to the National Vaccine Advisory Committee, which recommends ways to prevent infectious diseases through vaccine development and provides direction to prevent any adverse reactions to vaccines, in an effort to highlight the impact of NAIP implementation activities, as well as to identify any areas where progress is lagging and propose corrective action where needed.

*Question.* Please describe CMS's approach to adverse event tracking for biosimilars in both Part B and Part D. Are PBMs and insurers capable of tracking product-specific biosimilar adverse events in Part B given the current code modifier process proposed by CMS?

Answer. Patient safety is a top priority at HHS. In the final CMS rule finalizing Part B payment policy on biosimilars issued late last year, CMS addressed concerns about the need to track the particular biosimilar a beneficiary receives. CMS noted that it was developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance, and would be providing guidance on mechanisms for tracking drug use through claims information in the near future. Since the publication of the final rule, CMS has implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product and has published guidance on the use of the modifier. Each biosimilar, as CMS begins to pay for it, will be assigned a unique modifier to identify that particular biosimilar. This unique HCPCS-modifier combination allows the tracking of exactly which biosimilar a beneficiary receives. PBMs, insurers, the FDA and other bodies interested in pharmacovigilance will be able to identify the biosimilar each beneficiary received.

*Question.* CMS recently announced its intent to test new payment methods for Medicare Part B drugs through CMMI. What additional payment changes is CMS considering beyond modifications to the ASP reimbursement rate? Will these payment methods go through regular notice and comment rulemaking, and what is the timeline for beginning this demonstration? How will CMS select the drugs to which these additional payment modifications will apply?

Answer. We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. We continue to look at a number of options in this area.

Last fall, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from State and Federal government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation while protecting access and affordability. We came away with feedback to address these challenges in a holistic fashion addressing three important areas: (1) increasing access to information to support better health care decisions, (2) driving innovation that improve and save lives, (3) and strengthening incentives in the delivery system to reward quality care to patients and encourage value-based and outcomes-based decision making.

Coming out of that forum, we have identified several areas of potential opportunity for consideration and collaborative policy development. The need for better information about drug prices and impacts on patients and providers in making better health care decisions was one theme that we heard across multiple panels. To that end, in December, we took a first step forward by providing more detailed information on Medicare spending on prescription drugs, for both Part B (primarily drugs administered in doctors' offices and other hospital outpatient settings) and Part D (primarily drugs patients take themselves) to better inform decision making. The Medicare Drug Spending Dashboard provides important information to the public in an accessible format, and also serves as a first step to provide other information that can enrich the picture.<sup>8</sup>

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QUESTIONS SUBMITTED BY HON. MICHAEL B. ENZI

*Question.* Please detail what the Department of Health and Human Services' plan and steps for implementing the recommendations made by the Government Accountability Office (GAO) in their report published February 23, 2016. It should be concerning to every taxpayer that the undercover work done by GAO went forward with largely no check by the Department.

In the GAO report, they highlighted eight recommendations. The Department has agreed that those changes should be made. You provided comments on those recommendations to GAO, please outline what process will be put in place to effect those changes.

In your response please include the Department's understanding of the problem, what policies will be changed to address the problems, what kind of action plan will be put in place, what kind of steps will need to be taken by the agency—including any changes in guidance or rulemaking, what other entities or sectors will be impacted by these changes, and a timeline for when the problems will be solved.

<sup>8</sup>All responses are accurate as of February 11, 2016.

Answer. We look forward to receiving the final report and recommendations from GAO and take seriously our responsibility to implement these findings. As with all GAO reports, we will continue to work with the GAO to improve HHS programming.<sup>9</sup>

*Question.* GAO found an opportunity to reduce duplication and achieve greater results in their “2015 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits,” making the following recommendation:

Please help ensure that the eight Federal agencies administering over 100 programs supporting individuals with serious mental illness are able to develop an overarching perspective in order to understand the breadth of programs and resources used—including any potential gaps or overlap—greater coordination of Federal efforts is needed from the Department of Health and Human Services, and within it, the Substance Abuse and Mental Health Services Administration, which is required to promote coordination of programs relating to mental illness throughout the Federal Government.

Please detail what HHS currently does to coordinate this work and what steps, if any, are being considered to improve that work? Please include any gaps that the Department has identified, any areas that require additional authority to take coordinating action, and what formal or informal processes are in place to work with other agencies.

Answer. HHS has been working to build upon and expand intra- and inter-agency Federal coordination efforts related to individuals with serious mental illness (SMI). The primary mechanism for intra-agency coordination is the Behavioral Health Coordinating Council’s (BHCC) Subcommittee on Serious Mental Illness, which is comprised of 22 members and 24 contributors from more than 15 Federal offices and agencies, including Substance Abuse and Mental Health Services Administration (SAMHSA); National Institutes for Health (NIH), including the National Institute for Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA); Assistant Secretary for Planning and Evaluation (ASPE); Assistant Secretary for Community Living (ACL); Health Resources and Services Administration (HRSA); Agency for Health Care Research and Quality (AHRQ); Assistant Secretary for Financial Resources (ASFR); Centers for Medicare and Medicaid Services (CMS); Food and Drug Administration (FDA); Centers for Disease Control and Prevention (CDC); Office of Civil Rights (OCR); Office of the National Coordinator (ONC); and Office of the Assistant Secretary for Health (OASH).

In 2015, the Subcommittee produced a comprehensive compilation of Federal programs that specifically target and/or support individuals with SMI. In support of its overall mission, the SMI Subcommittee has established the Secretarial Initiative on SMI to address the needs of Americans living with SMI. The aim of this initiative and the HHS Action Plan will center on improving outcomes for people with SMI and support for their families. HHS prioritizes action in three areas reducing the duration of untreated SMI in individuals through early engagement in care soon after these conditions arise; improving the quality of care through stronger measurement and accountability; and increasing access to evidence-based and community-based treatment and support services. These Priorities are reflected in the President’s budget proposal.

SAMHSA continues to advance the three priority SMI priority areas (Early Engagement in Care, Increased Quality of Care, and Availability of Community Based Supports), as well as other priority behavioral health issues, through its leadership of several other Federal efforts, including:

- Working closely with the U.S. Interagency Council on Homelessness (USICH), which I currently chair, and the Departments of Housing and Urban Development (HUD) and Veterans Affairs (VA) to implement the Federal strategic plan to prevent and end homelessness called “Opening Doors.”
- Expanding the Behavioral Health Treatment Court Collaborative working with the Department of Justice, courts, and criminal justice agencies to enable more courts and providers to collaborate on supporting individuals with SMI in their communities.
- Continuing to collaborate with the Departments of Education and Labor, and States on supported employment grants that enhance a State’s ability to sus-

<sup>9</sup>All responses are accurate as of February 11, 2016.



tain and bring to scale the use of evidence-based supported employment programs for adults with SMI.

- Leading, in partnership with many Federal departments such as the Department of Defense, Veterans Affairs, Interior, and HHS agencies such as the CDC, ACL, Indian Health Service (IHS), and the Office of the Surgeon General, the National Strategy for Suicide Prevention and the National Action Alliance for Suicide Prevention to reduce the number of suicides. Continuing to promote supportive housing services through Projects for Assistance in Transition from Homelessness (PATH) collaborating with HUD.

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QUESTIONS SUBMITTED BY HON. ROB PORTMAN

CMMI DEMONSTRATIONS

*Question.* Last fall, CMS's Center for Medicare and Medicaid Innovation (CMMI) released two model test announcements related to Medicare Advantage and Part D to be implemented in 2017. The first relates to testing value-based insurance design (VBID) and the second relates to testing enhanced medication therapy management (MTM) strategies. As I understand it, applications for both demonstrations were due to CMMI last month. How many plan sponsors applied to participate in each demonstration? How many applications do you anticipate will be approved for each demonstration? What is CMMI doing to ensure that the operation of these demonstrations are aligned with the regular preparations for the 2017 bid cycle and plan year?

*Answer.* As part of the Health Plan Innovation Initiatives, in 2015, CMS announced two models that will test different innovations in Medicare health and prescription drug plans, and the impact they have on improving health outcomes and lowering expenditures for plan enrollees. As you know, applications for the Medicare Advantage VBID model were due in November 2015, and applications for the Part D Enhanced MTM model were due in January 2016. CMS is currently evaluating applications received.

The model timelines were established to align with the annual bid cycle process in Parts C and D and information related to these models will be included in the 2017 Call Letter.

SAMHSA

*Question.* 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 program, in lieu of other ones listed in their National Registry of Evidence-Based Programs and Practices (NREPP). In December, the Mental Health Awareness and Improvement Act, passed the Senate by unanimous consent. In this bill, we reauthorized mental health awareness training programs that will help train our country's educators to recognize and understand mental illness and we did so in a way that allows States to choose the type of training programs that will best suit the needs of their schools and communities. 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 State and local agencies should be able to choose the evidence-based and proven program that works best for their school and community?

*Answer.* Mental health is a priority that we share with you and your colleagues in Congress. As part of SAMHSA's overall efforts to improve the behavioral health awareness among school-age youth and their communities, SAMHSA administers three Project AWARE grant programs: one at the local level as you note, one at the State level, and another at a broader community level.

As you know, the Project AWARE program expands the capacity of State and local education agencies to increase awareness of mental health issues, train school personnel and other adults, and connect children and families who may experience behavioral health issues with appropriate services.

SAMHSA has implemented Project AWARE following Congress's direction. To provide appropriate flexibility within the Mental Health First Aid program, grantees at the State level are able to use funds to support implementation of a range of other evidence-based programs to improve student behavioral health according to

the needs of their State and communities. In general, language in SAMHSA's Mental Health First Aid funding opportunity announcement is designed to give grantees flexibility to choose the practices that meet the goals of the grant program and meet the unique needs of the grantee in question.

#### MEDICARE ADVANTAGE

*Question.* The President's budget calls for \$77 billion in cuts to the Medicare Advantage program by establishing a competitive bidding program. After years of rate reductions and changes to the payment system, further cuts to the program will create more uncertainty at a time when beneficiaries need stability in Medicare Advantage. How will CMS ensure that competitive bidding will not jeopardize beneficiary choice of and access to health plans, or the current availability and generosity of supplemental benefits?

*Answer.* Medicare Advantage represents a growing part of the Medicare program with more than a third of all Medicare beneficiaries enrolled in a Medicare Advantage plan. If recent growth in the program continues, a majority of Medicare beneficiaries could be enrolled in Medicare Advantage by 2030. According to MedPAC analysis, net program spending by MA plans is approximately 2 percent above spending for fee-for-service, on average. Paying more for Medicare Advantage is not sustainable—for beneficiaries or taxpayers. As the proportion of Medicare beneficiaries who are enrolled in Medicare Advantage increases, the current financing model for the Medicare Advantage program that overpays relative to fee-for-service threatens the long-term fiscal sustainability of the overall Medicare program.

While the average Medicare Advantage plan margin per beneficiary may decrease under the proposal, projected increases in enrollment will continue to make Medicare Advantage attractive for private plans. This proposal would also reduce the rate of growth in overall Medicare spending, resulting in lower growth in Part B premiums for all beneficiaries. Additionally, the budget proposal is structured so that the majority of beneficiaries will maintain access to supplemental benefits and will allow higher quality plans to provide more supplemental benefits if they bid at the same rate as lower quality competitors. Implementing competitive bidding in the Medicare Advantage program would reduce the rate of growth in Medicare Advantage payments and premiums, contributing to a sustainable program over the long term.

#### IMPLEMENTATION OF COMPLEX REHAB TECHNOLOGY DELAY

*Question.* At the end of 2015, I worked with my colleague Senator Casey to pass S. 2425, the "Patient Access and Medicare Protection Act (PAMPA)." The bill included a provision that directed CMS from applying the competitive bidding pricing structure to complex rehabilitative equipment until 2017 and instead allow individuals who rely on complex rehabilitative equipment to maintain access to these products. However, on January 22, 2016 CMS announced that it cannot implement section 2 of the "Patient Access and Medicare Protection Act (PAMPA)" until July 1, 2016. I am very concerned with the impact this will have on providers and beneficiaries who rely on these complex rehab accessories. Paying at the reduced amount for 6 months of the 12 month delay creates the same financial hardship that would be in place without the delay.

I understand that CMS performs regular updates to its software and systems. While I understand that this bill was not signed into law until December 28, 2015, I know when Congress has approved last minute delays in the past CMS has been able to prioritize revised updates and guarantee that providers were paid appropriately.

- Can you explain why it will take CMS over 6 months to implement this provision?
- This access issue for people with disabilities was identified by Congress and communicated to CMS in early 2015. I joined 25 other Senators and 101 House members in a letter to CMS highlighting the need for a "fix" of this issue early in 2015. CMS's refusal to accept the recommendation in the congressional letters necessitated the passage of this legislation. Was CMS unaware of Congress's concerns of this issue?

*Answer.* We are aware of and 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.

To ensure beneficiary access to these accessories particularly for vulnerable populations, CMS recently posted on DME Spotlight web page of their website that advance payment may be available for suppliers. According to our regulations, an advance payment means a conditional partial payment made by the contractor in response to a claim that is unable to process within established time limits. Suppliers are able to submit a single advance payment request to their Medicare Administrative Contractor for multiple claims during this period. These advance payments may be issued if certain regulatory requirements are met.

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

#### WORKERS COMPENSATION MEDICARE SET-ASIDE PROGRAM

*Question.* The Workers Compensation Medicare Set-Aside (WCMSA) program requires the Centers for Medicare and Medicaid Services (CMS) to review workers' compensation settlements submitted to CMS to determine Medicare's interest in future medical amounts that may have been included in workers' compensation settlements involving Medicare beneficiaries.

As a sponsor of S. 1514, the Medicare Secondary Payer and Workers' Compensation Settlement Agreements Act, I look forward to working with you to improve the CMS process of reviewing Workers' Compensation Set-aside Arrangements and establishing a clear, predictable, and efficient system. S. 1514 also includes a provision that would authorize payment of amounts for future medical in workers' compensation settlements to be paid directly to meet Medicare Secondary Payer (MSP) future medical obligations.

The administration's Fiscal Year (FY) 2017 budget request includes a provision under which CMS would be authorized to accept lump sum certain payments to satisfy MSP obligations. The language specifically provides:

Allow Beneficiaries to Pay a Sum Certain to Medicare for Future Medical Items and Services Medicare beneficiaries are unable to satisfy Medicare Secondary Payer "Future Medical" obligations at the time of settlement, judgment, award, or other payment because the current law does not specifically permit the Secretary to deposit such payment in the Medicare Trust Funds. Future Medical is defined as Medicare covered and otherwise reimbursable items and/or services furnished after the date of settlement, judgment, award, or other payment. This proposal expands current Medicare Secondary Payer statutory authority to permit the Secretary to deposit into the Medicare Trust Funds a lump sum, upfront payment from beneficiaries when they obtain liability insurance, no-fault insurance, and workers' compensation settlements, judgments, awards, or other payments. [\$65 million in savings over 10 years]

Will your office work with me to review data and assumptions and determine the savings that can be identified through direct payment options, including those proposed in S. 1514?

*Answer.* We are happy to provide technical assistance on the legislation you mentioned.

Currently, individuals involved in certain workers' compensation situations are able to use Medicare's formal, yet voluntary, Medicare Set-Aside Arrangement (MSA) review process in order to determine if a proposed set-aside amount is sufficient to meet their MSP obligations related to "future medicals." Medicare beneficiaries are currently unable to satisfy their Medicare Secondary Payer Future Medicals obligations at the time of settlement, judgment, award, or other payment. Beneficiaries and their legal representatives have requested the opportunity to resolve a beneficiary's Medicare Secondary Payer obligation with respect to Future Medicals by paying a lump sum to Medicare, perhaps at a time close to or contemporaneous with the settlement, judgment, award, or other payment at issue.

As you noted, the President's FY 2017 Budget request includes a proposal to expand current Medicare Secondary Payer statutory authority to permit the Secretary to deposit into the Medicare Trust Funds a lump sum, upfront payment from beneficiaries when they obtain liability insurance, no-fault insurance, and workers' compensation settlements, judgments, awards, or other payments. This would benefit the beneficiary as he/she would have no need to track and administer the funds at issue, thereby avoiding administrative costs for the beneficiary as well as the Medicare program.

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QUESTIONS SUBMITTED BY HON. TIM SCOTT

*Question.* In response to my question about the solvency of State healthcare CO-OPs, you mentioned that HHS has sought to provide clarity in guidance issued to State directors. Could you expand on that and provide my office with the guidance you've issued? Have you gotten feedback on said guidance from the State directors?

*Answer.* On January 27, 2016 CMS issued additional guidance through Frequently Asked Questions (FAQs) about the CO-OP program.<sup>10</sup>

*Question.* Furthermore, when considering the future solvency of the CO-OPs, what steps is CMS taking to ensure stakeholders are made whole and consumers held harmless from costs incurred by the failed CO-OPs? What is the impact of the CO-OP closures on the wider market including insurers, providers, and agents/brokers?

*Answer.* The primary focus of all our efforts is to ensure that CO-OPs and other Marketplace plans are meeting the needs of their consumers and building for a successful future. Each of the consumers in the CO-OPs that closed at the end of 2015 maintained coverage until the end of the year, and nearly three-quarters<sup>11</sup> of the CO-OP Marketplace consumers have continued their coverage in a new plan in 2016. Affected CO-OP enrollees had access to a special enrollment period, and are able to shop for 2016 coverage on the Marketplace until February 28, 2016. In all cases, CMS is focused on making sure consumers continue to receive medical services.

The CO-OP program is only one part of the Affordable Care Act's overall approach to encourage competition and to give consumers a variety of affordable coverage choices. Whether consumers are getting coverage from a CO-OP, another issuer, or Medicaid, millions of Americans who were previously uninsured now have access to affordable, high quality health care coverage. As several of the Affordable Care Act's coverage provisions took effect, an estimated 20 million Americans gained coverage. In the years since the passage of the Affordable Care Act, we have seen increased competition among health plans and more choices for consumers.<sup>12</sup> During the third Marketplace Open Enrollment, 9 out of 10 returning customers were able to choose from 3 or more issuers for 2016 coverage, up from 7 in 10 in 2014.<sup>13</sup>

*Question.* States have been told there are sufficient funds in the temporary Reinsurance program to pay all reinsurance money owed to individual market issuers. For CO-OPs that are in a receivership but that have made all required payments to be eligible to participate in the reinsurance program, is the Federal Government considering offsetting amounts owed to CO-OPs through the Reinsurance program by payments owed by CO-OPs for their solvency/startup loans?

*Answer.* We take our obligation to taxpayers very seriously. The U.S. Department of Justice is responsible for collecting any debts owed the U.S. Government. While it is too early to tell how much money can be recovered, we are working in close collaboration with the Department of Justice and will use all available tools to recover money from these companies.

*Question.* If CMS intends to set off any amounts owed to failed CO-OPs to recoup the amounts provided under the loan agreements, this set-off will likely mean that State insurance directors will need to utilize guaranty associations (where available) to help pay providers for covered claims. Is CMS aware that it would then ulti-

<sup>10</sup> <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf>.

<sup>11</sup> Does not include consumers who enrolled in new plans outside the Marketplace.

<sup>12</sup> [www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html](http://www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html).

<sup>13</sup> [www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html](http://www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html).

mately be recouping these funds from the taxpayers of the States in which these programs were operating? Do you believe that to be fair to taxpayers?

South Carolina law provides for a guaranty association. The South Carolina Life and Accident and Health Insurance Guaranty Association will help pay some covered claims for South Carolina members and providers up to the limits provided under South Carolina law. What will happen to the providers and members with CO-OP claims in States where there is no guaranty fund protection? How will those CO-OP members be protected? How are States with no guaranty funds supposed to protect their citizens from this failed experiment?

Answer. As the primary regulators of insurance, States have their own laws that govern the orderly wind-down of any insurance company that goes out of business in their State. During closeout, most CO-OPs exiting the market were placed into a receivership or supervisory status that controls assets, expenses, and contractual rights and obligations including ongoing operating costs and claims payment. These arrangements protect remaining funds. As you mentioned, the availability of guaranty funds does impact the run-out of outstanding claims. CO-OP wind-downs are treated like the wind-downs of other health insurers and are overseen by State Departments of Insurance. Each State determines whether insurers participate in a guaranty association and HHS has no role in that decision.

*Question.* I understand that the purpose of the enrollment periods in Obamacare are to enroll people on a consistent basis and prevent those who would enroll immediately before they would actually need to use insurance. The latter scenario seems to place a significant cost burden on private insurers participating in the exchanges. At the same time, it seems that, in a way, HHS is essentially undercutting the purpose of the enrollment periods by allowing “special enrollment periods” for a wide variety of purposes, some of which may not be related to someone’s health condition. These special enrollment periods seem to again, place a lot of costs on the private insurers in the exchanges, and therefore make the exchanges much less sustainable and attractive for private insurers. How do we create consistency in enrollment so that the exchanges may be more attractive to private insurers?

Answer. Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- Clarifying language to make the rules of the road are clear to everyone,
- Reviewing all SEPs and eliminating those that are no longer necessary, such as:
  - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy;
  - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents;
  - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit;
  - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays;
  - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options;
  - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and providing stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes.

We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.

*Question.* As you know, the President has proposed additional—and costly—incen- tives for the remaining States to expand Medicaid. This is in addition to the Medi- caid expansion we have already seen under the ACA. Because of this rapid growth, the quality of care that the program is able to offer has diminished greatly. For example, even once they have coverage, it continues to be difficult for Medicaid bene- ficiaries to find a doctor that participates, particularly in underserved areas without lots of physicians to choose from. The system is overburdened. Given this, do you

still think that Medicaid expansion, and the President's request for additional incentives for further expansion, are responsible or in the best interest of millions of Americans?

Answer. For five decades, Medicaid has helped facilitate access to needed health services and provided financial security through protection from high out-of-pocket costs for millions of low-income Americans. We continue to see Democratic and Republican governors and bipartisan coalitions across the country working hard to expand. We know that Medicaid has played an important role in providing comprehensive care for children that helps support their growth, school readiness, and development. Medicaid has also supported working families whose employers do not offer affordable health insurance, and fostered better health for pregnant women and positive birth outcomes for their babies by facilitating access to critical prenatal services. It has helped address the frequently complex health needs of people with disabilities, and supported them in living independently. And it has covered long-term care services and supports for millions of America's seniors and works in concert with Medicare to meet critical health needs.

You raise financial incentives for States, and your concerns around cost. Studies show that Medicaid expansion is a net positive for State budgets, even after the Federal match falls below 100 percent.<sup>14</sup> Medicaid expansion brings additional Federal resources into State economies, which creates jobs and supports economic growth, ultimately improving State budgets. In Kentucky, expansion is projected to add 40,000 jobs and \$30 billion to the State economy through 2021. Expansion reduces the uncompensated care burden on States' health care providers. In 2014, uncompensated care was reduced by \$7.4 billion, compared to what it would have been had coverage remained at 2013 levels.

Importantly, expansion increases access to needed care. A recent *Health Affairs* study comparing two States that expanded Medicaid to one that did not found that the expansion States saw an increase in residents with chronic conditions getting regular medical care, and a decrease in residents skipping medications because of cost or having trouble paying medical bills.<sup>15</sup>

Multiple surveys show that Medicaid beneficiaries are satisfied with their coverage. According to a survey by Kaiser, two-thirds of those currently covered by Medicaid (65 percent) report that it is working well for most low-income people covered by the program. With respect to the concern you raise regarding providers, most providers accept Medicaid patients. According to the National Center for Health Statistics 93 percent of primary care physicians accept Medicaid and 72 percent of physicians accept new patients. Those numbers are similar to the private insurance industry.

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QUESTION SUBMITTED BY HON. RICHARD BURR

*Question.* It is important that the regulations implementing the Protecting Access to Medicare Act (PAMA) are consistent with the Clinical Laboratory Fee Schedule reforms envisioned by Congress. PAMA required the outdated payment methodology to be replaced with a process in which Medicare reimbursement rates will be determined based on the reporting of private market rates by clinical laboratories. These changes should be implemented in a manner consistent with congressional intent to ensure that all sectors of the clinical laboratory market are included in the reporting of private market rates. CMS has indicated that the agency received a number of public comments citing concerns that the definition of applicable lab does not represent the whole clinical laboratory market. How is CMS addressing these concerns and ensuring that the finalized definition of "applicable lab" captures the complete picture of the clinical laboratory industry?

Answer. On October 1, 2015, CMS published a proposed rule to implement Section 216 of the 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. We also

<sup>14</sup><http://kff.org/report-section/the-effects-of-the-medicaid-expansion-on-state-budgets-an-early-look-in-select-states-appendix-d/>.

<sup>15</sup><http://www.commonwealthfund.org/publications/issue-briefs/2015/jun/does-medicaid-make-a-difference>.

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, we 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.

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QUESTIONS SUBMITTED BY HON. MIKE CRAPO

PART B

*Question.* On February 5, 2016, CMS posted and then removed a notification to contractors of its intent to implement a new Part B drug payment model through the Center for Medicare and Medicaid Innovation (CMMI).

CMS’s new Part B CMMI demo appears to cover almost all Part B beneficiaries and almost all Part B drugs which treat a variety of complex conditions and illnesses in the selected regions. In what regions will CMS test the model, and how will CMS determine which areas will serve as testing versus control groups?

*Answer.* We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. For any model tested by the Innovation Center, we carefully consider the most appropriate design for implementing the model so that patients are protected while quality and spending can be meaningfully evaluated.<sup>16</sup>

*Question.* Does CMS plan to expand any existing Phase I models? If so, how would CMS determine if the model met the statutory criteria that the model improves quality of care without increasing spending or reduces spending without reducing quality of care?

*Answer.* We conduct a robust evaluation of all of our models on an ongoing basis throughout the life of the model. In every model evaluation, we strive to determine the impact of the innovation on the experiences of patients and providers, outcomes and quality of care, and program expenditures. We make sure that our models are well designed—and we use all appropriate scientific and statistical methods to study the impact of the model test relative to what would have happened in the absence of that model test. We study these results carefully in making decisions about models. Prior to any expansions, CMS’s Chief Actuary must certify that an expansion would not result in any increase in net program spending. Using this information, the Secretary (or the Secretary’s delegate) ultimately determines whether a model has met the statutory criteria. To date, the Secretary has determined that the Pioneer ACO program has met these criteria.

*Question.* Many of the patients who use Part B drugs are patients with COPD, cancer, autoimmune conditions and other serious illnesses who have few or no other treatment options. Won’t the abrupt reimbursement changes that will be implemented through this model negatively impact access to needed care for these patients? What steps are you taking to protect patient access and care quality?

*Answer.* Making certain that our beneficiaries receive high quality health care—and that the quality of their care improves over time—is one of our most important goals. For every model tested, CMS does this in two ways—real-time monitoring and rapid-cycle evaluation. First, each model has a monitoring strategy that is customized to the specific circumstances and model financial structure. Before launching a model, CMS carefully considers unintended consequences, such as care stinting, and designs monitoring strategies that actively check for such adverse outcomes. By receiving regular updates from 1-800-MEDICARE, a model team can quickly learn of any potential issues as they arise. Other monitoring strategies include: analysis of claims data to identify abnormal billing patterns, audits of participants, and analysis of EHR-based quality measures.

Second, every model has a rigorous, yet rapid-cycle, evaluation conducted by an independent team that unfolds concurrently with model implementation. A key component of each evaluation is measuring care quality. While each model is different and requires a customized evaluation approach, common components include: reg-

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<sup>16</sup>All responses are accurate as of February 11, 2016.

ular surveys of beneficiary experience of care, analysis of claims-based quality of care outcomes, and qualitative data collection, such as patient and caregiver focus groups. By conducting these activities as the model is implemented, the evaluation can quickly identify potential issues with care quality and access and allow CMS to take action.

#### BIOSIMILARS

*Question.* The Patient Protection and Affordable Care Act (PPACA) created a carefully balanced formula for biosimilar reimbursement. Under the PPACA, Medicare reimburses innovator biological products covered under Part B at the average sales price (ASP) plus 6 percent. Reimbursement for a biosimilar is the biosimilar's ASP, plus 6 percent of the ASP of the reference biologic. However, CMS recently finalized a rule stating its intent to change Congress' formula by blending reimbursement for biosimilars that share the same reference product. CMS finalized the rule even after health care providers, health plans and manufacturers expressed significant concerns that this policy would harm the emerging biosimilar market.

Have you considered the potential for this policy to discourage new biosimilars from entering the market?

*Answer.* We believe the new policy puts appropriate incentives in place for new development while helping to contain spending. Biosimilars hold great promise for all Americans, including Medicare beneficiaries, and CMS is committed to a payment approach that will provide a fair payment in a healthy Marketplace. Competition fosters innovations which redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries—improving quality, price, and access.

After considering the many comments CMS received on this proposal, they finalized a proposal for a biosimilar payment approach that groups biosimilars with a common reference product. They both have significant similarities with their predecessor product (a reference product for biosimilars and an innovator product for generics) and they are both approved through an abbreviated pathway. We believe that biosimilars and multiple source drugs will have similar Marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product.

#### MEDICARE ADVANTAGE

*Question.* We have seen dramatic volatility between CMS's proposed growth rates in Advance Notices and CMS's final growth rates in the final Rate Notices over the last few years. For example, for the 2015 plan year, CMS released a preliminary Medicare Advantage (MA) growth rate of  $-0.1$  percent in December, a  $-1.9$  percent growth rate in February in the Advance Notice, and a  $-3.4$  percent growth rate in the Final Rate Notice in April. For the 2016 plan year, CMS released a preliminary MA growth rate of  $+2.1$  percent in December, a  $+1.7$  percent growth rate in February in the Advance Notice, and a  $+4.2$  percent growth rate in the Final Rate Notice in April.

What assurances are there that for the 2017 plan year, the  $+3.0$  percent growth rate proposed by CMS in both December and February will remain in the Final Rate notice released in April?

*Answer.* Transparency is important and we have taken steps to increase transparency, including attaching economic assumptions and publishing additional information like the "Early Preview" of the growth rates 2 to 3 months before the release of the Advance Notice, with the aim of providing additional transparency and sharing the latest information available about growth rates, as we did on December 1, 2015. Beginning with the 2015 Advance Notice, we have also included historical and projected United States Per Capita Costs values by trust fund and year. We welcome your feedback on these issues.

*Question.* CMS has failed to provide full transparency on how the growth rate is calculated and what components are included. What, if any, plan does CMS have to improve the transparency and predictability of the growth rate?

*Answer.* Key economic assumptions underlying the USPCCs are included in an attachment to the annual rate notice. We publish additional information regarding the trends for the prior 5 years on our website, and we discuss this material on an actuarial user group call.



*Question.* Despite support from both parties and from the Administration for Quality Incentive Payments in Medicare Advantage, those payments have been reduced or eliminated for many 4- and 5-star plans because of the PPACA MA benchmark cap. This is a case where a strict reading of the law undermines the intent of the PPACA to pay for value in Medicare Advantage.

Will you re-examine your interpretation to find a way that you can exclude the quality payments from the calculation of the cap?

*Answer.* As part of a larger Medicare Advantage proposal, the President's budget would standardize quality bonus payments across counties by removing the doubling of the quality bonus payment which is only available in certain areas and lifting the cap on benchmarks for plans that are entitled to receive a quality bonus payment. This is also consistent with MedPAC's unanimous March 2016 recommendations.

#### FOSTER YOUTH

*Question.* Can you tell me how CMS is working with States to ensure that youth aging out of foster care get continued access to health care? What is the data for such coverage and how is CMS working with States to identify former foster care youth in need of coverage?

*Answer.* As you know, the Affordable Care Act requires each State to extend Medicaid coverage to individuals who were in foster care in the State but have aged out, and who were enrolled in the State Medicaid plan while in foster care. Medicaid coverage on this basis continues until age 26. This ensures continuity of Medicaid coverage for children aging out of foster care for physical and behavioral health services the children might need to live independently.

CMS has employed several different strategies to help youth aging out of foster care retain access to health care. In December 2013, we issued guidance to States that explained the ACA requirement for coverage of former foster care children. We encouraged child welfare agencies and State Medicaid agencies to begin incorporating as soon as practicable coverage for this group in the transition planning for foster care youth turning 18 that is required of Title IV-E/B agencies. CMS has used its State Operations and Technical Assistance (SOTA) initiative, as well as the Eligibility Technical Advisory Group, to allow States an opportunity to clarify the policy and share best practices about its implementation.

We have required States to include, on their single streamlined application for Medicaid, a question about an individual's potential eligibility as a former foster youth. We have also confirmed, via consultation with States, that their eligibility and enrollment systems have the required functionality to determine individuals eligible for coverage in this group and, if not, that they have implemented appropriate manual processes in the interim. CMS regulations also require that States seamlessly transition individuals already enrolled in the State Medicaid program while in foster care into coverage under this group when they turn 18 or age out of foster care at an older age, and we have reinforced this requirement with every State, both individually and on all-State audio-conferences.

CMS has also worked with consumer advocacy and support organizations, and with other organizations engaged with vulnerable youth, to ensure that they are able to facilitate the application and enrollment of individuals who may be eligible as former foster youth. In 2015, through our Connecting Kids to Coverage Campaign, CMS conducted webinars for application assistors and other outreach workers about this coverage, to provide them with the information they need to assist young adults formerly in foster care in obtaining coverage.

States have not yet reported data to CMS on the number of former foster care children enrolled in this new Medicaid eligibility category. We anticipate that the Transformed Medicaid Statistical Information System (T-MSIS), once fully operational with updated information from all States, will include these data and enable CMS to provide reliable information about the extent of coverage of this population.

*Question.* Some States, like New Jersey, have coordinated child welfare and behavioral health programs to help youth get services they need and safely stay with their families. What is CMS doing to highlight the success of such coordination and encourage more States to collaborate?

*Answer.* HHS is committed to supporting States' efforts to coordinate child welfare and behavioral health programs. CMS has issued several Informational Bulletins on children's mental health services and substance use disorder treatment

services offered through Medicaid, as well as several informational bulletins focused on addressing trauma for children and youth who are at risk of placement in the foster care system. These policy guidance documents describe how various Medicaid programs and services help children live more successfully in the community and with their families. These Informational Bulletins may be accessed at [www.medicaid.gov](http://www.medicaid.gov).

For example, we have worked closely with our Federal and State partners to address the needs of children and youth, especially those in the foster care, who have experienced trauma, which is closely tied to the over-prescription of psychotropic medications. This has included information to States regarding the interventions that address trauma and the various Medicaid authorities that are available to States for covering these services. In addition, the President's 2017 budget includes a demonstration program to address the use of these medications among youth in foster care. This demonstration is a joint program with Administration for Children and Families that would provide the tools and incentives for States to increase access to services that address trauma and over-prescription of psychotropic medications.

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QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

MARKETPLACE OUT-OF-POCKET CALCULATOR

*Question.* I applaud HHS for including an out-of-pocket (OOP) cost calculator tool to [HealthCare.gov](http://HealthCare.gov) this past open enrollment season. This tool has the potential to allow those shopping for coverage to have a more complete understanding of the costs they could incur on the various Marketplace plans available to them, ensuring that they enroll in the best plan for them and their family. This is especially important when it comes to prescription drug costs. However, in its current form, the OOP calculator tool has not reached that potential and does not allow enrollees to get results personalized to their specific prescriptions. This lack of personalization could end up providing enrollees with misleading information, and lead them to enrolling in the least optimal plan. While I understand that some limitations could exist to make providing such personalization difficult, that functionality has been part of the Medicare Part D Plan Finder tool since its launch in 2006. This would indicate that providing all beneficiaries with the ability to gauge the actual OOP based on their specific prescription medication needs.

Why do federally-facilitated Marketplaces lack the same personalized OOP calculators as those available for Part D plans? Does HHS expect this level of personalization to be available starting with next year's open enrollment period? If not, why?

*Answer.* Based on consumer feedback about the information they want to help pick the right health plan, a number of new features have been developed for [HealthCare.gov](http://HealthCare.gov). As you note, a new Out of Pocket Cost calculator has helped consumers better estimate the cost of their health insurance based on their own personal situation. The feature provides consumers with an estimate of what their premiums, deductibles, and co-pays may be, based on their own anticipated level of health care service utilization, for each specific plan. Understanding total out of pocket costs for any given coverage option is essential for consumers to select the most affordable plan. In addition to the out-of-pocket cost calculator we also added a prescription-drug lookup feature for the 2016 Open Enrollment, where consumers can check whether a plan covers their prescription drug. Consumers can get this information before they select a plan. The 2016 Open Enrollment was the first year for both of these features and we expect that as the Marketplace matures that these tools will continue to be refined and improved over time.

PUERTO RICO

*Question.* As you know, section 601 of the Consolidated Appropriations Act of 2016 (Pub. L. 114-113) updated the Medicare hospital Inpatient Prospective Payment System (IPPS) to provide some reimbursement equity to hospitals in Puerto Rico. Prior to this law being enacted, hospitals in Puerto Rico were reimbursed under the IPPS at a blended rate—25 percent based on a Puerto Rico-specific rate, with the remaining 75 percent based on the Federal rate. Thanks to this new law, hospitals in Puerto Rico will be reimbursed at a full 100 percent Federal rate, just like their counterparts in the 50 States and District of Columbia. It has been brought to my attention that CMS recently issued guidance on this provision and is only applying the 100 percent Federal rate to the hospital operational costs, while maintaining the

25/75 blended rate for the capital expenses. While this continued inequity was clearly not the intent of Congress, I recognize that the capital expense calculations are done in regulations under the broad authority provided to HHS by section 1186(g) of the Social Security Act. However, it is imperative that hospitals in Puerto Rico receive the *full* equity in IPPS payments intended by Congress as soon as possible.

To that end, can you confirm that the upcoming IPPS rule will include updates to the special capital rate for Puerto Rico hospitals, effective October 1, 2016, to bring it inline with the 100 percent Federal rate mandated by Congress? In the meantime, what immediate steps will be taken to provide hospitals in Puerto Rico with the full equity in reimbursements prior to an October 1st effective date in the IPPS rule?

Answer. HHS has taken a number of steps to help residents of Puerto Rico access quality and affordable health care and a more sustainable future and we will continue to look for additional opportunities. CMS is reviewing its rulemaking authorities to address this issue and will keep your staff updated when relevant rules are issued.

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QUESTIONS SUBMITTED BY HON. SHERROD BROWN

COMBATING INFANT MORTALITY

*Question.* Ohio ranks 45th in the Nation in infant mortality—and even worse among the States that collect data on African American infant mortality. Many organizations in Ohio have partnered with community leaders and providers to address this issue, and I am encouraged by their creative and innovative approaches to improve the infant mortality rate in our State.

A specific example is the Community Health Access Project (CHAP) in my hometown of Mansfield, OH. CHAP utilizes a “Pathways” model, which allows community health workers (CHWs) to connect expectant mothers with nurses, doctors, and social workers. Through CHWs, CHAP is able to ensure that patients’ needs—health, behavioral, housing, educational, and emotional—are met in a coordinated fashion.

CHAP’s initial focus was on at-risk pregnant women—with a goal of reducing the number of babies born at a low birthweight. The results have been impressive. In 1999, nearly a quarter (22.7%) of babies in Mansfield were born at low birth weights (less than 51 lbs, 8 oz). By 2008, that number had been reduced to 8 percent.

CHWs are integral to the success of CHAP, and have already been invaluable in Ohio’s effort to reduce infant mortality. The Affordable Care Act has helped expand opportunities for CHWs to contribute to increased value and care coordination, however, we should continue to evaluate ways in which CHW can be leveraged to improve health outcomes.

What resources are available through this proposed budget to ensure that we are maximizing the potential of CHWs, and ensuring that CHWs have adequate resources and funding to fulfill their vital role?

Answer. I appreciate your leadership on the critical issue of infant mortality, and I am glad to learn more about the Community Health Access Project in Mansfield. The Health Resources and Services Administration’s Maternal and Child Health Bureau (MCHB) FY 2017 budget request supports the use of Community Health Workers (CHWs) in the Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) and Healthy Start programs. Details on each of these programs, and their support for CHWs, are included below.

The Home Visiting Program supports voluntary, evidence-based home visiting services for at-risk pregnant women and parents with young children up to kindergarten entry in all 50 States, the District of Columbia, and five territories. The Ohio Department of Health, a grant recipient of the Federal Home Visiting Program since 2010, has implemented Healthy Families of America, an evidence-based model that: aims to reduce child maltreatment; improve parent-child interactions and children’s social-emotional well-being; increase school readiness; promote child physical health and development; promote positive parenting; promote family self-sufficiency; increase access to primary care medical services and community services; and decrease child injuries and emergency department use. The model requires home visitors (family support staff) have a minimum of a high school diploma, as well as experience working with culturally diverse communities, and providing services to children and families, and have the ability to establish trusting relationships. These

staff requirements and qualifications are consistent with the requirements for community health workers (CHWs).

The Healthy Start (HS) program aims to reduce disparities in infant mortality and adverse perinatal outcomes by: (1) improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality improvement, performance monitoring, and evaluation. HRSA funds five HS communities in Ohio (Cincinnati, Cleveland, Columbus, Dayton, and Toledo). Since its establishment in 1991, HS has had a strong commitment to the use of CHWs. CHWs provide outreach and client recruitment, case management, and follow up and referral services; and enroll eligible women and their families into health insurance.

*Question.* How will HHS work with States, localities, and other stakeholders to promote the inclusion of CHWs in various health care programs? Has HHS considered proposing reimbursement models to support the role of CHWs in team based care?

*Answer.* HRSA supports community health workers (CHWs) through grants or cooperative agreements, which are a form of Federal financial assistance. Grants and cooperative agreements provide funding to address an identified public need, and are not a form of reimbursement.

The Healthy Start and Home Visiting programs are examples of how HHS currently works with States, localities, and other stakeholders on health care programs targeted toward mothers and babies that include CHWs. Further, State title V programs support the use of CHWs to provide outreach/health education and to assist the maternal and child health (MCH) population in gaining access to needed services. Based on their identified MCH priority needs, States have discretion in determining the types of activities that they support under their title V MCH Block Grant funds, which include support for CHWs, based on the needs of the State's MCH population and the availability of other resources.

HHS also utilizes CHWs across the Department. The Federally qualified health center or health center network teams include CHWs to coordinate patient education, link families to community resources, and make referrals to social services such as Supplemental Nutrition Assistance Program (SNAP) and Women, Infants, and Children (WIC). The Center for Medicare and Medicaid Innovation has also fostered the use of CHWs through their Health Care Innovation Awards, State Innovation Models, and Multi-Payer Advanced Primary Care demos to provide support to CHWs and to encourage their integration into care delivery. Additionally, Community Health Representatives have been part of the Indian Health Service delivery system model for decades.

*Question.* Will you come visit CHAP so you can see first-hand the impact these individuals have on the health of many Ohioans?

*Answer.* Thank you for the invitation to visit your hometown and for your leadership in fighting for access to health care for all Americans. My staff has been working with your office to determine whether this trip will be possible.

#### THIRD PARTY PREMIUM ASSISTANCE

*Question.* After CMS released its Interim Final Rule entitled *Third Party Payment of Qualified Health Plan Premiums* in March 2014, a growing number of insurance carriers have refused to accept third party payments from non-profit organizations on behalf of low-income people with high-cost conditions who are enrolled in Marketplace plans.

As you know, the Interim Final Rule allows marketplace insurance plans to prohibit the acceptance of health insurance premium assistance from non-profit organizations. This means that charitable organizations such as the Rotary Club, churches, the American Kidney Fund, and Patient Services Inc., are excluded from providing third party premium assistance. However, the rule recognizes the value of many organizations that provide premium assistance and therefore mandates that health insurance providers in the State and Federal insurance marketplaces must accept third party premium assistance from certain entities, including State AIDS Drug Assistance Programs (State ADAPs), Indian Tribes/Tribal Organizations, and any other State and Federal assistance programs.

Why does HHS require insurers to accept third party premium assistance for certain categories of coverage (Federal, State, tribal and Ryan White HIV/AIDS programs), but permits insurer discretion to deny all other third-party payments from

non-profits on behalf of insured people with chronic conditions? Is there anything in the statute that bars you from requiring Marketplace plans to accept premium assistance from charitable organizations?

Answer. In the Interim Final Rule with comment “Patient Protection and Affordable Care Act: Third Party Payment of Qualified Health Plan Premiums,” issued in March 2014, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because Federal or State law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

For example, section 402 of the Indian Health Care Improvement Act and the relevant regulations, which implement the Affordable Care Act, provide that Marketplaces may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Marketplace.

In addition, the Ryan White HIV/AIDS Program has been authorized to provide insurance assistance for low-income people living with HIV since 1990 under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. States have the authority to use AIDS Drug Assistance Program grant funds to purchase or maintain health insurance or plans when the coverage includes the relevant therapeutics and the cost of such coverage does not exceed the costs of otherwise providing the therapeutics directly. This provision was added in 2000 by the Ryan White CARE Act Amendments of 2000.

As noted in the November 4, 2013 FAQ, it has been suggested that hospitals, other health care providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an uneven field in the Marketplaces.

CMS later clarified that the concerns addressed in the November 4, 2013 FAQ would not apply to payments from private, not-for-profit foundations if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees’ health status. In such situations CMS would expect that premium and any cost sharing payments cover the entire policy year.

*Question.* Due to the restrictions on charitable organizations like those listed above, CMS’s regulations are—in some ways—undermining the Affordable Care Act’s reform to the pre-existing condition. In fact, insurers in more than 30 States—including Ohio—have announced their intention to reject premium assistance payments from charitable organizations. This has given insurers the ability to reject payment assistance for individuals with pre-existing conditions, discouraging those individuals from seeking coverage. In addition, insurers are now migrating these discriminatory practices to Medigap, COBRA, and other types of insurance as well.

What appropriate guardrails could be put in place that would both protect patients’ access to qualified premium assistance plans—while also addressing insurer concerns about the risk pool?

Answer. The Affordable Care Act reformed the health insurance marketplace to ensure that individuals with pre-existing conditions are able to access care and to prohibit non-grandfathered insurance plans from discriminating against consumers with pre-existing conditions or charging them more because they got sick or placing annual or lifetime limits on their insurance. In addition, with respect to the Marketplace specifically, the ACA provides for both tax credits to help consumers afford their premiums, and reduced cost-sharing for consumers who qualify. These market reforms and financial assistance work together to ensure access to care.

As noted in the HHS Notice of Benefit and Payment Parameters for 2017 proposed rule, HHS is considering whether to expand the list of entities from which issuers are required to accept payment to include not-for-profit charitable organizations in future years. If such not-for-profit charitable organizations were included, HHS would also intend to include guardrails aimed at minimizing the impact on the risk pool, such as limiting assistance to individuals not eligible for other Minimum Essential Coverage and requiring assistance until the end of the calendar year.

*Question.* Non-profit organizations have a long and proven track record of helping people with chronic conditions maintain affordable health coverage. For example, for

individuals who have been diagnosed with end-stage renal disease (ESRD), where average out-of-pocket costs are \$7,000, enrollment in a Marketplace plan—even if a Marketplace plan is their preferred choice—remains out of reach and not a meaningful option without premium assistance.

Why would it be acceptable to deny the same protections to people battling kidney disease and other high cost conditions—as you’ve applied to those with HIV/AIDS? Do you agree that both groups should be protected from discriminatory insurance practices?

Answer. The Affordable Care Act reformed the health insurance marketplace to ensure that individuals with pre-existing conditions are able to access care by to prohibit non-grandfathered insurance plans from discriminating against consumers with pre-existing conditions or charging them more because they got sick or placing annual or lifetime limits on their insurance. In addition, the ACA provides for both tax credits to help consumers afford their premiums, and reduced cost-sharing for consumers who qualify. These market reforms and financial assistance work together to ensure access to care.

In the Interim Final Rule, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because Federal or State law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities. Specifically, section 402 of the Indian Health Care Improvement Act and related regulations, which implement the Affordable Care Act, provide that Marketplaces may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Marketplace.

The Ryan White HIV/AIDS Program has been authorized to provide insurance assistance for low-income people living with HIV since 1990 under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The Public Health Service Act provides authority for States to use AIDS Drug Assistance Program grant funds to purchase or maintain health insurance or plans when the coverage includes the relevant therapeutics and the cost of such coverage does not exceed the costs of otherwise providing the therapeutics directly. This provision was added in 2000 by the Ryan White CARE Act Amendments, and was subsequently renumbered. As noted in the November 4, 2013 FAQ, HHS has significant concerns with third party payments because they could skew the insurance risk pool and create an unlevel field in the Marketplaces.

#### MEDICAID AND JOB READINESS

*Question.* Medicaid managed care plans—particularly non-profit community-based plans—play a unique role in its members’ lives by helping connect beneficiaries not only to necessary healthcare services, but to other critical resources that help address health disparities across communities. Health plans are focusing on ways to increase access to affordable transportation, eliminate food deserts and improve nutrition, and even provide job readiness programs for their members.

What funding exists within HHS that would support Medicaid health plans voluntarily engaging their members to determine work readiness, provide job skills and mentor their beneficiaries through employment?

For example, in my home State of Ohio, there is an outstanding pilot that was launched using philanthropic funding, to do just this type of work and it’s proving successful. We need to support this type of program to help lift people out of poverty and connect them with stable, living-wage employment opportunities.

Can you please identify and report to the committee existing and potential means to support this program with the support of Federal programs and dollars?

Answer. I would like to learn more about the specific pilot you mention here and encourage you to reach out to Jim Esquea, my Assistant Secretary for Legislation, to discuss it further. Additional information will help us determine whether the pilot would be eligible for funding opportunities.

With respect to your question about support for States more broadly, CMS supports State efforts to provide supportive employment in both managed care and fee-for-service delivery systems. Supportive employment provides a wide array of services and supports to increase employment opportunities for individuals with disabilities. Medicaid provides Federal financial participation (FFP) for employment supports related to an individual’s physical or mental condition that are not covered

through other means (such as Vocational Rehabilitation or DOL funded supports) when a State elects to cover them under a long term care authority under either a managed care or fee for service payment. Specifically, States have the opportunity to provide Supported Employment Services through a 1915(c) Home and Community-Based Waiver authority and/or through the 1915(i) State Plan benefit. States also have the option to operate a 1915(c) or 1915(i) program under a managed care system. There are currently 288 1915(c) HCBS Waiver programs and 18 1915(i) State Plan benefits operating nationwide. Under either authority the Federal Government will provide FFP for Supported Employment if the State elects to include the service. For more information on supportive employment, including best practices for States in implementing their programs is available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-09-16-2011.pdf>. Finally, consistent with current regulations, a State may also craft individual incentive arrangements for managed care plans that meet defined employment outcomes in its disabled and elderly populations.

#### STRATEGIES TO ADDRESS PRESCRIPTION DRUG ABUSE

*Question.* Ohio has seen devastation from the epidemic of prescription drug abuse. In 2014, Ohio was one of five States with the highest rates of death due to drug overdose and more than 2,700 Ohioans overdosed on drugs, including prescription opioids. Those are startling numbers.

The situation is serious, but it isn't hopeless. There are steps we know we can take to reduce these numbers—and save lives. I was pleased to see that the President's budget included support for patient review and restriction programs. These programs reduce the likelihood that people will doctor shop and get multiple prescriptions from multiple providers or pharmacies. We know that they work in the private sector. But Medicare can't use this potentially lifesaving tool. The time has come to give Medicare this authority.

That's why Senators Toomey, Kaine, Portman, and I have introduced the "Stopping Medication Abuse and Protecting Seniors Act," which would let Medicare better protect seniors from dying from drug overdoses, and at the same time ensure that patients who need pain medication can get it.

Will you work with my office and this committee to pass this important legislation?

*Answer.* First, I would like to thank you and Senator Toomey for your leadership on this issue. We would be happy to work with you on this legislation, as a very similar proposal is included in the President's FY17 budget. 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 Opioid Initiative. The Initiative is a coordinated, multi-faceted approach 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.

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. Another proposal to prevent prescription drug abuse in Medicare Part D would give the HHS Secretary authority to establish a program in Medicare Part D that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to requirements many States have implemented in Medicaid. The Medicare program would be required to ensure that Medicare beneficiaries retain reasonable access to Medicare services of adequate quality, and, in addition, the restricted period for a given beneficiary could only last for "a reasonable period of time."

We have also seen some success in Medicare Part D where utilization review processes have reduced high end opioid use significantly. We continue to work across HHS, with our partner agencies and other stakeholders, and with Congress to identify and dismantle barriers as well as leverage our resources to effectively implement strategies to reduce the impact of opioid use disorder and overdose death.

We are very pleased by Congress's continued interest and support, and we would be happy to provide technical assistance and work with your offices to continue the progress and ultimately turn the tide of this epidemic.

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QUESTION SUBMITTED BY HON. ROBERT MENENDEZ AND HON. SHERROD BROWN

PROTECTING ACCESS TO MEDICARE ACT—CLINICAL LABORATORY PROVISIONS

*Question.* In 2014, Congress passed the Protecting Access to Medicare Act (PAMA; Pub. L. 113–93) to make several needed updates and changes to the Medicare program. Included in this law was a substantial update to the way Medicare prices, and therefore reimburses, services provided to beneficiaries by clinical laboratories. Specifically, PAMA requires that laboratories report to the Centers for Medicare and Medicaid Services (CMS) the rates and volume of tests paid by private payers. CMS is then directed to use this information to calculate new Medicare reimbursement rates using the weighted median of the reported private payer rates.

Late last year, we joined 17 of our colleagues in sending a letter to Acting CMS Administrator Andy Slavitt inquiring about CMS's actions on implementing this section of PAMA. The letter highlighted as the primary concern CMS's intent to use taxpayer identification numbers (TINs) to determine which laboratories are subject to the private payer reporting requirement. Based on CMS's own internal calculation they "do not expect hospital laboratories to meet the definition of an applicable laboratory, and . . . estimate that more than 50 percent of independent laboratories and more than 90 percent of physician offices will be precluded from providing private payer data." While Congress clearly intended on excluding many smaller and low-volume laboratories from the reporting requirement, CMS's exclusion of much of the laboratory industry, specifically hospital labs, will cause a potentially significant skewing of the pricing data. This will, in turn, result in inaccurate reimbursements throughout the Medicare clinical lab fee schedule.

As we wait for a response to the previously mentioned letter, there are timely issues we want you to address in the meantime. Specifically, what steps is CMS taking now to ensure that the full breadth and depth of the clinical laboratory industry is represented in the incoming private payer data? Will CMS consider using the Medicare National Provider Identifier (NPI) instead of the TIN to better account for more labs? If not, what remediating measures will be taken to ensure the data, and ultimately the new reimbursements, are as accurate as possible and do not cause any disruption in Medicare laboratory services or beneficiary access to care?

Additionally, under PAMA, CMS was required to issue final rulemaking on these updated reimbursements by June 30, 2015. This date was specifically chosen by Congress to ensure sufficient time for laboratories to properly report their private payer rates and to allow CMS time to create the necessary systems to collect, certify, report and calculate this new data in time for the statutorily-mandated January 1, 2017, effective date. Despite this statutory deadline, CMS didn't issue a *proposed* rule until October 1, 2015, and has yet to release a final rule. Given the ongoing delay in issuing a final rule, it seems implausible to assume everything will be ready for implementation by January 1, 2017.

What is the status of the final rule and when does CMS expect it to be released? Does CMS plan on providing laboratories and other key stakeholders additional time to properly comply with the yet-unreleased final rule beyond the January 1, 2017 deadline?

*Answer.* Senators, thank you for raising this issue. I believe CMS has responded to your letter, but will work with my staff to be sure you receive a copy if you have not already.

As you noted, on October 1, 2015, CMS published a proposed rule to implement section 216 of the 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, and to define an "applicable laboratory" at the Taxpayer Identification Number (TIN) level rather than the National Provider Identifier (NPI) level. 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, we 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” and whether to use the TIN or NPI in defining such laboratories. We will carefully consider those comments in developing a final rule implementing PAMA section 2016, which we expect to be available soon.

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QUESTIONS SUBMITTED BY HON. BILL NELSON AND HON. MARK R. WARNER

*Question.* As you know, prescription drug prices are of significant concern to millions of Americans. United States spending on prescription drugs is now growing at a rate faster than any other healthcare item or service, and, in 2014 alone, prescription drug spending rose by 12.2 percent.

Your budget recognizes the roles that the U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) play in limiting the impact of these rising costs and exploring alternative payment mechanisms for prescription drugs. The squeeze of these rising costs is being felt by both American families and also the budgets of Federal programs and State governments. Investments in and development of innovative drugs can provide life-saving treatments, yet we must ensure there is a balance between the prices we pay for these prescription drugs and the value they provide.

Given these roles, consider the following questions:

What recent actions have HHS and CMS been taking to put in place initiatives to move to a value-based payment system for prescription drugs? What additional investments does the FY 2017 budget proposal make to conduct comparative effectiveness research of prescription drugs to facilitate approaches that pay for value?

Answer. HHS has taken several steps to lay the groundwork to improve value in our health care system. Such steps include:

- **Medicare Drug Spending Dashboard:** In December, HHS announced a new online dashboard to provide information on Medicare spending on prescription drugs, for both Part B (drugs administered in doctors’ offices and other outpatient settings) and Part D (drugs patients administer themselves) to provide additional information and increase transparency. Having this information available to the public in an accessible format should inform health care decisions and policy considerations as well as encourage collective problem solving around these important issues.
- **HHS Forum:** In November, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from State and Federal Government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability. The conversation touched on many ideas to increase access to information, promote value, drive innovation, strengthen incentives and promote competition.
- **Payments for Biosimilars:** In November, as part of the Physician Fee Schedule, CMS finalized regulations clarifying that the payment amount for a biosimilar biological product is based on the average sale price of all biosimilar biological products included within the same billing and payment code.
- **Oncology Care Model:** In the spring of 2015, Center for Medicare and Medicaid Innovation developed a payment model for physician practices administering chemotherapy. Under this model, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. This model aims to provide higher quality, more highly coordinated oncology care at a lower cost.<sup>17</sup>

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<sup>17</sup>All responses are accurate as of February 11, 2016.

*Question.* How does the agency propose to use comparative effectiveness information, claims data, electronic health records, and other available health data on diagnosis, utilization, and cost to improve the prescription drug payment system?

*Answer.* We believe that data and information is key to supporting better decision making regarding prescriptions drugs on the part of patients, providers, policy makers, and others in the health care system.

We have taken steps recently to support informed and value-based decision-making specifically in Medicare. The Medicare Drug Spending Dashboard provided the first step towards improving access to information, by providing information on the high spend drugs in Medicare, along with links to available evidence on the efficacy of those drugs.

With regards to the budget proposals, we include several that support the administration's broader strategy to encourage better care, smarter spending, and healthier people by paying for what works, improve care coordination and integration, and distribute information to providers, consumers, and others to support better decisions while maintaining privacy. For example, we propose to allow the Secretary to negotiate prices for biologics and other high cost drugs, which will help control spending.

*Question.* The FY 2017 budget also proposes new transparency requirements that would help shine a light on factors that are driving drug pricing and costs. What does transparency mean in this case? How does HHS propose to ensure that patients and others are aware of this information, as well as the results of value-based evaluations?

*Answer.* Providing access to information such as the factors that underlie drug pricing can help inform decision making by policy makers, providers, and patients, and shift the focus on drug pricing to the value the drug brings to the health care system. Working with various stakeholders across all sectors of the health care system will be important to make sure that such information is useful to and is used by patients and others.

*Question.* The budget creates a new process for developing a "coverage with evidence development" policy for Part D drugs, so that Part D plans can use additional evidence to improve clinical treatment guidelines and coverage policies. Please provide information on how HHS plans to develop this process, and which drugs and subpopulations are likely to be the focus of initial development.

*Answer.* This proposal would be modeled in part after the coverage with evidence development process in Parts A and B of Medicare to ensure that Part D sponsors provide the highest value prescription drug benefits for high cost drugs.

First, CMS would establish uniform criteria and a process for evaluating the value of new high cost drugs entering the market. Next, CMS would set up an advisory committee to assist with evaluating the value of specific high cost drugs.

As a condition of coverage of these high cost drugs in Part D, manufacturers would be required to undertake further clinical trials and data collection to support use in the Medicare population, and for any relevant subpopulations identified by CMS. Evidence developed through this process would support plan management of these drugs through existing tools such as prior authorization and differential formulary placement.

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#### QUESTIONS SUBMITTED BY HON. BILL NELSON

*Question.* The most glaring example of Puerto Rico's critical underfunding of health care services is that U.S. citizens living in Puerto Rico are ineligible for the Medicare Prescription Drug Low-Income Subsidy (LIS) Program. This is why I introduced S. 2342, the Territories Medicare Prescription Drug Assistance Equity Act, which will help low-income seniors living on the Island afford their prescription drugs by making them eligible for the Medicare Part D Low Income Subsidy program—a program that's already available to seniors living in the U.S. mainland.

Since 2008, the administration has promised a similar fix to aid the citizens living in the U.S. Territories. Extending the Medicare Part D LIS program to the U.S. Territories would provide relief to approximately 60 percent of Puerto Rico's 730,000 Medicare beneficiaries. Does the administration believe that this type of solution is effective in alleviating some of the strain on Puerto Rico's health system?

Would the administration support the solution proposed in the Territories Medicare Prescription Drug Assistance Equity Act to improve health care access in Puerto Rico?

Answer. Senator, first let me thank you for your leadership on these issues. HHS is committed to helping Puerto Rico with the health aspects of its current fiscal challenges. Under statute, many HHS programs, including Medicare and Medicaid, are implemented differently in Puerto Rico. In addition, Puerto Rico has a unique health care market with many low-income individuals in both Medicare and Medicaid and a complex legal history that affects the health care system in many ways. We are cognizant of the particular challenges in not only Puerto Rico, but in all territories without Low Income Subsidy (LIS) and would support an additional analytical adjustment for contracts serving these areas exclusively to address the fact that the part D LIS is not available there. That said, we believe that the single most impactful step we can take is reforming Puerto Rico's Medicaid program. As part of the President's FY17 budget, the administration detailed its proposal to improve health care outcomes in Puerto Rico and prevent hundreds of thousands of Americans from losing access to health care. The proposal would lift the Federal cap on Medicaid funding to Puerto Rico and other U.S. territories, raise the Federal Medicaid match from 55 percent to 83 percent over time as territories strengthen and modernize their Medicaid programs, and expand eligibility to 100 percent of the Federal poverty level over time. These reforms are integral to the administration's broader roadmap to financial stability for Puerto Rico.

I appreciate your ongoing leadership for the people of Puerto Rico, and look forward to working with you on this important issue.

*Question.* I appreciate the thought and preparation that went into the President's request for emergency funding to combat Zika virus. I have a unique interest in this issue given Florida's long history with mosquito-borne illnesses. Florida last dealt with outbreaks of dengue fever and chikungunya, two diseases also transmitted by the same mosquito as Zika virus, in 2013 and 2014.

The potential for Zika virus transmission is great. Currently, there are 32 travel-related Zika cases spread across 11 counties in Florida, including three pregnant women. There is no cure, vaccine, or treatment for Zika virus and current diagnostic tests are also inadequate.

I joined Senators Brown, Isakson and Franken in introducing S. 2512, the Adding Zika Virus to the FDA Priority Review Voucher Program Act. This bill would add Zika virus to the list of diseases included in the Tropical Disease Priority Review Voucher program at the FDA. You can take this important step on your own, without congressional action.

Do you have any plans to add Zika virus to the list of tropical diseases?

Answer. HHS is committed to doing all that it can to facilitate the development of, and access to, medical products to respond to the Zika virus outbreak as quickly as possible. We fully believe that the incentives currently available for Zika product development—such as funding for research and development and clinical trial costs from government and non-governmental organizations—as well as extensive HHS technical assistance for product developers, are sufficient to help bring Zika products to market. As demonstrated during the Ebola response, FDA will provide all the necessary support to product developers and use its authorities to the fullest extent appropriate to help facilitate and expedite development of Zika virus medical countermeasures. In addition, it is likely that Zika virus medical countermeasures will be eligible for FDA's proven mechanisms to speed the availability of medical products for serious diseases, such as priority review, fast track designation, and potentially accelerated approval.

As you are aware, the Federal Food, Drug, and Cosmetic Act sets forth the conditions under which the Secretary of HHS is authorized to add infectious diseases to the list of tropical diseases that would qualify the developer of a licensed or approved product to prevent or treat an identified tropical disease to receive a Priority Review Voucher (PRV) under FDA's Tropical Disease PRV Program. The following conditions must be met: (1) there is no significant market in developed nations for the particular disease; and (2) the disease disproportionately affects poor and marginalized populations. This authority is delegated to FDA.

FDA has provided a process for requesting that additional diseases be added to the PRV list. The process involves the submission of a request to a special docket set up to facilitate the consideration of such requests; the request is accompanied

by information to document that the disease meets the statutory criteria required to be added to the PRV list.<sup>18</sup> FDA has not received a request to add the Zika virus to the PRV list via the docket. While the agency does not want to foreclose anyone from following that process and is fully prepared to evaluate any submissions that are made with respect to the Zika virus, it does not appear—based on the information currently available to FDA—that the Zika virus meets the criteria set out in the statute. While it appears likely that the Zika virus disproportionately affects poor and marginalized populations, it also appears that there is a significant market for Zika virus medical products in developed nations, which would render the Zika virus ineligible for addition to the PRV list under the statute at this time. There is a significant market in the United States, a developed nation, where there is active Zika transmission by mosquitoes in Puerto Rico, the U.S. Virgin Islands, and American Samoa, and a threat of local spread by mosquitoes in the continental United States—though likely more limited due to protective factors such as air conditioning and screened windows.

*Question.* I am concerned about the adequacy of our physician workforce and our ability to care for an aging population. I see that the administration proposed significant reductions in Medicare support for Graduate Medical Education (GME), with \$18 billion cuts over the 10-year budget window.

According to the Association of American Medical Colleges, our Nation is facing a workforce shortage of between 46,000 and 90,000 physicians by 2025, with shortages most acute in surgical specialties—the result of a growing, aging population.

Medical schools in Florida, and across the country, have increased enrollment, and teaching hospitals are expanding training to address the physician shortage. Medical schools and teaching hospitals are also working hard to ensure that new doctors coming into the system are well trained to serve in new delivery models—such as ACOs—that focus on care coordination and quality improvement.

As a long-time supporter of GME, I believe we need to invest in physician training to ensure an adequate number of physicians are available to serve an aging population. I am concerned that these proposed cuts would undermine our ability to do that.

With the projected physician shortages, why is the administration proposing these types of cuts to GME that would affect patient care, physician and workforce training, and research?

*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 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. The FY 2017 budget includes \$60 million in funding appropriated in MACRA, as an additional \$527 million over FYs 2018–2020 to support up to 876 residents and restore the per resident payment to \$150,000.

*Question.* I remain concerned about prescription opioid abuse and how this crisis may be contributing to heroin use in our Nation. According to the Centers for Disease Control and Prevention (CDC), there was a 16 percent increase in the number of prescription opioid deaths in 2013 and 2014. In total, there were 19,000 prescription opioid overdoses in 2014, as well as 10,000 heroin-related overdoses.

Several ideas have been proposed to address these issues, such as establishing prescription drug monitoring programs or improving how these prescriptions drugs are prescribed. On November 9, 2015, I joined several of my Senate colleagues in sending a letter to the CDC urging the agency to release its final guidelines for opioid prescribing. When does the CDC plan to release these guidelines?

<sup>18</sup> See <http://www.regulations.gov>, Docket No. FDA-2008-N-0567.

Answer. Thank you for your question and for your November letter expressing your support for the CDC Guideline for Prescribing Opioids for Chronic Pain. We agree that too many lives have been damaged by the opioid abuse and misuse epidemic. More than 16,000 deaths are due to prescription opioid overdoses each year. The goal of our draft guideline is to improve the safety of prescribing opioids and to curtail the harms associated with them.

The guideline is intended for primary care providers treating patients 18 years of age and older for chronic pain in outpatient settings. It is not intended for patients in active cancer treatment, palliative care, or end-of-life care. The guideline's recommendations will primarily focus on the use of opioids in treating chronic pain (*i.e.*, pain lasting longer than 3 months or past the time of normal tissue healing) outside of end-of-life care. Improving the way opioids are prescribed through clinical practice guidelines allows patients access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs.

Since November, CDC released the Guideline for a 30 day public comment period and received more than 4,300 comments. The Injury Center's Board of Scientific Counselors (BSC) met and established an Opioid Guidelines Workgroup to review the draft Guideline and provide observations. That workgroup provided its recommendations to the BSC. The BSC voted unanimously to support the observations made by the BSC Opioid Guideline Workgroup; recommend adoption of the guideline recommendations that had unanimous or majority support; and recommend that CDC further consider the guideline recommendations for which the workgroup had mixed opinions. CDC has taken the BSC's recommendations, as well as comments received from the public, into consideration and is reviewing all of the information to determine what revisions might be necessary. Once this process is complete, the guidelines shall be finalized and released to the public. We expect the release to occur in the Spring of 2016.<sup>19</sup>

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QUESTIONS SUBMITTED BY HON. MARK R. WARNER

*Question.* Fully leveraging the potential of the Digital Accountability and Transparency (DATA) Act of 2014 presents a unique opportunity for agencies to facilitate better management and reduce the compliance burden on Federal grantees. The Department of Health and Human Services plays a critical leadership role as the executing agent for the Grants Pilot under section 5 of the Act, and I am pleased that the Department's \$10.3 million request for DATA Act implementation reflects that role. To that end, please answer the following questions.

The pilot is required to facilitate the development of recommendations for "standardized reporting elements across the Federal Government, the elimination of unnecessary duplication in financial reporting, and the reduction of compliance costs for recipients of Federal awards." The pilot has the potential to fundamentally transform and improve the Federal grants reporting process for both agencies and grantees, beyond merely the consolidation of forms. Such a broad vision to improve data quality reflects the legislative intent of the law. Can HHS fully commit to this vision of the pilot program?

Answer. HHS is fully committed to implementing the section 5 Grants Pilot to support the pilot's vision to improve efficiencies within the grants process which will benefit all Federal agencies and their respective grant recipients. In order to fulfill its responsibilities as the Office of Management and Budget's (OMB) executing agent of the Pilot, HHS is working in close collaboration with OMB. In May 2015, HHS launched a Common Data Elements Repository Library and has deployed a "Learn Grants" tab on *Grants.gov*. HHS has also coordinated with OMB to launch a National Dialogue in May 2015 that provides opportunities for recipient engagement in discussions on compliance costs and burden reduction and in addition, HHS has been collecting recipient feedback with these tools and additional outreach, which it has used to create the pilot test models. HHS has also created a section 5 Grants Pilot Framework which outlines how the six Test Models, used to conduct the pilot tests, collect data, and create the final report to OMB and Congress.

*Question.* As you begin the collection of pilot data this spring, both Congress and the Office of Management and Budget should provide appropriate support to the HHS DATA Act Program Management Office. What congressional assistance or

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<sup>19</sup>All responses are accurate as February 11, 2016.

oversight role would be most of use to the PMO? How can OMB facilitate these efforts? Would the support of other Federal entities, such as the U.S. Digital Service or 18F, be of use?

Answer. Execution of the section 5 Grants Pilot has been arranged into a series of phases—each designed to inform subsequent phases within the interconnected pilot activities. The Federal Government is the target audience for early phases of the Pilot, while grant recipients (or public) are engaged in later phases. Data collection involves focus groups, participant feedback, user experience, and analytics. The section 5 Grants Pilot launch schedule and Test Model planned activities (subject to the OMB concurrence and resource availability) will largely occur in the data collection phase. The passage of requested funding in my FY 2017 budget in support of these efforts would be beneficial. HHS believes that the test models as designed will provide significant improvements within the grants lifecycle and organizations such as the U.S. Digital Service or 18F would likely be able to advance the path forward based on recommendations resulting from this Pilot work.

*Question.* With fully electronic grant reporting, as tested by the pilot, data fields in grantee forms that are standardized across the Federal Government would enable grantee software to generate reports automatically. Do you believe that focusing on data fields, rather than the forms containing them; can help to reduce grantee compliance costs?

Answer. Under the PRA, burden is calculated based on the aggregate of elements required for reporting by the grantee versus individual data elements. However, by standardizing individual data elements, it could enable data elements to be automatically populated for the grantee, which would reduce burden for the required sets of data elements (forms) that grantees must report.

*Question.* HHS provides grants to a wide range of recipients in a variety of fields. Under the pilot, the PMO has compiled the Central Data Element Repository Library, or CDER-L; does HHS plan to use the CDER-L data fields across its own grant reporting regardless of their adoption on a government wide basis?

Answer. The Common Data Element Repository (CDER) Library is designed to be a repository for standards to facilitate consistency of Federal terminology for financial assistance terms and definitions for purposes of the Pilot. Through the Pilot, the CDER Library will be tested for its utility to reduce recipient burden with the goal of better managing or reducing forms necessary for information collections. Furthermore, HHS will be working with grant recipients to determine if this tool will help them in completing forms by using a single reference tool to ensure there is a solid understanding of the terminology which should result in more accurate information being provided and increase the speed in which that information can be provided. HHS will be gathering feedback on whether it is easy to for standard terminology provided and to identify duplicative use of information across financial assistance forms. HHS would need to determine the sustainability and associated ownership costs to better determine the potential long-term uses of this tool. Based on the feedback to date from the private sector, other government agencies, and counsels, such as Council of Agency Officials for Paper Work Reduction, this appears to be a solid investment.

*Question.* What elements of the DATA Act Grants Pilot Framework does the Department view as most promising for scaling up on a government wide basis, and to informing the changes needed to meet the DATA Act's reporting requirements? Which elements have been most challenging to implement, to date, or would be most challenging to implement on a government wide basis?

Answer. The section 5 Grants Pilot framework takes a holistic approach to meeting the section 5 Pilot goals. HHS will integrate the components of the framework and collect grant recipient feedback through the National Dialogue tool and the Test Models. The Test Models will focus on five areas: the CDER Library, Consolidated Federal Financial Report (Consolidated FFR), Single Audit, Notice of Award, and Learn Grants. The Test Models will use existing technologies and tools during execution. The execution of each Test Model aligns with the requirement to conclude the pilot by May 2017. HHS will analyze the data collected during the pilot period and make recommendation based on an analysis of the data collected during the pilot testing phase. As the test models are still pending Paperwork Reduction Act clearance, it would be premature to make any determinations related to challenges surrounding implementation, but HHS views this as a promising approach given the preliminary feedback during our pre-test meeting with representatives from the grant recipients' community.

## QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

*Question.* The Department of Health and Human Services (HHS) is to be congratulated for publishing the 2015–2020 Dietary Guidelines for Americans, which are important to help guide Americans towards eating a healthier diet. However, there are specific vulnerable populations—such as older adults, particularly those with chronic disease—who may have critical nutrition needs that are not addressed by these general population guidelines. Indeed, malnutrition has been identified as a new senior crisis which should be reflected in national health goals.

How is HHS addressing the issue of older adult malnutrition as a public health crisis?

*Answer.* Adequate and nutritionally balanced food is vitally important for promoting health, decreasing the risk of chronic disease, maintaining functionality, and helping older adults remain independent at home in their communities.

The Administration for Community Living (ACL) manages the Older Americans Act (OAA) nutrition services programs which have been a core element of our national strategy for reducing food insecurity and delaying or avoiding adverse health conditions, including malnutrition, among older adults for over 40 years. The OAA requires that Meals on Wheels meals meet nutritional and safety standards. These community-based programs, which serve persons aged 60 and over, provide access to meals in a group setting or delivered to the home, a service that is not provided by other Federal nutrition programs. In addition to providing access to nutritious meals, ACL's nutrition programs also provide nutrition education, counseling, and opportunities for socialization. Although the majority of the older adults who participate in these programs have low incomes, income alone is not an adequate measure of the need for nutritious food. For the majority of program participants, these meals provide more than one-half of their daily food intake.

The President's budget request for OAA nutrition services is \$13.8 million above the FY 2016 enacted level. At this level, the budget request, combined with State and local contributions, would support an estimated 205 million home-delivered and congregate meals to more than 2.2 million elderly individuals in a variety of community settings. While investments in nutrition services are clearly needed, it is also critical that we work with State and local partners to modernize these services and ensure that every dollar is spent effectively. Providing nutrition services improves the health of participants and reduces their need for more expensive medical interventions and institutional care. Translating research into evidence-based models for delivering services at the community level is important to ensuring the continued effectiveness of these programs. To that end, the FY 2017 budget would also allow for up to 1 percent of the appropriations provided for nutrition to be invested in evidence-based innovation projects, including efforts to address malnutrition.

*Question.* What plans are there to include it in national public health goals such as updates to Healthy People 2020?

*Answer.* HHS supports the inclusion of reducing older adult malnutrition as a national public health goal in the updates to Healthy People 2020 (HP2020). The work on HP2020 is winding down and the establishment of new and updated goals for HP2030 will soon start, so the timing is good for bringing needed attention to these issues.

## QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

## RAISE FAMILY CAREGIVERS ACT

*Question.* Senators Ayotte and I lead the ACT Caucus here in the Senate. It represents the 42 million family caregivers in this country who sacrifice their time and energy to care for a loved one. We recently passed the RAISE Family Caregivers Act in the Senate to direct HHS to develop a National Family Caregiving Strategy.

While we wait for the House to act, are there areas of this bill that HHS could start implementing today? Is this something you can prioritize this year?

*Answer.* First, I would like to commend you and Senator Ayotte for your leadership and the Senate's efforts to support our Nation's family caregivers. The vast majority of long-term care support in the U.S. is provided by family, friends, and neighbors—almost 18 million Americans provide care for a chronically ill, disabled, or an aged family member or friend during any given year. We are committed to helping

them meet the challenges of caregiving by identifying and expanding evidence-based practices which better enable them to help take care of their loved ones.

The FY17 budget requests increases for programs at ACL that support essential services for family and informal caregivers and improve quality of and access to respite care. Eighty percent of the caregivers served by OAA programs report that these services allow them to provide care longer than they otherwise could.

Caregivers may also benefit from the home- and community-based services provided through ACL, such as nutrition programs, and through Medicaid. These can offer additional help that can make a difference in being able to keep a loved one at home and include:

- CMS has taken steps to enhance the quality of home and community-based services, provide additional protections to individuals that receive services under these Medicaid authorities, and provide States with additional options to expand home and community-based services and target services to specific populations. States may choose to provide services such as respite care, which can relieve caregivers of their responsibilities for time periods of up to several days, or services to care for beneficiaries during the day, such as adult day health care services, enabling caregivers to maintain employment. There are a number of additional services available at State option that provide relief for the caregiver as well as the individual requiring services and supports. CMS is available to provide technical assistance to incorporate these services into Medicaid programs.
- The National Family Caregiver Support Program was created with the 2000 reauthorization of the OAA. It provides each State and territory with formula grants to establish a base of supports for family caregivers consisting of information, assistance, counseling, training and support groups, respite, and supplemental services, on a limited basis.
- The Alzheimer's Disease Supportive Services and the Alzheimer's Disease Initiative Supportive Services programs both work to advance capacities to meet the complex needs of family caregivers of persons with Alzheimer's disease and related dementias at State and local levels by enhancing the dementia-capability of the systems and programs that serve them.
- The Lifespan Respite Care Program provides funding to States to enable them to develop and strengthen respite services for family caregivers of persons with disabilities of all ages. Under this program, States work with state-wide respite coalitions and in consultation with aging and disability resource centers to create systems of accessible and high quality respite services.

Providing support that makes caregiving easier for family caregivers, such as information, counseling and training, respite care, or supplemental services, is critical to sustaining caregivers' ability to continue in that role. 80 percent of caregivers served by OAA programs report that these services allow them to provide care longer than they otherwise could.

*Question.* In Colorado, we've seen huge price variations in what providers charge for services. In Eagle County, located in the mountain regions of Colorado, a person has a choice to have a knee surgery for \$20,000 locally or in Denver for \$6,000. In Lafayette, a knee replacement costs nearly \$20,000, while the same procedure in Greeley costs \$60,000. What can we do to address this kind of price variation?

*Answer.* Researchers have conducted various studies on the geographic variation in hospital pricing. While Medicare pays hospitals pursuant to a formula set by statute, hospitals negotiate prices with commercial payers, which leads to variation in payment. Medicare is promoting more value in our health care system by paying providers on an episode basis such as through the Comprehensive Joint Replacement model, or holding them accountable to the costs and quality of care, such as through hospital participation accountable care organizations. In this way, we can encourage smarter spending and better care.

Creating more transparency in price and quality is also important. Through Medicare, we regularly post information on provider charges. I look forward to working with you on further addressing this issue.



## QUESTIONS SUBMITTED BY HON. DANIEL COATS

*Question.* The Medicare Competitive Bidding Program (CBP) has successfully reduced the amount Medicare spends on Durable Medical Equipment (DME), including diabetic testing supplies (DTS). However, a recent study (“CMS Competitive Bidding Program Disrupted Access to Diabetes Supplies with Resultant Increased Mortality,” American Diabetes Association 75th Scientific Sessions, 5–7 June 2015, Boston, MA) reported that Medicare beneficiary testing compliance decreased, and that drop-off coincided with a higher number of deaths and hospitalizations among persons with diabetes. More recently, a November 2015 report by the National Minority Quality Forum titled “Centers for Medicare and Medicaid Services Competitive Bidding Program: Assessment of Impact on Beneficiary Acquisition of Diabetes Testing Supplies/and DMEPOS Associated Health Outcomes” found that the CMS data supporting patient access claims was flawed. Have you reviewed these studies?

Please provide evidence that Medicare beneficiaries will not suffer further disruptions in access to DTS or deterioration of health outcomes as a result of the CBP for diabetes testing supplies.

*Answer.* The Durable Medicare Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program is an essential tool to help Medicare set appropriate payment rates for DMEPOS items by replacing the existing, outdated, excessive fee schedule amounts with market-based prices. The program has resulted in reducing beneficiary out-of-pocket costs, providing significant savings to the Medicare program and taxpayers, and reducing over-utilization and fraud. Additionally the program has ensured continued beneficiary access to high quality items and services without compromising beneficiary health and safety.

CMS has reviewed the National Minority Quality Forum (NMQF) abstract with great interest, and we look forward to viewing the peer reviewed published study so we can better understand the methods leading to their conclusions. We take seriously any beneficiary access or health outcomes concerns, and that is the primary reason CMS has implemented a robust monitoring program to track and resolve any issues that might occur with DMEPOS competitive bidding program implementation. To the extent an issue arises, CMS will act promptly to address it.

Our extensive real-time monitoring results differ from the conclusions of the study. Our monitoring identified no changes in health outcomes, including death, hospitalization and emergency department visits. In addition, we have found that prior to the DMEPOS competitive bidding program, it appears that some past mail-order suppliers routinely shipped diabetic testing supplies to beneficiaries every 90-days, regardless of need. We also note that there have been high improper payment rates and evidence of fraud and overutilization in the Medicare DME area, which CMS and Office of Inspector General have continued to address.

*Question.* I'd like some more information on the coverage decision process at CMS. Specifically, can you please tell me how many requests, both internally at CMS and by outside stakeholders, for a National Coverage Decision (NCD) were made in 2015? Of those requests, how many were approved for review by CMS? How many NCDs were ultimately issued in 2015?

*Answer.* Each year, as required by statute, CMS reports to Congress on the Medicare National Coverage Determinations (NCDs) implemented in the prior fiscal year. On February 3, 2016, CMS delivered its report for FY 2015 detailing the completion of five NCDs. Further detailed information on each NCD is available in the coverage indexes on CMS's website at <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>, including a “tracking sheet” with links to the requestor's letter, proposed and final decision memoranda, public comments received when the NCD review was first initiated and in response to the proposed decision, and any other information relevant to the analysis of evidence that led to the NCD. Additional information on the coverage process is available on the “Medicare Coverage Center” website at <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html>.

*Question.* Additionally, has the coverage group identified the National Coverage Decisions it plans to conduct in FY 2017? If yes, what are they and how were they selected?

*Answer.* CMS receives and considers requests for National Coverage Analyses (NCAs)—the first step in the NCD process—on an on-going basis. Once a request is determined to include the necessary information and supporting evidence needed for an NCA, the opening of the NCA is posted on the CMS website at <https://>

*www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx*, and is open to a 30 day public comment period, prior to development of a proposed coverage decision. Public comments are again invited when a proposed decision is issued, to help inform the development of a final NCD.

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**INDIAN HEALTH SERVICE**  
**No-Year Budget Authority**  
**History of Unobligated Balances FY 2010—FY 2015**

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
SERVICES—75 × 0390 Programs						
Catastrophic Health Care	272,734	5,514,880	644,797	3,274,461	8,677,527	11,607,454
Federal Medical Care Recovery Act	592,390	614,213	766,279	570,312	729,491	700,274
Domestic Violence Prevention Initiative	7,436,629	12,279,341	17,006,209	13,511,120	13,802,681	11,435,589
Indian Self-Determination	12,802	12,802	13,633	13,633	12,802	12,802
Private Insurance Collections	23,829,208	36,131,208	50,963,367	60,816,737	58,277,392	72,099,025
Medicare	20,524,558	35,875,591	62,154,819	66,570,104	76,071,359	96,486,270
EHR Incentives—Medicare			—	1,380,400	6,151,690	6,203,724
Medicaid	44,296,964	109,267,945	165,129,546	197,706,432	216,119,796	264,016,198
EHR Incentives—Medicaid			27,018	12,586,901	16,538,583	13,661,404
IHS and VA Dual-Eligible Beneficiaries					248,016	4,854,262
Diabetes	44,161,096	29,209,247	44,703,803	46,261,076	48,737,462	50,472,501
Alcohol and Substance Abuse/Meth Prevention	5,016,524	6,165,464	20,071,390	11,040,452	11,522,922	5,542,027
Office for Victims of Crime (OVC) Reimbursement		—	85,000	—	—	254,016
CHIPRA of 2009 Pub. L. 111-3		—	418,457	163,318	101,548	101,548
Buybacks	134,972,002	107,950,426	62,388,999	68,844,691	58,563,030	51,929,889
Crime Victim Equipment-Interagency Agreement with Department of Justice	162,558	514,936	500,036	420,273	328,968	114,587

**INDIAN HEALTH SERVICE—Continued**  
**No-Year Budget Authority**  
**History of Unobligated Balances FY 2010—FY 2015**

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
SERVICES—75 × 0390 Programs						
PRC Services—PY for California and Tucson Only	39,210	39,210	39,210	39,210		
Indian Health Professions—Scholarship	2,938,833	3,016,883	18,033,667	21,662,389	8,742,951	7,369,101
Indian Health Professions—Loan Repayment	1,840,145	1,968,942	13,582,469	7,315,123	8,032,928	1,146,905
Purchased/Referred Care	55,439,426	80,106,327	43,162,641	48,272,657	43,753,885	70,007,963
Services TOTAL	341,544,079	428,667,415	499,691,340	560,449,289	576,413,031	668,015,539
FACILITIES—75 × 0391 Programs						
Maintenance and Improvement	46,485,826	54,347,347	57,607,439	49,616,278	48,300,125	46,114,304
Sanitation	5,028,069	1,292,291	1,409,469	1,353,026	5,307,821	2,007,803
Health Care Facilities Construction	42,378,338	28,624,623	15,848,006	17,324,786	6,742,024	27,315,506
Facilities and Environmental Health Support	47,058,255	58,615,163	62,997,381	62,523,351	57,439,429	62,710,182
Equipment	21,522,272	22,941,083	25,597,070	21,349,923	22,080,753	19,675,038
Reimbursements	16,310,851	8,561,376	27,225,378	4,805,757	4,123,899	3,600,591
Balancing Adjustments and Miscellaneous Budget Activity Programs			(795,619)	26,823	28,357	28,358
Facilities TOTAL	178,783,611	174,381,883	189,889,124	156,999,944	144,022,408	161,451,782

## Awards Guidance on Spending Limitations

The Office of Personnel Management (OPM) and the Office of Management and Budget (OMB) are issuing this awards guidance that applies to awards paid during the Fiscal Year (FY) (*e.g.*, FY15 is October 1, 2014, through September 30, 2015) and shall continue to remain in effect until further notice. This guidance is applicable to all departments and agencies (referred to collectively as agencies).

### **Budgetary Limitations for Individual Monetary Awards**

These budgetary limits apply to agency spending for individual monetary awards only, which include rating-based performance awards and individual contribution (*e.g.*, special act) awards.

Agencies must limit total awards spending on the following categories of awards:

- Agencies may spend no more than 4.8 percent of the aggregate salaries of their career executives at the end of the previous fiscal year on individual performance awards for career members of the Senior Executive Service (SES).
- Agencies may spend no more than 4.8 percent of the aggregate salaries\* of their senior-level and scientific and professional employees (SL/ST) at the end of the previous fiscal year on individual performance awards for SL/ST employees.
- Agencies may spend no more than 0.96 percent of the aggregate salaries\* of all employees at the end of the previous fiscal year on the combination of (1) individual performance awards for non-SES/SL/ST employees, and (2) individual contribution awards (*e.g.*, special act awards) for all employees (*i.e.*, SES/SL/ST and non-SES/SL/ST).

OPM and OMB will continue to monitor awards data that agencies provide to OPM under the agencies' regular reporting procedures for compliance with these limitations.

In addition, if overall Government-wide discretionary funding levels are reduced below the discretionary spending caps set forth in the Budget Control Act (the BCA) of 2011 (Public Law 112-25), each agency shall further reduce awards spending pools for SES and non-SES by an amount proportional to the Governmentwide reduction made from the original BCA discretionary spending cap, as determined and communicated by OMB.

### **Other Covered Awards**

Consistent with previous awards guidance, the limitations on the following remain unchanged:

- **Other awards and incentives**, such as group awards, referral bonuses, or suggestion/invention awards, are frozen at FY 2010 spending levels. Travel savings and foreign language awards are not frozen.
- **Time-off awards** are not direct monetary expenditures and are not included in the 0.96 percent limit; however, agencies should continue to use time-off awards judiciously as they do represent a cost to the agency.
- **Recruitment, relocation, and retention incentives** are not awards and are not covered by the budgetary limits; however, agencies should ensure that spending on these incentives in the aggregate during the calendar year does not exceed calendar year 2010 levels.
- **Quality step increases** for General Schedule employees is another category of rating-based payment that does not constitute an award. These payments are not covered by the 0.96 percent budgetary limit; however, agencies may not exceed their FY 2010 spending levels on quality step increases granted during the fiscal year.

These budgetary limits apply to all Executive branch agencies for all members of the SES as well as non-SES civilian employees, including SL/ST, General Schedule, wage grade and others, except political appointees covered by the freeze on discre-

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\*These budgetary limitations do not apply to political appointees. Therefore, the salaries of political appointees are not included when calculating the awards funding. The President's August 3, 2010, memorandum freezing discretionary awards, bonuses, and similar payments for political appointees continues in effect until further notice. Agencies should continue to apply this freeze in accordance with OPM's guidance at <http://www.chcoc.gov/Transmittals/TransmittalDetails.aspx?TransmittalID=3060>.

tionary spending. Agencies retain the flexibility, however, to apply these budgetary limits on awards programs to all employees, regardless of applicable pay authority, to accommodate current budget constraints, provided they meet all legal requirements and agency contractual obligations.

In applying these budget limitations, agencies should discuss their agency award programs in agency labor-management forums and should honor all collective bargaining obligations and existing agreements prior to implementation.

#### Additional Information

Agency Chief Human Capital Officers and/or Human Resources Directors should contact Stephen T. Shih, Deputy Associate Director for Senior Executive Services and Performance Management, in OPM's Employee Services, at (202) 606-8046 or [performance-management@opm.gov](mailto:performance-management@opm.gov) if they have any questions regarding this guidance. Employees should contact their agency human resources offices for assistance.

Agencies that did not spend anything in 2010 on the types of awards/payments limited to 2010 spending should contact their Resources Management Officer at OMB to establish appropriate baseline spending amounts.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

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Assistant Secretary for Administration  
Office of Human Resources  
Workforce Management and Vitality Division

November 18, 2014

#### MEMORANDUM FOR—SEE DISTRIBUTION

SUBJECT: Supplemental Guidance on Awards for Non-Senior Executive Service (SES)/Senior Level and Scientific and Professional Employees Fiscal Year 2015

December 31, 2014 marks the end of the calendar year (CY) 2014 Performance Management Appraisal Program (PMAP) Cycle for non-Senior Executive Service (SES)/Senior Level and Scientific and Professional employees. The attached guidance is provided to assist supervisors and managers with the closeout and awards process. All CY 2014 PMAP closeouts must be completed no later than February 17, 2015. Once your closeout has been completed, we ask that you submit your compliance with this requirement to [OSPMAP@hhs.gov](mailto:OSPMAP@hhs.gov). PMAP policy information is available on the HHS intranet at (<http://intranet.hhs.gov/hr/ohr/pmap/policy.html>).

On November 1, 2013, the Office of Management and Budget (OMB) and the Office of Personnel Management (OPM) issued a memorandum superseding their FY 2013 memoranda, which placed a moratorium on awards while under sequester. On January 8, 2014, the Department issued additional guidance on this matter. On February 27, 2014, the Department issued OMB guidance on revised performance awards spending caps. OMB's calculation results in a new cap of 0.96 percent for all employees for spending on non-SES/SUST performance awards and individual contribution awards. The previous cap of 1 percent *is no longer in effect*, and has been replaced by the lower cap.

As a result, the attached Awards Guidance is consistent with the previously-issued Guidance on Awards for Fiscal Year 2014 (M-14-02), with the following exceptions (1) the Guidance incorporates the reduced aggregate spending percentage caps (as reduced by the Budget Control Act and communicated to the CHCO community in February 2014) (2) the Guidance on Awards for Fiscal Year 2014 included a requirement stating "agencies may not exceed FY 2012 spending levels on either category of awards." **This limitation is removed and agencies are expected to adhere only to the budgetary percentage limitations in the Awards Guidance.**

Taken together, the OMB, OPM, and departmental supplemental guidance on discretionary awards, including awards in performance systems established by, or managed under, HHS authority is attached, along with the OPM and OMB memorandum.

Please ensure that all collective bargaining obligations are met prior to implementing any provisions contained herein. My point of contact for this matter is Mr.

Nicholas Troilo and Mr. Zacharias Russell. You may contact Nicholas Troilo at nicholas.troilo@hhs.gov or (202) 725-8872. Mr. Zacharias Russell may be contacted at zacharias.russell@hhs.gov or (202) 619-0125

Darrell R. Hoffman, SPHR  
**Director, Workforce Management and Vitality**

**Attachments:**

- OPM and OMB Joint Guidance on Awards for Fiscal Year 2015, issued November 14, 2014
- OPM and OMB Joint Guidance on Awards for Fiscal Year 2014, dated November 1, 2013; OMB Guidance on Revised Performance Awards Spending Caps issued February 27, 2014 to HHS HR Directors and HR Deputies
- Guidance on Awards for Fiscal Years 2011 and 2012, dated June 10, 2011

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**Guidance on Awards for Non-SES/ST/SL Employees Fiscal Year 2015**

1. References:

- a. Continuance of Office of Personnel Management (OPM) and Office of Management and Budget (OMB) memorandum, Subject: Guidance on Awards for Fiscal Year 2014 (M-14-02), issued November 14, 2014; OPM and OMB Joint Guidance on Awards for Fiscal Year 2014, dated November 1, 2013; to include Departmental guidance dated January 8, 2014 and OMB Guidance on Revised Performance Awards Spending Caps issued February 27, 2014 to HHS HR Directors and HR Deputies.
- b. Office of Personnel Management memorandum, Subject: Guidance on Awards for Fiscal Years 2011 and 2012, dated June 10, 2011.

2. In reference 1a above, OPM and OMB established that agencies must reduce performance award and individual contribution awards spending for all Non-Senior Executive Service (SES)/Senior Level and Scientific and Professional employees to no more than 0.96 percent of their aggregate salaries.<sup>1</sup> Further, these award-spending targets apply for awards with effective dates during Fiscal Year 2014 and 2015. Accordingly, this memorandum provides the Department of Health and Human Services (HHS) guidance for individual awards in which include rating-based awards and individual special act awards for FYs 2014 and 2015 and other categories as specified in the aforementioned guidance. This guidance is applicable to all non-Senior Executive Service (SES)/Senior Level and Scientific and Professional civilian employees, including General Schedule, wage grade and others, except political appointees covered by the freeze on discretionary spending.

The Office of Personnel Management, reference 1b, this memorandum provides the Department of Health and Human Services (HHS) guidance that placed aggregate spending caps on agency award spending for FYs 2011 and 2012; agencies must limit award spending to no more than one (1) percent of total aggregate salaries for non SES performance awards plus individual contribution awards (*e.g.*, special act, or spot) for all employees. The above referenced 1a supersedes the June 2011 guidance that placed aggregate spending caps on agency award spending for FYs 2011 and 2012 to no more than one percent of total aggregate salaries for non-SES/SL/ST performance awards plus individual contribution awards (*e.g.*, special act, or spot) for all employees.

3. It should be noted that reference 1a acknowledges that though agency executives retain flexibility, “it is critical that agencies’ use of performance awards be managed in a manner that is cost-effective and leads to increased employee performance and organizational results,” you are expected to meet all legal requirements and agency contractual obligations to include collective bargaining obligations.

4. The recently revised OPM/OMB guidance requires that for FY 2014, agencies must reduce spending on performance awards and individual contributions awards for all employees to no more than .96 percent of aggregate base salary (base salary rate plus locality adjustment). This guidance is still in effect for FY 2015.

5. This policy guidance neither limits the sum of monetary performance award to a particular employee nor the percentage of employees receiving awards. A reduc-

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<sup>1</sup>Amounts budgeted for, or paid to, employees as recruitment, relocation, or retention incentives or the use of non-monetary rewards (to recognize performance and contributions to mission) are not included in the definition of an “award” and, thus, are not subject to the OPM/OMB awards limitation. Spending on these incentives in FY 2015 can’t exceed FY 2010 spending levels. (See Use of Non-Monetary Awards, pg. 4.)

tion in current award spending levels may be required to achieve the mandated cap of .96 percent in FYs 2014 and 2015. Performance awards are discretionary and are based on the employee's rating of record. In this challenging economic environment, we must continue to maintain the high performance of our civilian workforce and recognize excellence; it is imperative that management officials fully utilize our awards system to fairly and meaningfully recognize our employees. There should be equitable distribution of awards between manager/supervisors and non-supervisory employees.

6. A quality step increase (QSI) may also be granted to a GS employee based on his/her rating of record. The quality step increase for a GS employee is another category of rating-based payment that does not constitute an award under this guidance. These payments are not covered by the .96 percent budgetary limit. However, when determining the previous QSI spending level, keep in mind agencies may not exceed their FY 2010 spending levels on quality step increases granted during FY 2011, FY 2012, FY 2013, FY 2014 and, FY 2015. In other words, each location (OPDIV/STAFFDIV) award amount cannot exceed the CY 2010 dollar amount for the entire FY 2015 they gave in FY 2010. Agencies should be cautious in awarding these payments until final funding levels for FY 2015 are determined.

Note: QSIs dollar amount is the difference in pay between the two steps.

OPDIV/STAFFDIV Heads and rating officials must continue to exercise due diligence in maintaining the integrity of the awards systems. A QSI should only be approved for employees who have demonstrated exceptional accomplishments that are expected to continue and warrant an ongoing increase in pay. OPDIV/STAFFDIV Heads should ensure that these awards are not used to circumvent the .96 percent limitation, and are expected to monitor awards nominations for anomalies. These payments must be managed carefully as they create ongoing financial obligations for the Department.

7. Non-Senior Executive Service/Senior Level and Scientific and Professional GS employees provide invaluable contributions to the Department mission. The goal of the Department Awards program is to foster mission accomplishment by recognizing excellence. OPDIV/STAFFDIV Heads are encouraged to consider the full range of the department incentive awards program, which includes honorary awards, time-off-awards, etc., to recognize performance excellence.

8. HHS organizations must ensure all collective bargaining obligations are fulfilled prior to implementing any provisions of this guidance.

#### **Applicability**

For purposes of equity and fairness in their application, restrictions on discretionary monetary awards prescribed by OPM/OMB<sup>2</sup> will apply to all performance awards programs in HHS with limited exceptions. The budgetary limits specified in this memorandum apply to spending for individual monetary awards only, which include rating-based performance awards and individual special act awards.

These restrictions include but are not limited to organizations whose employees are covered by provisions of title 5 United States Code (U.S.C.) and title 5 of the Code of Federal Regulations (CFR), regardless of the source of their funding.

#### **Use of Non-Monetary Awards**

A well-managed recognition program provides managers non-monetary options to recognize performance and contributions to the mission. Managers are strongly encouraged to make full use of the many honorary awards available throughout the Department to recognize and reward hard work. Recognition in any form should be done publicly to maximize awareness that good performance and solid contributions will be recognized.

Other awards and incentives, such as group awards, referral bonuses, or suggestion/invention awards, are frozen at FY 2010 spending levels, except travel savings and foreign language awards. Time-off awards<sup>3</sup> are not direct monetary expenditures

<sup>2</sup>The budgetary limits in this memorandum apply to all executive branch agencies for all members of the non-SES civilian employees. Agencies retain the flexibility, however, to apply these budgetary limits to awards programs for their employees to accommodate current budget constraints, provided that those flexibilities meet all legal requirements and agency contractual obligations

<sup>3</sup>Time-Off awards: Agencies are encouraged to leverage existing award programs to reward employees who identify improvements that result in documented, validated cost savings and pro-



and are not included in the .96 percent limit; however, agencies should continue to use time-off awards judiciously as they do represent a cost to the agency.

The “3 Rs”—recruitment, relocation and retention incentives are not awards and are not covered by the budgetary limits. At the same time, the memo states, “spending on these incentives in calendar years 2014, or 2015 does not exceed calendar year 2010 levels.”

As stated in the OPM/OMB guidance, time-off awards are permitted. When granting time-off awards, management should remember that time-off awards:

- Cannot exceed 80 hours in one leave year or 40 hours for a single contribution (adjusted applicably for part-time employees).
- Cannot be converted to cash payment under any circumstances.
- May not be transferred to gaining Agencies.

### Labor Relations

All collective bargaining obligations must be met prior to implementing the provisions of either OMB or this supplemental guidance. Collective bargaining agreements or past practices may provide for a structure and minimum award amounts or percentages based on the ratings received by employees. Management must reach agreement with the union prior to implementing a change to an agreement or past practice. Management cannot unilaterally change the agreement or practice based on the prescribed limitations.

### DISTRIBUTION: OPDIVS/STAFFDIVS Covered by this Guidance

ASA	Assistant Secretary for Administration
	– EEO Compliance and Operations (EEOC)
	– Office of Business Management and Transformation (OBMT)
	– Office of Security and Strategic Information (OSSI)
	– Office of Human Resources (OHR)
	– Office of the Chief Information Officer (OCIO)
	– Program Support Center (PSC)
ASA IO	– Immediate Office of the Secretary
ACF	– Administration for Children and Families *
ACL	– Administration for Community Living *
AHRQ	– Agency for Healthcare Research and Quality *
ASFR	– Assistant Secretary for Financial Resources
ASH	– Office of the Assistant Secretary for Health
ASL	– Assistant Secretary for Legislation
ASPA	– Assistant Secretary for Public Affairs
ASPE	– Assistant Secretary for Planning and Evaluation
ASPR	– Assistant Secretary for Preparedness and Response
CDC	– Centers for Disease Control and Prevention **
CFBPNP	– Center for Faith-Based and Neighborhood Partnerships
CMS	– Centers for Medicare and Medicaid Services **
DAB	– Departmental Appeals Board
FDA	– Food and Drug Administration **
HRSA	– Health Resources and Services Administration **
IEA	– Intergovernmental and External Affairs
IHS	– Indian Health Service **
NIH	– National Institutes of Health **
OCR	– Office of Civil Rights
OGA	– Office of Global Health Affairs
OGC	– Office of General Counsel
OHCR	– Office of Healthcare Reform
OIG	– Office of Inspector General **
ONC	– Office of National Coordinator for Health Information Technology
OMHA	– Office of Medicare Hearings and Appeals
SAMHSA	– Substance Abuse and Mental Health Services Administration *
(*)	– OPDIVS serviced by National Capital Region Human Resources Center
(**)	– OPDIVS serviced by independent HHS Human Resources Center

ductivity improvements. An emphasis on awards of this nature is particularly important in light of the fiscal challenges the Federal Government is currently experiencing.

PREPARED STATEMENT OF HON. ORRIN G. HATCH,  
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R-Utah) today issued the following opening statement at a hearing examining the Obama Administration's Fiscal Year (FY) 2017 budget request for the Department of Health and Human Services (HHS):

It's a pleasure to welcome everyone to today's hearing, which will be our third and final hearing on the President's proposed budget for Fiscal Year 2017. We've already had the Treasury Secretary and the IRS Commissioner appear before us. Today, we'll be talking with the Secretary of Health and Human Services.

Thank you Secretary Burwell, for being here today. It has been over a year since we last had the pleasure of seeing you before the committee, and we are glad to have you back, because, as you might expect, we have a lot to discuss.

I'll begin with the most obvious topic that I think people will want to discuss today. I don't think anyone was surprised to see that, in his final budget, President Obama chose to continue bolstering the so-called Affordable Care Act.

Secretary Burwell, I think you know my opinion on this matter. In my view, providing any further funding for Obamacare would simply be throwing good money after bad, because, quite simply, the law is just not working.

Let me offer a few examples that demonstrate this point.

**Problem Number One:** While the administration and its supporters in Congress like to tout the numbers of "newly insured" people under the health law, the vast majority of those people have gained coverage through Medicaid, not through the health insurance exchanges.

The relative decline in the number of uninsured people under Obamacare cannot be attributed to supposed improvements in the private insurance market, or to the coverage mandates imposed on employers and individuals. In fact, any increases in enrollment we've seen in private insurance plans have been almost entirely offset by the number of people who have lost the insurance they obtained through their employer before the law went into effect.

But, according to a recent report, more than 9 million people gained coverage through Medicaid in 2014, the vast majority of them in states that expanded their programs.

This is problematic for a number of reasons, most notably because Medicaid, as it is currently constituted, is a fiscally unsound program that is crippling state budgets all over the country. And, in terms of the quality of care, Medicaid is one of the worst health insurance options in the country.

Long story short, I'm not sure that the administration should be bragging about enrolling people into Medicaid.

**Problem Number Two:** The State Exchanges are not working.

To date, the Centers for Medicare and Medicaid Services, which oversees the exchanges, has issued more than \$5.5 billion in grant money to build exchanges in 17 states. Yet, every single state exchange faces significant budgetary shortfalls. For example, CMS gave \$733 million to establish state exchanges in Hawaii, Nevada, New Mexico, and Oregon. All four of these exchanges failed to become self-sustaining and were forced to transition consumers to the federal marketplace, and it is increasingly unclear whether the government will ever recoup that money.

**Problem Number Three:** Premiums are going up.

HHS recently announced that premiums for benchmark plans will rise by an average of more than 7 percent nationwide, and many communities across the country are experiencing much larger rate increases.

For example, one prominent health insurance expert reported earlier this year that Care First Blue Cross of Maryland, which controls 80 percent of the market in that state, requested a 34 percent rate hike. The Blue Cross plan in Tennessee, which controls 70 percent of that market, asked regulators to approve an increase of more than 36 percent.

One of the chief claims proponents of the Affordable Care Act made when the law was being drafted and passed was that it would reduce health care costs. Clearly, by its authors' own standards, Obamacare is failing.

I've listed three specific problems here today. There are obviously many others. I'm sure we'll talk about quite a few of them during this hearing.

I have one final item to mention with regard to Obamacare, specifically as it relates to Puerto Rico. In his budget, the President requests nearly \$30 billion in Medicaid funds for Puerto Rico, partly to avert a coming cliff in the island's program funding.

It needs to be specifically noted that this cliff—this steep drop in future Medicaid funds for Puerto Rico—was purposefully written into the Affordable Care Act by its authors. Many people—including many who supported the law that instituted this cliff—have been quick to tell us that we need act swiftly to fix this problem to help alleviate Puerto Rico's debt crisis. What they won't tell us is why the cliff was written into the law in the first place.

What's even more puzzling, Secretary Burwell, is that I have repeatedly asked senior administration officials, including you, for their views on legislation pending before Congress to address this cliff, including legislation that would provide precisely the funds the President is now requesting with his budget. Yet, until the day before yesterday, no one in the administration would offer any specific views on the matter.

We know that some members of Congress have been all too willing to turn Puerto Rico into a political football. The fact that the administration, including HHS, is so reluctant to provide basic information about its views demonstrates, at least to me, that it also is more interested in politics than solutions when it comes to Puerto Rico. This is unfortunate, to say the least.

Before I conclude, I'll try to end on a happy note. While there are many parts of the President's budget I find disagreeable—and that's being generous—I think there are some areas where we can find common ground.

For example, the budget proposes several steps to address the appeals backlog in the Medicare claims payment system. Over the past year, this committee has worked with HHS to find ways to address this problem. As you know, we even reported legislation on this issue.

Secretary Burwell, we appreciate your partnership on this important issue. I hope you'll continue working with us to get our legislation passed this year.

The budget also proposes additional spending to combat opioid abuse. This is an issue of critical importance to many members of this committee, so I am glad to see a focus on it in the budget and hope we can find some common ground there as well. As you can see, we have a lot to talk about today.

I just want to once again thank Secretary Burwell for being here today. As I've said many times before, I don't envy your position. You have a difficult job. And, I expect that we'll be making it a bit more difficult today. But, we do need to address these issues and get some answers. I look forward to hearing your views on these important matters.

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

Thank you, Secretary Burwell, for appearing before the Finance Committee to outline President Obama's budget proposal for Health and Human Services one final time. Today I'd like us to begin to talk about how Congress and the administration can build on the Affordable Care Act. And I use that term because the list of the ACA's achievements is long and growing.

People can no longer be discriminated against and denied health coverage because of a preexisting condition. The number of Americans without health insurance is at or near its lowest point in half a century.

Expanding Medicaid has put a big dent in the cost of uncompensated care, which has long been a major economic drag on hospitals across the country and a cause of rising premiums. So beyond the fact that expanding Medicaid is an opportunity to extend coverage to millions of people who struggle to get by, the numbers show that it has proven to be a good economic deal for states.

And although there is certainly more work to be done, the rate of growth in national health care costs—the line on the graph that used to have budget economists quaking in their boots—has dropped significantly from where it was a handful of

years ago. The law is not perfect, but that is undeniable progress to build on in ways that address the next big challenges in health care.

For example, there are going to be a lot of spectacular cures available in the future. You're already seeing it with certain cancer treatments and Hepatitis C drugs. There is a real question, after the bipartisan investigation Senator Grassley and I conducted that looked into the pricing of one Hepatitis C treatment, as to whether our health care system will be able to afford these blockbuster drugs. Solving this issue is going to take bipartisan work, but I strongly believe that Democrats and Republicans can work together on health care.

I think you're seeing an opening for bipartisanship on an ACA initiative called section 1332. It was born out of a proposal I first authored with former Senator Bennett—Bennett with two Ts. It is all about fostering innovations in the states, and it says they should be allowed to forge their own paths on health care as long as they meet the high bar set by the ACA—bringing high-quality, affordable health care to millions of Americans who didn't have access before.

A recent op-ed ran in the *Washington Post* calling for all sides to come together and make these State Innovation Waivers work wherever possible. That op-ed was co-authored by Senator Tom Daschle and Speaker Newt Gingrich, who nobody would accuse of being two peas in a pod on most issues.

This committee is also making bipartisan progress with respect to Medicare. It comes down to this: Congress has a responsibility to take Medicare's historic guarantee and reinforce it for a new generation of Americans. Too many older people in the program are one serious accident or illness away from a huge medical bill. And seniors too often are weighed down by a mountain of paperwork having to coordinate their own care—particularly those with chronic conditions.

I believe this committee is closing in on a bipartisan plan of attack when it comes to improving chronic care. I want to thank Chairman Hatch for his partnership and Senators Warner and Isakson for being at the forefront of this issue. Bottom line, it's time to move Medicare away from a one-size-fits-all approach and begin doing more to take into account the individual needs of patients with chronic diseases.

Now to step away from health care, I'd like to address the administration's important efforts to reduce poverty and help families. There has been real success over the past few years helping people who can find work climb out of poverty. In particular, making the expansions of the Earned Income Tax Credit and Child Tax Credit permanent as part of last year's tax deal is right up there with the ACA as some of the biggest anti-poverty achievements in decades. However, there's more that needs to be done helping families who remain struggling to find work. I was pleased to see that the administration acknowledged this issue and boosted the Temporary Assistance for Needy Families program in the budget.

Finally, I should also note there is a real effort underway on this committee to improve the child welfare system in a number of areas that need urgent attention. Last fall, I introduced the Family Stability and Kinship Care Act to prevent traumatic foster care stays by helping parents keep their children safely at home. Right now, Chairman Hatch and I are working to wrap that bill into a broader child welfare proposal to reduce unnecessary foster care stays, lessen congregate care stays, and put in place stronger protections to keep kids in foster care safe. It's about making sure the system works better for the children, and I hope the committee is able to act very soon.

Thank you again for joining us here today, Secretary Burwell, and I look forward to working with you on all these important issues over the year ahead. And thank you once more, Chairman Hatch—particularly for scheduling these three budget hearings this week.

## COMMUNICATION

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### NATIONAL ASSOCIATION OF CHAIN DRUG STORES (NACDS)

1776 Wilson Blvd., Suite 200  
Arlington, VA 22209  
703-549-3001  
[www.nacds.org](http://www.nacds.org)

#### **Introduction**

The National Association of Chain Drug Stores (NACDS) thanks Chairman Hatch and the members of the Committee on Finance for the opportunity to submit the following statement for the record regarding pharmacy-related provisions contained within the Fiscal Year 2017 Department of Health and Human Services (HHS) Budget. NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve the quality and affordability of healthcare services.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS's chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit [www.NACDS.org](http://www.NACDS.org).

As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Through personal interactions with patients, face-to-face consultations, and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow—in partnership with doctors, nurses and others.

#### **Concerns With Budget Proposal**

NACDS appreciates HHS's proposed goals to reduce healthcare costs and produce a more efficient healthcare system; however, we have concerns with some proposals contained in the FY 2017 HHS Budget. HHS has proposed excluding brand and authorized generic drugs from the calculation of average manufacture price (AMP), thereby calculating Medicaid Federal Upper Limits (FULs) based only on generic drug prices. While the goal of this provision may be to decrease Medicaid costs, we believe it may in fact reduce access to prescription drugs and pharmacy services for Medicaid patients, resulting in increased overall healthcare expenditures.

Given that AMP has not yet been used as a basis for pharmacy reimbursement, and that AMP-based FULs remain in draft form, we believe the FY 2017 budget proposals changing the calculation of FULs are premature. It is necessary for the Centers for Medicare and Medicaid Services (CMS) to meet its goal of ensuring that pharmacies are not reimbursed below their costs using the reimbursement formula created by the Affordable Care Act. Therefore, we urge Congress to reject this proposal that would conflict with CMS's objective of ensuring fair and adequate reimbursement for pharmacies so that the Medicaid population does not suffer a loss of access.

The FY 2017 HHS Budget also includes a number of proposals to cut waste, fraud and abuse in the Medicare and Medicaid programs, including the ability to suspend coverage and payment for questionable Part D prescriptions, the ability to impose

civil monetary penalties for providers and suppliers who fail to update enrollment records, and the authority to establish a program that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions (*i.e.*, a pharmacy lock-in program). NACDS applauds HHS for working to eliminate fraudulent activities from federal programs. However, NACDS urges HHS to move forward in a cautious manner so as not to disrupt beneficiary access or jeopardize beneficiary health. This can be done by ensuring that overly burdensome requirements are not placed on providers to the point of interfering with the ability to treat and care for patients. For example, any potential program which limits a beneficiary's ability to obtain their prescription medications must ensure legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must be balanced with maintaining access to prescription medications by the beneficiaries who need them most.

We have specific concerns that a lock-in provision may actually be a barrier to care as supply chain issues exist around controlled substance medications that are beyond the pharmacy's control. If a pharmacy is unable to obtain the medication for a lock-in patient, then it creates a barrier that could result in harm to the patient's health. Mechanisms must be developed and executed to allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment for beneficiaries. To minimize any potential harm and address supply issues, a beneficiary should be allowed to use all locations for a pharmacy organization if that pharmacy uses a common database with an integrated patient profile. Additionally, to reduce the potential for further abuse and confusion, claim rejections should occur at the point of sale, otherwise pharmacies will have no way to determine whether a beneficiary is enrolled in a lock-in program.

The FY 2017 budget includes several provisions to increase the utilization of generic drugs. NACDS applauds the inclusion of these important provisions, which would encourage the use of generic medications by Medicare Low Income Subsidy beneficiaries, and promote generic competition for biologics. Increasing generic utilization is one of the most effective ways of controlling prescription drug costs, and the generic dispensing rate of retail pharmacies—83.5 percent—is higher than any other practice setting.

NACDS believes there are other opportunities to reduce program spending while vastly improving the health of Medicare beneficiaries; including improving access for underserved beneficiaries and the better use of medication therapy management (MTM) services.

#### **Pharmacists as Providers**

As the U.S. healthcare system continues to evolve, a prevailing issue will be the adequacy of access to affordable, quality healthcare. The national physician shortage coupled with the continued expansion of health insurance coverage in recent years will have serious implications for the nation's healthcare system. Access, quality, cost and efficiency in healthcare are all critical factors—especially to the medically underserved. Without ensuring access to requisite healthcare services for this vulnerable population, it will be very difficult for the nation to achieve the aims of healthcare reform.

The medically underserved population includes seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Significant consideration should be given to innovative initiatives within the medically underserved population to enhance healthcare capacity and strengthen community partnerships to offset provider shortages and the surge in individuals with healthcare coverage.

Pharmacists play an increasingly important role in the delivery of services, including key roles in new models of care beyond the traditional fee-for-service structure. Pharmacists are engaged with other professionals and participating in models of care based on quality of services and outcomes, such as accountable care organizations (ACOs). Pharmacists now commonly provide immunizations and medication therapy management (MTM) services.

In addition to medication adherence services such as MTM, pharmacists are capable of providing many other cost-saving services (subject to state scope of practice laws). Examples include access to health tests, helping to manage chronic conditions such as diabetes and heart disease, plus expanded immunization services. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, limits the number and types of services pharmacists can provide, even though fully qualified to do so. Retail pharmacies are often the most readily

accessible healthcare provider. Research shows that nearly all Americans (94 percent) live within 5 miles of a retail pharmacy. Such access is vital in reaching the medically underserved.

We urge you to increase access to much-needed services for underserved Medicare beneficiaries by supporting H.R. 592/S. 314, the Pharmacy and Medically Underserved Areas Enhancement Act, which will allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services (subject to state scope of practice laws) not currently reaching them. This important legislation would lead not only to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality.

#### **The Benefits of Pharmacist-Provided MTM**

Poor medication adherence costs the U.S. healthcare system \$290 billion annually. Pharmacist-provided services such as MTM are important tools in the effort to improve medication adherence, patient health and healthcare affordability. Studies have shown that patients who are adherent to their medications have more favorable health outcomes, such as reduced mortality, and use fewer healthcare services (especially hospital readmissions and ER visits). These studies included patients with cardiovascular disease, chronic obstructive pulmonary disease (COPD), high cholesterol and diabetes. Current MTM restrictions require that Medicare Part D beneficiaries suffer from multiple chronic conditions, be prescribed multiple medications, and meet a minimum annual cost threshold of \$3,138 in 2015 for their prescriptions before they are eligible for Part D MTM. According to the CMS MTM Fact Sheet, approximately 85% of programs opt to target beneficiaries with at least three chronic diseases in 2014. This is a contributing factor to the lower than projected eligibility levels in the MTM program.

NACDS has long been supportive of exploring new and innovative approaches to improve the Part D MTM program. One of the approaches we believe can be successful is the Enhanced MTM Model pilot allowing Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. The Enhanced MTM Pilot program presents an opportunity to create better alignment of program incentives and has the potential to lead to improved access to MTM services for beneficiaries and greater medication adherence. NACDS believes that the MTM Pilot program should include retail pharmacies, as a successful model test must include retail community pharmacists. Medication management services provided by community pharmacists improve patient care; improve collaboration among providers; optimize medication use for improved patient outcomes; contribute to medication error prevention; improve hospital and readmission cost avoidance; and enable patients to be more actively involved in medication self-management.

Since the pilot is scheduled to last for 5 years beginning in 2017, we also urge lawmakers to explore new and innovative approaches to improving the MTM program that could be implemented in the short term. NACDS believes one short term approach is more efficiently targeting beneficiaries who can most benefit from the services that will improve medication adherence and overall program effectiveness. Congress recognized the importance of MTM on a bipartisan basis, including it as a required offering in the Medicare Part D program. We urge Congress to build on this earlier action and strengthen the MTM benefit in Medicare Part D through support of legislation such as that introduced by Senator Pat Roberts (R-KS) and Senator Jeanne Shaheen (D-NH), S. 776, the Medication Therapy Management Empowerment Act of 2015, which will provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD, and high cholesterol.

#### **Conclusion**

NACDS thanks the Committee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

