

NOMINATION OF SYLVIA MATHEWS BURWELL

HEARING
BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ONE HUNDRED THIRTEENTH CONGRESS
SECOND SESSION
ON THE
NOMINATION OF
SYLVIA MATHEWS BURWELL, TO BE SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 14, 2014



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**NOMINATION OF SYLVIA MATHEWS
BURWELL, TO BE SECRETARY, DEPARTMENT
OF HEALTH AND HUMAN SERVICES**

WEDNESDAY, MAY 14, 2014

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

The hearing was convened, pursuant to notice, at 2:19 p.m., in room SH-216, Hart Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

Present: Senators Rockefeller, Schumer, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Brown, Casey, Warner, Hatch, Grassley, Crapo, Roberts, Enzi, Cornyn, Thune, Isakson, Portman, and Toomey.

Also present: Democratic Staff: Joshua Sheinkman, Staff Director; Jocelyn Moore, Deputy Staff Director; Michael Evans, Chief Counsel; Elizabeth Jurinka, Chief Health Policy Advisor; Anderson Heiman, Tax Policy Analyst; and Juan Machado, Professional Staff Member. Republican Staff: Chris Campbell, Staff Director; Kimberly Brandt, Chief Counsel, Oversight; Jay Khosla, Policy Director; Tony Coughlan, Tax Counsel; Nicholas Wyatt, Tax and Nominations Professional Staff Member; and Anna Bonelli, Detailee.

**OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR
FROM OREGON, CHAIRMAN, COMMITTEE ON FINANCE**

The CHAIRMAN. The Finance Committee will come to order.

The Finance Committee meets today to discuss the nomination of Sylvia Mathews Burwell to be the Secretary of the Department of Health and Human Services. If one thing has become clear in the month since the President announced Ms. Burwell's nomination, it is that she is tremendously well-respected, not only by those she has led and worked with in the administration, but by Democrats and Republicans in the Congress as well.

That should not come as any big surprise. Last year, the Senate confirmed her nomination to be the Director of the Office of Management and Budget by a vote of 96-0. That was a big and well-deserved bipartisan endorsement, and Ms. Burwell's accomplished background and long record of results show why she has earned that respect.

She is a graduate of Harvard and Oxford, where she was a Rhodes Scholar. She served in the Clinton administration as a top economic advisor to the President and the Secretary of the Treasury, and she has years of experience in the non-profit sector. First,

as chief executive officer and then as president of Global Development at the Gates Foundation, she led efforts to address some of the most pressing global health challenges of our times. As the head of the WalMart Foundation, she was a tireless advocate for the veterans' hiring programs, and she was a leader in the fight against hunger in our communities.

Ms. Burwell has also been a steady hand and an effective, communicative leader at the Office of Management and Budget. She helped navigate the difficulties of the government shutdown last fall, and, in the year that she has served as Director, the Federal deficit has continued to plummet.

There is also one other important fact to keep in mind as the committee considers Ms. Burwell's nomination. That is, you simply cannot lead this generation's Office of Management and Budget without being thoroughly steeped in health care. Health care is simply the biggest structural challenge in the budget and an essential part of the job.

Now, everyone understands the biggest task ahead for Ms. Burwell, should she be confirmed as HHS Secretary. The Affordable Care Act will be her central focus each day she serves as Secretary. My view is, there are plenty of ways both parties can work together to improve the law and ensure America does not go back to the days when health care was just for the healthy and the wealthy.

Now, there is also a great deal of promising news about Medicare for Ms. Burwell to build on as Secretary. For example, Medicare's rate of spending growth is slowing. According to the latest data, spending went up by only 1.9 percent over a 2-year period. That is slower than the overall economy, and it is far behind the historic pace. The cause of lower premiums and a stronger, more secure future for Medicare is significantly boosted by these developments.

With the bipartisan support of members of this committee, there have been big improvements in Medicare transparency. As the country's largest single purchaser of health care, Medicare has to lead the way in making sure that all consumers and taxpayers have the information they need to get the best value for their dollar. We look forward to working with you, once you are confirmed, to continue that effort, Ms. Burwell.

Next, the Congress has never been closer to repealing the flawed Medicare physician payment system and replacing it with bipartisan reforms that reward the quality of care rather than the quantity of care. I am looking forward to working with you again, Ms. Burwell, once you are confirmed, to fix the Medicare physician payment system this year. After that is accomplished, the committee looks forward to working with you on what I view as the single biggest challenge for Medicare's future, that is, dealing with chronic disease.

Outside of the health care arena, the committee is going to have to maintain its close relationship with the HHS Secretary on issues like foster care, child welfare, and family support services. Today I will wrap up by congratulating our nominee and thank her for joining the committee today. The Senate's 96-0 confirmation vote for your current role was clear evidence that you are respected for your commitment to work with people and for your thoughtfulness.

Following a thorough review, I hope to have your nomination approved by the committee and the Senate as quickly as possible and with equally strong bipartisan support.

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

The CHAIRMAN. Let me recognize Senator Hatch now.

**OPENING STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH**

Senator HATCH. Well, thank you, Chairman Wyden. I appreciate you convening this hearing to consider the nomination of Sylvia Mathews Burwell to serve as Secretary of the Department of Health and Human Services. I am very pleased that you have one of my all-time favorite Senators here to testify for you, really a doctor in the Senate, who has served the Senate very, very well.

I want to thank Director Burwell for her willingness to serve in this capacity. It is a tough job. Director Burwell, let me start by saying something that I think you already know. If you are confirmed to this position, you will have your work cut out for you. The size and scope of the Department of Health and Human Services surpasses that of any other Federal Cabinet-level department.

The HHS fiscal year 2014 budget totals almost \$1 trillion, which makes it larger than that of even the Department of Defense, basically double what the Department of Defense is. More importantly, HHS touches the lives of hundreds of millions of people. From cradle to grave, HHS oversees many programs, from finding and approving new treatments for diseases to providing a safety net for those who have run out of other options. The agencies under the HHS umbrella include the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, and the Centers for Medicare and Medicaid Services, or what we call CMS.

CMS alone is the world's largest health insurer, with an annual budget of roughly \$860 billion. While I believe you have the qualification to do the job, there is still much you will need to do in order to assure members of this committee that HHS is heading in the right direction and that your leadership will help steer the agency through the very turbulent times that we know lie ahead.

One of the greatest challenges facing HHS is shoring up the Federal and State-based health insurance exchanges. Ensuring that the exchanges are operating efficiently and effectively will be one of your biggest challenges. Recent reports of the numerous issues being faced by the State exchanges attempting to implement the law have been cause for great concern among many members of Congress, including some on this committee.

As part of the Affordable Care Act, States are required to have an online health care exchange where citizens can go and shop for health insurance. States have the option of either building their own exchange, using the exchange provided by the Federal Government, or a hybrid. Every State is given a \$1-million grant for the purpose of determining what type of exchange they would implement. Additional grants were given in stages for those States that are building all or part of their own health care exchange. HHS also awarded seven early innovator grants to States that quickly

decided to build their own exchange, in order to help support the development and implementation of the necessary IT systems.

In total, HHS paid \$4.7 billion to help States build their exchanges. What is troubling is that at least seven States and the District of Columbia failed to build a successful website and exchange. These seven failing States received more than \$1.25 billion from HHS to build their exchanges. That is a huge amount of taxpayer dollars that has apparently been spent with little or no accountability.

Now, many of these States are looking to rebuild their systems and are seeking additional funds from the Federal Government. That is why today I am joining Senator Barrasso in introducing the State Exchange Accountability Act. This bill requires States that operated a State-based exchange in 2014 and then decided to abandon that exchange to repay all of the establishment and early innovator grants that they received from HHS.

In addition to overseeing this massive new expansion of benefits the exchanges have created, you are also going to be charged with helping to ensure the longevity and the solvency of the existing Medicare trust fund, which is projected to go bankrupt in 2024. All told, between now and 2030, 76 million baby boomers will become eligible for Medicare. Even factoring in deaths over that period, the program will grow from approximately 47 million beneficiaries today to roughly 80 million beneficiaries in 2030. Maintaining the solvency of the Medicare program while continuing to provide care for an ever-increasing beneficiary base is going to require creative solutions and a skillful Secretary at the helm working with CMS, and I am counting on you to be that.

Finally, one of the most important responsibilities that you have to this committee is to be responsive. I have heard several commitments made by nominees in these confirmation hearings about providing timely and substantive responses. More often than not, I have been deeply disappointed. So I hope today that your commitment will stand the test of time beyond your confirmation, because words and promises matter a great deal to me, and I think to other members of the committee. I hope you will be up to that challenge.

Like I said, overseeing the complex infrastructure of a department like HHS is not a job for the faint of heart. Naturally, I wish you the best of luck as you work to address these challenges and as you continue going through the confirmation process. You are going to need all the luck you can get. But I am grateful to people like you who are willing to take on these tough responsibilities and lend your best expertise to them. We are grateful that you are willing to serve.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hatch. As we have done ever since Chairman Baucus went to China, you and I will be working very closely in a bipartisan way on this, and I thank you for it.

Senator HATCH. I think we will. Thank you.

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

The CHAIRMAN. Director Burwell, before we get started with your testimony, it is a Finance Committee tradition to have the nominee

introduce any family members who are here today, so why don't you do that?

Ms. BURWELL. Thank you. Thank you, Mr. Chairman. I would like to introduce my husband Stephen Burwell, my sister Stephanie O'Keefe, and two very good old friends, Jackie Long Ebert and Linda Lurie. Thank you.

The CHAIRMAN. Thank you. We are glad you are here. As Senator Hatch noted, public service is not, for a family, exactly for the faint-hearted either, so we are glad that all of you are here.

Now, the ever-gracious Chairman Rockefeller, who is here to welcome another West Virginian, has as always been very gracious. Dr. Coburn is on a tight time schedule. Dr. Coburn, why don't we begin with you, and then we will have an introduction from home-State Senator, Senator Rockefeller.

**STATEMENT OF HON. TOM COBURN,
A U.S. SENATOR FROM OKLAHOMA**

Senator COBURN. Thank you very much, Mr. Chairman. First of all, let me say what a privilege and an honor it is to be able to introduce Ms. Burwell to the committee. I have worked with her for the last year or so and prior to her confirmation as OMB Director.

I actually look for people who have strong traits, and the fact that she is willing to make this family sacrifice—and it is a family sacrifice—to me is very reassuring for us as a country.

I thought I would talk about five areas of Sylvia Burwell that maybe not everybody else knows. The first is, she is competent. To me that says something, because so often we have people placed in positions in Washington who are not competent for the task at hand.

The second thing is, she has an outstanding character, and I have experienced that over the past year in working very closely with her and the people at OMB on the problems that we have seen at Homeland Security, both on cyber and other areas. So the fact is, when you have somebody who is competent and also has strong character, you find a way to get past your differences to try to solve problems.

Third, as Senator Hatch mentioned, responsiveness is a key for the Congress. I have to tell you, I found her remarkably responsive. My partner at Homeland Security, Tom Carper, has as well. That comes along with her commitment. The fact is, she is going to be committed to do the right things and to keep Congress involved. I will let her answer those questions on her own.

Another trait that I think will make her an outstanding Secretary is, she is a great listener. Even when she has her mind made up, which sometimes happens, she will listen to another point of view to gain information that she might not have. That is a characteristic too often that we do not see as members of Congress and members of the administration, whether they are Republican or Democrat.

Then finally, because she is from West Virginia, Hinton, a town of 3,000 people, she comes to Washington with a lot of common sense. My favorite quote is, "There's a thimble and a half full now of common sense in Washington, and she's the half."

So it is my pleasure to recommend her to my colleagues on the Finance Committee. I will support her nomination on the floor, and I will do everything to help her be successful at Health and Human Services, if she is so given that responsibility. I thank the committee.

The CHAIRMAN. Senator Coburn, thank you very much for those powerful words and the focus on competence, common sense, and accountability. That is really the coin of the realm in terms of a nominee, so we are very pleased that you are here. I know you are on a tight time schedule, and we will excuse you at this time.

Chairman Rockefeller is here for another West Virginian.

**OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV,
A U.S. SENATOR FROM WEST VIRGINIA**

Senator ROCKEFELLER. I too want to thank Senator Coburn. Ms. Burwell, it is not usual to get introduced by him in such terms. He has a very strict judge of character and has a strong moral aspect to everything he does. I am very happy that he has introduced you. It is an easy thing for me to do.

But first I have to point out something of interest. The Commerce Committee was going to have a really interesting hearing in this room today on the NCAA and the whole concept of the student athlete, or is that really athlete student, and what are we doing, what is the NCAA doing, what are universities doing, to make sure that athletes are getting the academic training that they need to. I think it is going to be a very interesting hearing.

The reason we were going to come to this room is because it was going to be absolutely packed, because it is a subject of great controversy, and the NCAA is very unhappy that we are having the hearing. But then we were pushed aside by a higher order.

But for today's hearing, actually this room is not even half full. What makes me happy about that is, I think there is a general understanding in this body, and certainly on this committee, that you are that really competent person who relishes challenges and can balance challenges with family responsibilities. I mean, you are just that way, and that is one of the wonderful things about growing up in a small community.

So I introduced you for the first time 16 years ago, and you were becoming Deputy Director of the OMB at that point. More recently, I introduced you again to become Director, and that was easily done. Today, I could not be more proud to speak for you and to present you to this committee.

I have done this a lot with people, but I do not think I have ever been as proud of the person, and as sure of my feelings, as I am about you. I have respect for your intelligence, for your integrity, what I would call a ferocious integrity. You have a work ethic beyond contemplation, but all the while you are relaxed. You appear relaxed, anyway.

As Senator Coburn said, you do listen. You are a very good listener. That is terribly important. The business of writing letters you will do, not because you have to do it but because it is in your interest to do it, and you will find a way to do it. I think you are going to be a superb, superb Secretary.

The Department is absolutely gargantuan in size, and it affects millions and millions of Americans. It is food and drug supply, protection of our country from outbreaks of disease or bio-terror attacks, the medical research that we rely on for cutting-edge treatments but which we are under-funding, and the Federal investments in global health, which I think most people do not know that much about and do not necessarily associate with your position.

I think it is impossible to overstate how important it is that the Secretary of HHS have that degree of organizational intuitive skill, not that they have to work at it hard, but it is just borne with them, and it is part of how they do things. People come to understand that, and they draw people to them because of, in the words of Senator Coburn, competency. Competency is a cherished commodity. When people are in a very high position and have that, people want to come work for them. People want to work harder for them. The country feels prouder of them, and maybe even the press is nice to them.

So anyway, here you are, a proven manager, both public and private, and so much the right person for this job that it is just a cliché to even say it. Yes, the fact that you are a proud native of Hinton, WV, 3,000 people, is very important. It is very important in character formation and in one's world view. In that case, not a large world view, but in the currents of your life, a total world view.

I have known Sylvia her entire life and her wonderful parents, Cleo and Bill, and her family and friends from Hinton. I have attended church with your family. I was at your wedding reception. You interviewed me, I think you told me, when you were 6 years old on the Hinton County courthouse steps. I have no idea what the question was, but I probably did not answer it very well. I was probably terrified. [Laughter.]

But the effect then is that I just have a deep and abiding feeling about you and, because of you, your family. I think your family and you come together in a perfect way in American life.

You are brilliant—you will not say that, so I will have to do it for you—as has been indicated—Harvard, Rhodes Scholar—and yet somehow you remain humble, always hardworking.

Again, I use this term “ferocious integrity,” which means everything to me. Sort of the central devotion of your purpose of public service is to help people better their position in life. You do not focus just on one group, but everybody has to have a better shot in life, and you are possessed by that public passion. That had to come partly from your grandparents, because they got here and they somehow helped instill that in you.

You could have made a fortune when you graduated from Harvard and gone to anyplace in the world, any law firm. You did not. You headed directly into public service. You spent the majority of your life in public service, which is filled with controversy and not enormously high wages, a lot of frustration, and a lot of sleepless nights.

When you have not been doing that, you have been working for organizations that were trying to do that: the Gates Foundation and out in Bentonville, that foundation. In both cases, you were working on a worldwide basis, and when we met in my office we

were talking about one of the things I want to work on after I leave the Senate, which is on baby teeth, the health of teeth, which most people overlook but which is absolutely essential in the morale and self-confidence development of any young person, and in Appalachia is a real problem. You have spent a great deal of your time at the WalMart Foundation doing exactly that.

When it comes down to it, you want people to have health insurance. You want them to have that peace of mind. I do not need to do this, but I am going to do it because I so enjoy doing it. Your service in the Federal Government is absolutely unmatched—the Clinton administration Staff Director for the National Economic Council. Well, wow. I mean, that is complex stuff. Not that anybody could tell you what goes on there, but the future of the country depends enormously on what does go on there.

Chief of Staff to Secretary Robert Rubin, Deputy Chief of Staff to the President of the United States, Deputy Director of the Office of Management and Budget, and then Director of that agency—you were central to crafting the Clinton budget in the late 1990s, which led to budget surpluses for 3 years in a row, something almost impossible to imagine, and enormous growth economically in our country.

You learned—I have down here through your work with the Clinton administration, but that is nonsense. You just worked because of the way you are; you could work across the aisle with other people. It is your instinct to try to find common ground.

You are very, very tough. I am thinking of the example that we discussed about the respirable dust decision in underground mines. I wanted it to be one, it is now two—I apologize to the audience for not going into this—and Ms. Burwell did the right thing and she came down at 1.5, which was the first time in 41 years that the U.S. Government had addressed the problem of breathable dust—or unbreathable and die dust—leading to Black Lung. I mean, it was a remarkable decision. You made that decision, and, because of it, it is now in effect.

Your philanthropic works speak for themselves. You are going to be speaking for yourself. I just cannot think of anybody more perfect to head HHS. There were so many bumps in the road. I think that is innate, and we discussed that—enormous programs with vast consequences. I do not think it ends.

I think there will be a period of 15, 20 years before things kind of settle out and the various nooks and crannies are taken care of and people feel comfortable. All of a sudden, they will just realize they feel comfortable, and then you just get down to the business of doing health care.

So we need you, Sylvia Mathews Burwell, very, very much. I think you can gather from my statement that I am probably going to vote for you. [Laughter.]

But you are not just about budgets. You are about people, and you are about fighting for people whom other people will not fight for, and you are about fighting for people who could use a little help, and you are fair to people who do not need any help. You are just a fair person, a tough manager, and probably the smartest person in the city.

Mr. Chairman, I am proud to present to you Sylvia Mathews Burwell.

The CHAIRMAN. Thank you, Chairman Rockefeller. That was a wonderful introduction. I will tell you, Director Burwell, I am really curious what you interviewed Chairman Rockefeller on when you were 6. [Laughter.] So perhaps we will learn that secret one day.

Now at this point, we would like you to deliver your testimony, then we have four standard questions for nominees that we will, I think, be able to deal with quickly, and then we will begin questions from the Senators. So we will make your prepared remarks a part of the record in their entirety, and please proceed.

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

Ms. BURWELL. Thank you, Chairman Wyden and Ranking Member Hatch, members of the committee. I want to thank you for inviting me here today. I am honored that President Obama has nominated me for the Secretary of Health and Human Services, and it is a privilege to appear before this committee.

I want to thank Senator Rockefeller and Dr. Coburn for their kind words. I am honored to be introduced by two such extraordinary public servants who have both spent their lives helping others and delivering for the American people.

I am especially grateful to my husband Stephen and our children for their tremendous support. And, while my parents could not be here with us today, I want to recognize them for their instilling within me and my sister the enduring value of public service.

As a second-generation Greek immigrant, I was raised to be thankful for the tremendous opportunities this great Nation offers and to appreciate the responsibilities that come with those opportunities. Throughout my childhood in Hinton, WV, my father, an optometrist and small business owner, and my mother, a teacher, set a great example for me and my sister through their engagement in service through our community and our church. It is that example that is an important part of why I stand here today.

Whether in the public or private sector, working across a range of issues, I focus my work on three things: building strong teams, strengthening relationships, and delivering results. In my role as OMB Director, I have worked closely with members of this committee and others to support efforts to return the budget process to regular order and drive towards progress on issues that we all care deeply about.

If confirmed, I look forward to working alongside the remarkable men and women of the Department of Health and Human Services to build on their work to ensure that children, families, and seniors have the building blocks of healthy and productive lives. These issues are fundamental to all of us, whether it is the chronic condition of a child we love or the safety of the food we eat every day, so I respect and appreciate the importance of the challenges before us.

As we meet here today, scientists and researchers at the National Institutes of Health are working to find cures for some of the world's most serious diseases, and experts at the Centers for Dis-

ease Control and Prevention are working to prevent them from spreading. The Food and Drug Administration is protecting the food we eat and the medications our doctors prescribe us. Our parents and grandparents rely on the Centers for Medicare and Medicaid Services, and millions of our children benefit from Head Start. Thanks to the Administration for Community Living, millions of Americans are living with dignity in their own communities. The Department's work to ensure accessible, affordable, quality health care through the implementation of the Affordable Care Act is making a difference in the lives of our families and our communities, while strengthening the economy. Together, all this work forms the foundation of a stronger middle class, a more prosperous economy, and healthier communities.

Mr. Chairman and members of this committee, thank you again for the invitation to speak with you today. I have valued the conversations that we have had over the course of the past several weeks, and I am hopeful that we will have the opportunity to continue to work together closely in the months ahead to deliver impact for the American people.

With that, I would be pleased to answer your questions. Thank you.

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

The CHAIRMAN. Director Burwell, thank you. We have several questions that are essentially standard questions for all nominees, so let me just go through those now.

Is there anything that you are aware of in your background that might present a conflict of interest with the duties of the office to which you have been nominated?

Ms. BURWELL. No, sir.

The CHAIRMAN. Do you know of any reason, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities of the office to which you have been nominated?

Ms. BURWELL. I do not.

The CHAIRMAN. Do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of Congress, if confirmed?

Ms. BURWELL. I do.

The CHAIRMAN. Do you commit to provide a prompt response in writing to any questions addressed to you by any Senator of this committee?

Ms. BURWELL. Yes, sir.

The CHAIRMAN. Very good.

What we will do now, colleagues, is we will all proceed with questions, and we will go with the 5-minute round.

Let me, if I might, start with a question about another priority of the committee—we have already identified that we will have many questions about the Affordable Care Act. That question is about fixing this broken-down system of reimbursing physicians under Medicare. What has happened is, we have a system that is poorly coordinated and does not reward quality.

What the Congress does is just put patch after patch after patch on it. We are now on something like our 17th patch. During the

most recent debate, Senator Murphy was in the chair when we were discussing this, and he is the youngest U.S. Senator. I looked up and said, I do not want, when Senator Murphy is eligible for Medicare, for us to still be patching and patching and patching some more.

So the President, in his budget, made a commitment to working with the Congress to reform this, and particularly to repeal the SGR and replace it with a system that would reward coordinated care and reward quality. Our colleague Senator Hatch, in my view, deserves a great deal of credit for this effort. If confirmed, will you commit to repealing and replacing the current broken Medicare reimbursement system for physicians before the end of this year?

Ms. BURWELL. Senator, I am very glad that you have raised the issue, and I am very glad that in my meetings—and this is something that is bipartisan—this issue has come up and that, even though there is a fix that takes us till March, people are interested and excited about a permanent fix.

There is bipartisan legislation, bicameral support, for changes that can help get us there. You yourself have played a leadership role in proposals that will make a difference. If I am confirmed, and in my current role, I am excited about the opportunity that we can work together to get a permanent solution that has both reforms which are important and a permanent solution that helps our physicians have predictability through time. So for those reasons, that is something that I would look forward, if confirmed, to working on, and in my current role am excited to work on as well.

The CHAIRMAN. Thank you. It is clearly urgent business, because we can get it right now at rock-bottom prices. I mean, it is only going to get more and more expensive, so we appreciate your commitment on that.

Let us turn to chronic disease. There has been bipartisan interest in this committee on it. I see my colleague Senator Isakson; Senator Toomey and Senator Bennet have had a great interest in this.

The reality is, Medicare in 2014 is dramatically different than Medicare when the program began in 1965. It is largely about cancer and diabetes and stroke and heart disease and Alzheimer's. So, if a senior breaks their ankle, and we certainly hope that does not happen, that is something like 15 percent of Medicare. It is really all about chronic disease.

I would be interested in your thoughts about how Medicare can step up and address this extraordinary challenge, because this is really going to be what Medicare is all about. I am very appreciative of my colleague from Georgia. He and I have introduced a bill which my colleague, Senator Isakson, appropriately named the Better Care, Lower Cost Act. Congressman Welch and Congressman Paulsen in the other body have been supportive as well. As I mentioned, Senator Toomey, Senator Bennet, and a number of Senators have interest in this.

What is your take about the next best steps to address what is going to be the premier challenge for Medicare in the years ahead?

Ms. BURWELL. The issue of chronic disease is one that I actually think cuts across the entire Department. Certainly Medicare is where it is being paid for, and a big part of the delivery of that service is with regard to chronic care. But I actually think one also

needs to back up to NIH and the issues of research and all through the issues of CDC and actual delivery, as well as the Health Resources and Services Administration, in terms of how we train our providers.

So the issue of chronic disease, I think, is one of the things—as we think about many health care issues, but particularly one as large and influential as this—that you need to think about across the pieces that are within the Department so that we are getting the right solutions in place, the right data and analytics that show us how we can work on these issues at the front end of them, before they get to the point where they are costing us so much.

We work on the delivery systems in terms of how we, as both communities and directly within hospital systems and insurance systems, are providing that care. So I think Medicare is an important part of it—and the tools that we can use in Medicare, because it is such a large and influential part of the system—but I think we have to think about it across a number of different areas, including with providers.

The CHAIRMAN. Let me see if I can get one other question in, because I am in effect starting the questioning. Obviously with the ACA, it is all about improving access, improving quality, decreasing costs. But I think, as with any landmark law, there are challenges.

Since we are starting now, I think it would be helpful if you could just briefly outline—because you are going to get plenty of other questions, we know—what are going to be your priorities in terms of ensuring the success of the Affordable Care Act?

Ms. BURWELL. With regard to the Affordable Care Act specifically, when I think about the Act, there are three main things that seem to be, for me, the North Stars: one is access; the second is affordability, and that is affordability for the individual, affordability for actually the government in terms of all that we spend that has been mentioned, as well as affordability for our economy; and the third issue is quality.

When I think about the Act and the implementation of it, what I want to do is, if I am confirmed, work to try to maximize against all three of those areas and think about the ways that we can do better.

The CHAIRMAN. Senator Hatch?

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

Ms. Burwell, one of the most sacred responsibilities that we as public servants have is to safeguard the hard-earned taxpayer dollars that American families entrust to us. Now, seven States, including the District of Columbia, are having a dismal time building their own exchanges. In fact, the failure in some of these States is nothing short of spectacular.

Two of the States are abandoning their broken websites. Based on the most recent reports, these States have received more than \$1.25 billion to plan and build their exchanges. Now, some of these States are looking for additional Federal funds to continue their failed experimentation, at least in my view.

So I have two very simple questions to ask you, and I would really appreciate a “yes” or “no” answer to these, if you can. First, do you believe that these States that have so negligently managed their funds should be required to reimburse the taxpayers for their

incredible failures? If you could say “yes” or “no,” I would appreciate it.

Ms. BURWELL. Senator, with regard to the specifics of each of the State cases, that is something, if confirmed, I would want to learn about. I think what I would say “yes” to is that we need to understand and, where the Federal Government and the taxpayer had funds misused, we need to use the full extent of the law to get those funds back for the taxpayer.

Senator HATCH. All right. The second question is, can you give me and the American taxpayers a public commitment today that HHS will not give any more dollars to those failed exchanges for more failed experiments?

Ms. BURWELL. Senator, with regard to the specifics of how the exchanges and those funds go forward, I guess what I would do is right now—because I am not familiar with the specifics because I am not there—there are three things: (1) we have to understand what went wrong; (2) when we do understand that, as I said, we need to go to the full extent of the law, if there are contractors or others that have misled through their contracts or other things, to fully recover; and (3) I think we need to make sure that we both learn from the mistakes of the exchanges that are not working and learn from the exchanges that are, such as Washington State’s where Senator Cantwell is from.

Senator HATCH. All right.

Now, your first and foremost responsibility as an appointed official is to be accountable to Congress and the American people. Now, one important way Congress fulfills its obligation to the taxpayers is by asking for information about your Department’s activities. Over the past year, we have sent at least five letters to HHS that have gone unanswered. Responses to questions for the record take months. In fact, we now need action-forcing events like this confirmation hearing to get answers, which are often incomplete.

My colleagues all share similar frustrating experiences. So I have, again, two straightforward questions to you: (1) do I have your public commitment today that you will respond to our inquiries in no more than 30 days?

Ms. BURWELL. Senator, with regard—

Senator HATCH. Unless you ask us for extra time.

Ms. BURWELL. Senator, you have my commitment that, with regard to being responsive, that is something I consider important. And I think, hopefully, you have heard from your colleagues who have had the chance to work with me in the past year that it is something I prioritize in terms of responsiveness and communication.

Senator HATCH. I was very impressed with what Senator Coburn had to say, and I agree with that, by the way, and will appreciate that.

Now the second question is, what, in your opinion, should be our recourse as a committee if this public commitment is not kept?

Ms. BURWELL. Senator, with regard to, if there are frustrations, and if I am confirmed, I hope that you would pick up the phone and call me.

Senator HATCH. All right.

Ms. BURWELL. One of the things that I think actually is a very important part of working and getting to a solution, as I think Dr. Coburn said, is we do not always agree. But if we can have conversations and those conversations can be specific, I think that is something we can use to figure most things out, even at times when we may not agree.

Senator HATCH. Thank you. Director Burwell, to date, the administration has made at least 22 unilateral changes to Obamacare without consulting any of us up here in Congress. Most recently, HHS announced it was raiding a Medicare fund to provide extra payments to Medicare Advantage plans to forestall benefit cuts. On April 10th, I asked Secretary Sebelius whether or not there would be any more changes to Obamacare, and her answer, in my opinion, was not very reassuring.

So again, I have two questions for you. Will you commit to considering Congress in obtaining legislative changes to the law in the future?

Ms. BURWELL. Senator, with regard to the issues of implementation, when there are things in place—I think the core objective is common-sense implementation and improvements within the context of the law, and, where one needs changes with the law, we should seek that. In the President's current budget, actually we do seek changes, and they have to do with small businesses and some of the tax issues. That is a place where we think that we can improve that, and we need the support of the Congress in order to do that.

Senator HATCH. All right. My last question: if you do expect more changes or delays to Obamacare, what will they be?

Ms. BURWELL. Senator, with regard to the implementation of such a large and complex thing that is such a large part of our economy, I am not sure that I can sit and predict. But I think what is important, as one moves along and is implementing, is listening and learning as you go, making those common-sense changes within the context of the law and, where there are changes that require legislative changes, to work with the Congress to make them.

It is a very complex system. It was complex before the Affordable Care Act. Our health care system in the United States is a large, complex system. The law itself will hopefully make, and is making, improvements, but it is a complex system that I think will be evolutionary as we learn. One of the things that I am hopeful about, if I am Secretary, is that listening and learning and hearing and making changes that are appropriate is something that one would want to do.

Senator HATCH. Well, thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Rockefeller?

Senator ROCKEFELLER. Director Burwell, there is an understandable rage for lowering costs. I remember—Ron, I am not sure if you were here or not—when Dick Darman was in your present position, and he came before the Finance Committee at that time to talk about the runaway costs of health care.

He was sheet-white. He had sort of disappeared for a week. That was the impression; nobody knew what he was going to say or could ask him any questions. Then he came and he was sheet-

white, and he just predicted—he had this horrible, dire prediction of the cost of health care eating everything up and squashing other good programs, which leads to my question. Making things cost-effective and cutting costs, lowering costs, which Democrats love to boast about, runs sometimes—let us take, for example, the dual-eligibles—into the providing of adequate and good care.

That is sort of a sloppy, philosophical thing to say, but there come very difficult decisions when it is more expensive to take care of certain kinds of people, certain kinds of illnesses. When we lifted the annual cap and then the lifetime cap, that, you see, was quite the opposite. That was saying, oh, it is important to spend more money because having really good health care for people is what we are here for.

So those things are in conflict with each other. I wonder if you have sort of an operating philosophy?

Ms. BURWELL. I think there are difficult choices, and I think that is a key and operative word: choices. At the Office of Management and Budget, we have had the opportunity, under what are tight budget levels, our current 2015 levels—when you take into account FHA receipts and the growth of veterans' benefits, our levels are the same as last year.

So one of the things I think about, when I think about making these difficult choices, is getting as many of the facts as one can and making sure that you lay out the different choices as best you can. And some things are hard to compare and choose between, but I think that is part of putting budgets together and part of the kinds of choices that we are going to have to make in the health care space, understanding quality as well as understanding cost.

Senator ROCKEFELLER. You have been Director of OMB, which I think one could also say is one of the most difficult positions around. Your life is full of choices, and many of them are ones that only you can make, in effect. So you have your experience as Deputy Director and Director. It is your inclination—when you have difficult problems, you love that. You devour the facts and nuances of difficult problems and try to solve them.

But from your OMB experience, as you look at HHS at large, there have to be some things that occur to you, impressions from the position of OMB about HHS and how, over the years—I do not just mean the recent years, but over the years—how things have not always gone as smoothly as we would like.

Ms. BURWELL. With regard to that issue, I do have impressions in terms of beyond the Affordable Care Act and the Department as a whole. One of the things that I believe in about setting priorities in a new organization when I go to something new—and it reflects one of the comments that Dr. Coburn made—is listening. That is why I am very appreciative of all of your time. I actually have had the opportunity to speak with each of you in terms of what your priorities are.

The second thing I think I need to do is listen to stakeholders, and I cannot do that until the Senate speaks and this process moves further. And then the third thing is the Department. Once I have heard and listened, that is the point, I think, at which one has the correct information to set priorities, which I think is an important part of managing any situation.

Senator ROCKEFELLER. I have 44 seconds. One of the things that has always interested me, and as a citizen, neither liberal nor conservative, it has always amazed me that in very large and powerful organizations with a lot at stake, where people wear stars on their shoulders and where people have reputations built up over a lifetime, that they become deficient, and they clearly become deficient. They probably know it; you would probably know it.

It is the question of people never being held ultimately accountable. For strange reasons, and not always kind reasons, the only thing Americans will settle for is that somebody is fired, because that shows that "the administration really means it."

I do not necessarily walk away from that action at all, but there are other ways of disciplining people, but they have to somehow radiate out to the American people also. So the symbolism of reigning in and controlling your department and how you do it is important to me. What say you?

Ms. BURWELL. I agree that it is important. I think one of the things that is very important is actually having people around you who actually tell you when you are wrong as a leader. That is a very important thing, making sure you create a culture where it is rewarded for people to actually question you in terms of your leadership and make sure they are pointing out if there are other facts you should know or things like that. I think that is an important part of it.

With regard to creating accountability, one of the most important things I think you do in an organization, when you come in, is clarify what the goals are, move to what people's roles are, and articulate their responsibility. By setting that out at the front end, I think it makes it much easier to check yourself at the back end in terms of how people delivered.

Senator ROCKEFELLER. Thank you.

The CHAIRMAN. Thank you, Senator Rockefeller.

Senator CRAPO?

Senator CRAPO. Thank you, Mr. Chairman.

Ms. Burwell, I appreciate you being before us today. I also appreciate the good working relationship that we have had as you have been involved in a number of different aspects of this administration.

Ms. BURWELL. Thank you.

Senator CRAPO. I want to use my time today to talk to you about Medicare, and particularly Medicare Advantage, and secondly about some of the implementation concerns I had with regard to Obamacare in general.

With regard to Medicare, back during the debate over the Affordable Care Act, there were massive cuts to Medicare in the Act. We debated that at the time. I am not trying to go through that debate right now, but, as a part of that, many of us pointed out that there were significant reductions to Medicare Advantage included in what the Affordable Care Act itself did and that that was probably the most popular part of Medicare today among seniors.

In fact, we are now seeing that the cuts to Medicare Advantage are real, they are occurring, and, in addition, the administration seems to be pushing for additional cuts to Medicare Advantage beyond even those that were contained in the Affordable Care Act.

I will not go through all the statistics I have here about how the CMS analysis shows one thing and then other analyses from independent sources indicate other things. The bottom line is, from all the analysis that I am seeing, what we are viewing coming down the pike with regard to Medicare Advantage is that the program will be facing double-digit reductions over 2 years.

In Idaho, we have already started to see the effects of this: eight counties in Idaho no longer even offer Medicare Advantage options. In Adams County, where 44 percent of the Medicare beneficiaries have chosen Medicare Advantage plans, the beneficiaries saw their plan options limited in 2014 down to just five plans from nine in 2013. We see this dynamic continuing.

My question to you is, do you understand the dynamic that is happening in Medicare Advantage? Do you agree with the observations I have made? Do you believe it is reasonable to implement additional cuts on Medicare as we see this dramatic impact the downsizing is already having?

Ms. BURWELL. Two starting premises. Thank you for the question; I think it is important. I will start by saying it is something which is, Medicare Advantage, I think, a very important part of the system.

Senator CRAPO. Good.

Ms. BURWELL. The second thing is, it is an issue that we have talked about and I am sure we will talk about more, which is the question of health care costs as an important part of achieving fiscal responsibility and lowering our deficits in the out-years. So those are two guiding premises that I think we need to keep our eyes on with regard to Medicare Advantage.

When I think about Medicare Advantage, I think about the starting point that you mentioned, in terms of going back to where those initial changes were put in place and the predictions of what would happen with those changes. I know of two different sets of changes we are talking about.

With the context there, we had a situation where Medicare Advantage was put in place, and we thought it was going to make things cheaper. However, we saw 14-percent cost overruns to regular Medicare patients, so how do we think about that within the system?

We made some changes. We have seen those changes. Medicare Advantage has grown. One-third of people are now part of Medicare Advantage. We have seen Medicare Advantage premiums drop by 10 percent as those changes have been implemented. The other thing we have seen is an increase in quality. Thirty-seven percent of the people had 4- or 5-star ratings in terms of that quality. That is now up to 50 percent.

The question of the additional changes that are being put in place—

Senator CRAPO. Right.

Ms. BURWELL [continuing]. Need to be monitored and watched with regard to—I think everyone's objectives are to keep that quality access and to keep premiums under control. So I think the proposals that are in place, we believe are things that could work. But we need to understand and keep monitoring if we are seeing things

that are not working, which are some of the things I think you are starting to describe.

Senator CRAPO. All right. I appreciate that. I am concerned that what you are going to see as you monitor it is that we have done some unnecessary damage to the program. But I hope that your commitment to supporting it and to helping it become stronger and more viable is going to work out.

In my just 1 minute left, let me ask one other quick question. Changing quickly to Obamacare in general, a recent McKinsey survey found that only 26 percent of individuals who gained insurance under the Patient Protection and Affordable Care Act were previously uninsured. If this statistic is accurate, it means that the vast majority of individuals who are now covered under the Act previously had health insurance that was canceled due to the mandates in the law.

First of all, the administration has allowed non-compliant plans to continue through 2014. Do you support allowing this continuation of non-compliant plans to qualify or can Americans expect another round of cancellations this fall?

Ms. BURWELL. With regard to where we are in terms of the current plans and what will be continued or not, I think we have made all the decisions and announcements that will take us through the next enrollment season.

With regard to what we want to do, I think we need to watch and manage. As with Medicare Advantage, one of the things I think is important is, how do we do common-sense implementation that works for people? The system needs to work for individuals, it needs to work for insurers, and actually providers as well.

Senator CRAPO. Well, thank you. I have a lot more questions. My time is up. I will submit those to you in writing.

[The questions appear in the appendix.]

Ms. BURWELL. Thank you. Thank you.

Senator CRAPO. Thank you.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Welcome. Thank you very much, Mr. Chairman. Congratulations on well-deserved support and praise.

Ms. BURWELL. Thank you.

Senator STABENOW. I am looking forward to working with you on so many different issues.

Let me first follow up on my friend and colleague's statement on Medicare Advantage and just share this. During the process of writing the Affordable Care Act, I will never forget the Budget Office telling us that, even if we capped the payments to Medicare Advantage at 150 percent of what doctors and hospitals receive under regular Medicare, we would save money—even capping it at 150 percent.

So given that fact, I think it was the right thing for us to do to deal with cost overruns. And I certainly share with my colleague the view that we want to make sure that services are there and provided. But clearly there were cost overruns.

The good news is, as we brought down the costs connected with Medicare, we saved money. And yet, at the same time, we provide annual check-ups with no out-of-pocket costs, and we are seeing

prescription drug costs going down about \$1,200 per person, back in their pocket to help pay for medication. So it is all good news.

In general, I want to ask about the Affordable Care Act, because the good news is we have more than 8 million people who have been able to sign up for a better plan at better prices—in Michigan, over 270,000 people, which is way more than we thought, over 100,000 more than we thought were going to be signing up.

In fact, even though Michigan did not start until April 1st on the Medicaid expansion, we have enrolled about one-third of people who are eligible. So that means low-income working folks working minimum wage, 40 hours a week, trying to make it, finally are going to have the opportunity to see a doctor and take their kids to the doctor.

So my question is related to the ACA overall. When we look at the fact that CBO announced last month that, due to lower-than-expected premium rates, the Affordable Care Act will reduce the deficit another \$104 billion over the next 10 years—I know in Michigan we are seeing Pioneer Accountable Care Organizations that are already, within 2 years, showing savings, a big piece of this, to bring down costs for our businesses, for our economy, for families.

So what do you see as the opportunities to continue to use the tools in the Affordable Care Act to really bring down costs the right way, not by taking away service but by dealing with the costs in the system?

Ms. BURWELL. I think that one of the things is continued implementation. CBO, when they score the changes that are in the Act from 2014 to 2020, has a \$900-billion reduction in health care costs. So, implementation.

But I think there are a number of tools and opportunities, and they are related to the delivery system and moving the delivery system into a space where it is both about quality as well as cost reduction. I think there are a number of tools. You mentioned using Accountable Care Organizations that are moving to that space as a way to think about how one can do both of those things.

I think the other thing is looking at the innovations. I think there are innovations State by State. Some of the things that I had the opportunity to hear about in the conversations that I had with a number of you were specific examples of things that are either focused on quality improvements, either hospital readmissions, falls, other issues, or actually cost improvements, and some of those come together.

So I think what we need to do is look at those models, figure out which of the models deliver the greatest impact with regard to both costs and quality, and then figure out which ones are scalable, because I think that is the issue. I think sometimes you can get things to work. My experience in grant-making is, you get things to work at a small level, but the question is, can you scale it?

Senator STABENOW. I agree.

One other comment and then one other quick question. I know we are following up to have a discussion about the pilot project we have just passed on community mental health funding for critical expansions of quality and care in the community for mental health. I understand in talking with you that your mom works in commu-

nity mental health, so I feel much better now because I know we have a secret ally there whom we are looking forward to enlisting. So I look forward to working with you as we implement this very important 8-State effort that Senator Blunt and I were pleased to work on.

Finally, Alzheimer's disease. One out of eight people is diagnosed with Alzheimer's. What is important for us in this context is that \$1 out of every 5 Medicare dollars—that is a lot, \$1 out of 5 Medicare dollars—is spent on someone with Alzheimer's.

So I do not know if you have had an opportunity to really focus on this yet. One out of 5 Medicare dollars, and yet we have less than 0.25 percent that goes to research. I know things are—the President is focusing on the brain research effort, and so on. But we certainly want to work with you on more effective ways to address what is clearly a disease affecting every family in America.

I do not know if you have any comments, if you have had a chance to look at this at all, but certainly I want your commitment—we would appreciate it—to really focus on this.

Ms. BURWELL. Senator, first, thank you for your leadership in the mental health space and on Alzheimer's. These are both issues that I think are very important. I think, as you articulated, they are important both in the form of research as well as delivery of care, and care for those who are caregivers.

I think the issue of Alzheimer's cuts across the research we need to treat and help prevent the problem—if we can find that out, what we do to treat patients who are currently suffering—and also how we treat the families, because that is a part of the care that is very important for those individuals as well.

Senator STABENOW. I look forward to working with you.

Ms. BURWELL. Thank you.

Senator STABENOW. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Stabenow.

Senator Grassley?

Senator GRASSLEY. Congratulations, Ms. Burwell. I have just two questions. I want to start with what I consider a very important function that I have of oversight on the use of taxpayers' dollars. I think I take that job very seriously. I have done so both under Republican and Democratic administrations.

So my first question to you is, would you commit to answering the letters I send to your department promptly, fully, and without reservation?

Ms. BURWELL. Senator, I will work to make sure that we are giving you all the tools you need to do the work that you need to do.

Senator GRASSLEY. Yes.

I have a long lead-in before my next question, so please be patient. When you were nominated, I said that anyone put in charge of Obamacare would be set up to fail. The theme of this law really has been "by any means necessary." The legislative process certainly was by any means necessary, and the implementation has operated similarly.

The department we are considering you for has ignored the plain read of the statute whenever it was considered necessary. Deadlines were considered to be written in pencil. If a statute needed

to be creatively reinterpreted to make the program work, the Department did so.

As I said on the day that you were nominated, you have a fresh start with Congress and with the public. But, if you are going to make the most of that opportunity, you are going to have to do things differently than they have been done.

I will use Marilyn Tavenner as an example. She sat in the same chair you are in a few months ago. She committed to do things differently. Now it seems like she has gone into the Witness Protection Program, it has been so long since she was last in the chair or at my door. I hope that does not happen with you. I hope you do not disappear into the same bunker.

But this is what you face moving forward. The Department is supposed to implement the employer mandate a year overdue and significantly altered from the statute. The Department is supposed to implement risk corridors this year, though the legal authority to distribute funds is questionable and the standards used to make those distributions will likely be kept very quiet.

Speaking of things that will be kept quiet, Congress is going to want to know what the premiums will be for next year. We consider the information important and relevant. Iowa is considered to be one of those States where we might have the highest premium spike.

The Department will want to use any means necessary to hide the premiums until after the November elections, unless of course the premium numbers are good, and then the Department will shout from the rooftops how low they are, much as I think was done in the case of enrollment numbers.

Now, we can be very cordial today, but, if you want to change the relationship your department has with Congress, you are going to have to be willing to break the “by any means necessary” mindset that we have seen for the past 5 years.

My question to you then is this: do you think it is possible for you to change the “by any means necessary” culture at HHS that some of us in Congress view as bordering on lawless?

Ms. BURWELL. Senator, thank you. Harkening to my experience and what I have done at the Office of Management and Budget, there are challenging issues. And, as I look around this dais, I think with many of you I have had the opportunity to have to call with things that are positive, and actually to call about things that are difficult in terms of a number of the members.

That is something that I consider my responsibility to do, and I hope that people feel, in my role at OMB, that I have done that. Whether that is moving to more timely responses, the regulatory agenda, it is something that actually is sometimes a controversial thing. But since I have been the director of OMB, we have been on time, getting that out in both the spring and the fall.

The mid-session review—a document that has a lot of numbers that some may use one way or some may use another—came out a week early. That is something that actually I did not have to wait for numbers from the Congress to do. So I take the issues very seriously. And as I have said, this is a space where I actually hope that there will be direct communication if there are concerns.

Senator GRASSLEY. I will yield back my time, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you, Senator Grassley.

Senator Nelson is next.

Senator NELSON. Senator Grassley, Senator Rockefeller assures me that anybody from Hinton, WV, population less than 5,000, is going to do okay. I would assume that you can tell a lot about where a person is going by where they have been.

You have had such accolades from no less than Senator Coburn, and the same from me, for the way that you have handled yourself in a very difficult department that is as hard-headed, from this Senator's perspective, as is HHS, and yet you were there, you were responsive, and I want you to know I appreciate it, and I think there are a lot of other folks here who do as well.

I want to just ask you quickly about Medicaid and Medicare. If our Governor and legislature in the State of Florida expanded Medicaid under the ACA, it would cover an additional 1.2 million people who otherwise, when they get sick, are going to end up in the emergency room. And all the rest of us are going to end up paying for them through our insurance premiums, not even to speak to the fact that it is the humanitarian thing to do for people to have access to health care. But the State legislature and the Governor have so chosen not to do it for two legislative sessions. We have tried to show them that there is a local tax base that is paying for a lot of things for low-income people already.

Now, what the legislature's position has been is, they want you to expand the Medicaid waiver so that they can continue offering Medicaid through an HMO, but they do not want, under the ACA, to expand that Medicaid population up to 138 percent of poverty. So we have shown them an ingenious way that you can utilize if the State does not want to pay their 10 percent in the 4th year and in the future years, where they can actually utilize what is already being used in a local property tax or sales tax for these low-income people.

So what I would ask is, if the State chooses not to expand Medicaid up to 138 percent, what would you think the Department would plan to handle the States' request to consider continuing doing business as usual?

Ms. BURWELL. Senator, with regard to the specifics of the negotiations that are occurring between HHS and the States, that is something that, in my current role, I am not familiar with.

What I can talk about, though, is my philosophy with regard to how to think about these issues in terms of Medicaid and the Medicaid waivers. There are a couple of principles. One is, I actually think it is very important in starting the conversation to be clear about what are the fundamental core principles that are essential to implementing it, whether that is the implementation of the Affordable Care Act or the other State waivers that some States may be applying for.

I think the second thing that is a principle that I think is important is flexibility. I think that States do have different situations and we need to consider that, but bringing those two things together, I think, is an important thing to do from the beginning of

the conversation as one works through how to get to a potential “yes.”

Senator NELSON. Ground zero for Medicare fraud is South Florida. Just yesterday there was another bust. Law enforcement took down 50 more people. But the problem is, in the past, when you take them down, they have already fleeced the system. Do you have any thoughts?

Ms. BURWELL. Well, a couple of things. I think that we need to work towards a system that is not pay-and-chase, by getting in front of the system before the dollars go out. That is the place where we need to have a system. I think there are a number of tools that we need to use.

I think we need to use some of the things that we see in the private sector in terms of predictive capabilities, in terms of using technology. I think the partnership that actually did do the work that you were referring to yesterday that was across the Nation, the strike force with the Justice Department, is an important part of making sure we do that.

The issue of Medicare fraud is something I take very seriously, and, in my current role as OMB Director, the issue of improper payments is one that I have focused on across the entire government. As we all know, the numbers are very large in Medicare, so it is a place that we need to focus on deeply.

So I would hope, if I am confirmed, to be able to bring some of the focus that we have had on broad improper payments across the Federal Government to the issues that are specific in Medicare and Medicaid as well.

The CHAIRMAN. Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman.

Ms. Burwell, congratulations on your nomination.

Ms. BURWELL. Thank you, Senator.

Senator CORNYN. Thank you for meeting with me and my staff in my office. I am glad to hear your answer about getting away from pay-and-chase. There are not enough resources in the Federal Government or through the False Claims Act or otherwise to go after all the fraudsters.

The only way you are going to get ahead of them is to screen who gets paid on the front end, and there are a lot of very powerful and loud people who will complain to high heaven if you do that. But I appreciate your commitment to deal with pay-and-chase, because it just does not work, and it will not work.

So McKinsey, which you once worked for in addition to other aspects of your distinguished career, has just come out with an estimate that about 22 percent of the 8 million people whom the administration was celebrating enrolling in exchanges, only 22 percent were people who previously did not have insurance coverage, which means that only about 1 out of 5 people were newly added to the insurance rolls who previously did not have coverage.

The President said, when he sold the idea of the Affordable Care Act, that if you like what you have you can keep it, your premiums as a family of four would go down \$2,500, and oh, by the way, if you like your doctor, you can keep your doctor.

In many, many, many—too many—instances, that has proven not to be true, which has been very damaging not only to the Presi-

dent's credibility but to the credibility of anybody who is saying that the Affordable Care Act will work as advertised.

Are you aware, since to my knowledge there have been no official figures released by the Federal Government or by the administration, whether there are any figures available which contradict or disagree with what the McKinsey study estimates, that only about 1 in 5 of the 8 million people did not have insurance?

Ms. BURWELL. Senator, in my current role, with regard to knowing what the insurance companies have said to HHS, that is not something I do know. What I do know are the public figures that we have seen. While we have seen the McKinsey numbers, I have not delved into the analytics. The question of, did some people switch for quality reasons, I am not sure if McKinsey divides that out.

The other thing is, what we have seen is, we have seen Gallup and a number of other organizations show numbers in terms of the percentage drop in uninsured in the Nation, and those provide different numbers. But with regard to specifics from the government, I do not, in my current role, have access or know. But the insurers are the point at which that information will be provided.

Senator CORNYN. Well, the distinguished Senator from West Virginia who introduced you earlier talked about 20 or 30 years. I do not know whether he was suggesting that there would be 20 or 30 years before we got health care right or not. Maybe we will have that conversation later. But right now there are a lot of people who feel enormously discouraged and misled, frankly, about the promises made over the implementation of Obamacare.

Let me ask you, in the short time I have remaining—my notes indicated that Health and Human Services employs roughly 78,000 people—78,000 people—and is authorized to spend about \$888 billion. There is another government organization in the news these days, the Veterans Administration, that has 278,000 employees. It has got, if the reports are to be believed, enormous problems with regard to delivering the promise of health care to veterans who have earned that right.

Could you tell me how you would deal with an organization that has the sorts of problems that are being reported in the VA today? I realize that that is much bigger than what you are getting ready to take on at HHS, but I am not asking you how to fix the VA in particular, but I am asking about how you, with your experience, which is considerable, would approach an organization of that size that has that many problems.

Ms. BURWELL. I think first is getting to what is causing the problems and the magnitude of the problem. Anytime you have a situation like that in an organization, I think you quickly have to establish, what is the problem coming from and how large is it? Is it systemic or is it cultural, or is it something that is a targeted problem?

I think once you understand what type of problem you are dealing with, then you have different types of solutions depending on what it is. If it is a cultural issue, you are going to need to do change management, and that is something that takes energy, effort, leadership, buy-in, and problem-solving that works from the ground up.

If it is something in a targeted space, that is a different kind of problem. So what I would want to do very quickly is understand what is the problem, the magnitude of it, and, as I said, is it systemic or otherwise, and then go about creating a solution based on that. At least my experience is, setting culture, sending signals, and how one goes about doing that, are important parts to changing if there are problems in an organization.

Senator CORNYN. And do you think that that approach that you just described would be appropriate for Congress to take or just somebody in your position?

Ms. BURWELL. With regard to—I think there is a role that Congress and the executive branch play together. There is an important oversight role that the Congress plays, and I think that is about a back-and-forth in a conversation.

I think it is one of the places where working together is the way to get the greatest impact, coming up with the solutions, listening and understanding that there are ideas that come from experience that is on the ground. I think one of the most important things that in my visits I hear is, you represent what happens in your States.

What I hear when I have a conversation and ask you about priorities, it is a means by which one hears from the American people as directly as you can. So I think there is an important role in how one goes about doing these solutions and working with Congress to do it.

Senator CORNYN. Thank you.

The CHAIRMAN. Thank you, Senator Cornyn.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Congratulations on your nomination.

Ms. BURWELL. Thank you, Senator.

Senator MENENDEZ. Yesterday, the *Star Ledger*, a major newspaper in my State of New Jersey, reported that while 140,000 people were successfully enrolled in Medicaid, at least another 25,000 still have their application waiting to clear the backlog and another 7,000 are waiting for their Medicaid cards.

Now, I realize this is a problem whose solution lies predominantly at the State level, but I also know that CMS has a vital role in making sure that States get all applications processed in a timely manner.

If confirmed, will you commit to prioritizing this issue so families in New Jersey and across the country can rest assured that their Medicaid enrollment has been processed and that they are able to receive the care they need, and have CMS work to educate individuals and providers about their presumptive eligibility rights so they are able to receive and provide health care while they are waiting for their formal enrollment?

Ms. BURWELL. Senator, if I am confirmed, I would look forward to working with you and CMS on that issue.

Senator MENENDEZ. Because the promise of the Act—if, at the end of the day, you do everything that is right and you register and apply and qualify but you are just not processed, at the end of the day, that is really unfortunate.

As you may know from our conversation, New Jersey has the highest rate of autism incidents in the Nation, with 1 in every 48 children diagnosed by the age of 8. That is why one of my top health care priorities is ensuring that individuals with autism have the therapies and services they need to fulfill their God-given potential.

Now, one of the steps I took to try to achieve this goal was ensuring autism services were required under the essential health benefits package for plans sold on the health insurance marketplace. Despite this requirement, however, I am worried that plans are not living up to the standards that I envisioned when I wrote this provision into the law, especially in States without existing State coverage requirements.

Specifically, I am concerned that plans are taking advantage of the regulation that allows them to use non-dollar caps on benefits since they are no longer allowed to impose dollar limits. So this is clearly in violation of the intent of the provision as I authored it and that is part of the law, and it has the potential to deny access to care to families across the country.

But can you assure me that, under your leadership, HHS will conduct the necessary oversight of plan benefit structures to ensure that they are providing all of the required benefits?

Ms. BURWELL. Senator, thank you. I appreciate your leadership in this space and our conversation about this issue. If I am confirmed, this is something we will want to work to figure out so we can make sure that those children and adults are receiving the benefits and health care that they need.

Senator MENENDEZ. Two last questions. One of the issues I have been involved with over the last year is responding to CMS's so-called "2-midnight rule," which is designed to create an unambiguous policy that a beneficiary spending more than 2 days in the hospital is designated as an inpatient. However, the rule failed to acknowledge an instance where a beneficiary needs a high level of inpatient care for a shorter amount of time, even if the physician determines it is medically necessary or appropriate.

Now, I am pleased to see that CMS took the initiative and is soliciting comments on this issue as part of the fiscal year 2015 inpatient payment rules, but I am afraid that a year might not be enough time. Once the current delay is over, we will still be in a situation where the rule is unworkable and unenforceable.

Can you provide an assurance that CMS will have policies in place that ensure the rule's viability once the statutory enforcement delay expires next year?

Ms. BURWELL. Senator, this is one of the issues I have heard about from a number of your colleagues in all of my visits, so it is one where I think we need to continue getting the best ideas that people have for implementation, and that is something that I hope, if I am confirmed, I can work on with CMS and others to get that input on.

Senator MENENDEZ. All right. Thank you.

Finally, delivery system reform and quality improvement. For those of us who supported the Affordable Care Act, we saw it as not only about having more health care accessibility for families across the country who did not have health care, but also about

controlling costs, about changing the nature of health care from a disease base to a preventative base, and also changing the nature of how we pay for it and how we deal with health care, from alternative payment and delivery models, bundled payments, patient-centered medical homes, to performance and outcome.

I had suggested, for example, multi-dosing when it is appropriate to reduce prescription drug costs. So are you open to consider these types of initiatives as a primary effort to try to change the nature of how we pursue both our outcomes and how we pay for them?

Ms. BURWELL. Senator, I think that the delivery system reform issues are a very important priority that we need to focus on. And I believe the way that we are going to focus on them is by taking examples and models and figuring out which of those provide the best quality and the best cost, and then which of those we can scale quickly. I think it is important to get things in place, start to get traction on changing the system to one that moves towards what you described, as quickly as possible.

Senator MENENDEZ. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Menendez.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Ms. Burwell, congratulations on your nomination, and thank you as well for taking time to meet with me. We have, of course, serious disagreements about the substance of Obamacare, but, as I conveyed to you in our meeting, I am more concerned at the moment—well, I am very concerned about the substance, but, since we cannot change that, I am very concerned about what is going on with regard to the enforcement of Obamacare, the selective enforcement of Obamacare, with regard to certain groups. We have seen exemptions, delays, parts of the law ignored as they pertain to certain favored, it would appear, political groups.

One of those is the reinsurance tax, which was imposed on self-insured, self-administered plans to help pay for covering people with preexisting conditions. Under your direction at OMB, there was a rule issued that carves a lot of plans out from that tax. I guess my question has to do with whether or not that is appropriate and whether or not that is fair.

I want to read for you a quote that came out shortly after that rule was issued. It said, “Asked for clarification on how the change would affect other plans’ rates and fees for 2015 and 2016, Health and Human Services officials said it is true that the fee will be higher for plans that do not have to pay the fee in 2015 because some plans are exempt.”

So, in your view, is that an accurate statement, that others are going to have to pay a higher tax, the reinsurance tax that is paid by self-insured, self-administered plans, because groups like unions got carved out?

Ms. BURWELL. Senator, with regard to the specific provision that you are referring to, I think this does fall into trying to improve and find better ways to implement the law. While some unions are exempted, this does apply to some, many unions it does not apply to, and it applies to other groups. It has to do with the definition as well of self-administered versus third-party administered, in terms of what the law was trying to do.

Those are not synonymous terms, and the reason they are not is because, what we found as we were moving forward is, there actually are plans that are self-administered not using the third party administrator, and creating that distinction was a way to provide better clarity. That is what was intended in terms of what was being done.

Senator THUNE. My understanding is, it does affect about 25 percent of union plans. And it is something that I believe that they requested. So the question is really a very simple one. I mean, it does not require a lot of subjectivity, it is just simply a function of math. If there are groups exempted from that reinsurance tax, does that not mean that those who are subject to the tax are going to have to pay higher taxes?

Ms. BURWELL. I think the question is, what was higher and what was lower is one question, and one is implementing what your starting point is. So yes, it is a smaller group, but what was the actual starting point in terms of what is higher?

Senator THUNE. Well, but we know what the tax is supposed to raise. It is a finite amount. It was very clear. If you are going to raise a certain amount of revenue and it is going to be paid for by a certain number of people, if that pool shrinks, the people who are left in the pool are going to pay more. That is simple math. I mean, I think the answer is "yes," and I would like to hear you say "yes."

Ms. BURWELL. Senator, I think with regard to what was intended, it was to implement the law in a better way that was common-sense, that was responding to a situation that was not just unions, and then put the pool in place——

Senator THUNE. But that is——

Ms. BURWELL [continuing]. Whatever the size of the pool is, to get the numbers.

Senator THUNE. That is theory. Again, this is mathematics. Are people going to pay more? The answer is "yes." That is what I am saying when it comes to this issue of selective enforcement. I do not think that is fair. I mean, you have had exemptions now twice for small businesses under the employer exemption.

You have had, I think, 20-some exemptions or delays or other parts of the law that have been sort of waived, I guess, just unilaterally. But this particular provision is really problematic for the people who still have to pay the reinsurance tax.

All I am simply saying is, as a matter of fairness in the way that this is implemented, carving out favored groups should not be the *modus operandi*. We ought to be going about this in a way that treats everybody fairly under the law.

I do not think you can argue that, based on the number of exemptions, the number of carve-outs, the number of delays that have been issued already, that that is the case. This particular one was a rule that was issued by OMB under your direction.

Ms. BURWELL. Senator, with regard to the implementation, I think what one does seek to do is, when one finds places where you can implement better within the law, that you seek to do that. With regard to the question of employer responsibility, what we heard is that the private sector was having difficulties in terms of meeting the reporting requirements that they would need to meet to do this accurately.

With regard to other complex pieces of legislation, one of which is Part D, and there are others—we have not had anything as large and complex as this in a while, but we have had examples—as one moves to implement, you do listen and try to implement in a better fashion in terms of trying to hear, listen, and make the transition one that is workable. On the individual side, what one sees is an opportunity for individuals to apply for hardship exemptions in terms of trying to make that transition a plan that works.

Senator THUNE. Mr. Chairman, in the interest of transparency, though, some of these things, these waivers and delays, would you agree to submit, when you get them from the insurance company, the new filing rates that they file for next year? Because the enrollment date has been delayed now until later this year.

The date at which plans get approved has been delayed until, I think, the day right before the election, which is very convenient. But we know they are going to be filing rates, we know there are going to be real-world impacts on these things. In the interest of transparency, which you have talked a lot about, would you submit to us those rates when you get them from the insurers?

Ms. BURWELL. Senator, the issue of premiums and rates is one I think that we all are very interested in and all actually want to see move in the same direction. With regard to the specifics of what HHS receives and when and how, that is something, in my current role, I am not familiar with and would want to look into when I get to the Department. What I will say, Senator, is, if I am confirmed, that is something that I want to understand and work with you on.

Senator THUNE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Thune. And just very briefly, Ms. Burwell, I very much appreciate your reference to Part D, because I was one who voted for Part D. It was George Bush's major domestic initiative. We worked in a bipartisan way. I hope we will be able to work in a bipartisan way in the days ahead on the ACA, and I appreciate your reference.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

Ms. Burwell, thank you very much. I want to thank you, and I want to thank your family—because this is a family service—for allowing you to continue in public service.

The Affordable Care Act sets up the right structure for moving forward in the right manner to achieve quality, affordable health care for all Americans. There are many provisions of the law that I would like to see strengthened and improved, and I hope we can work together to do that.

In the few minutes I have, I want to go over a couple of issues that you and I have had a chance to talk about that I want to get on the record. First, the Affordable Care Act established Offices of Minority Health in several agencies of the Department of Health and Human Services and elevated the National Center on Minority Health and Health Disparities at NIH to an Institute. There are reasons for that.

I gave you the example of Baltimore, which was the focus of a study funded by that Institute, where life expectancies across the city vary by as much as 30 years—an entire generation—depending

on the zip code in which you live. A significant part of that is related to access to and quality of health care and to the social determinants of health. The statistics on the incidence and prevalence of specific diseases and the differences between various racial and ethnic populations are well-documented. It is imperative that we address these disparities if we are to achieve health equity and reduce health care costs.

So Congress intended that the focus on minority health and health disparities would be a priority as we try to improve our Nation's health care system and correct some of the previous failures in this area. I was disturbed when I looked at the President's budget that was submitted for fiscal year 2015. The budgets of six Institutes at NIH did not get any increase at all. The National Institute for Minority Health and Health Disparities was one of those Institutes that was frozen in the budget proposal.

Are you committed to implementing the intent of Congress to put a priority and spotlight on minority health and health disparities?

Ms. BURWELL. Yes, Senator, and thank you for your leadership in this space. The issue of minority health is one that is important and is, I think, being addressed in parts by the Affordable Care Act, as well as the President's budget.

When one looks at the National Health Service Corps and the doctors who are being trained, a number of those, in terms of percentages, disproportionately represent minorities. I think that is an important part of getting providers to the types of communities that we are talking about. In addition, in the NIH budget this year, for the first time there is a program to actually promote researchers, minority researchers, in the work that NIH does.

In addition, as we work across the whole realm of implementing the Affordable Care Act, as well as other parts and provisions—whether that is some of the work in preventive care or community health centers—thinking about how those entities and parts of implementation of care can help minority communities is something that I think is very important.

Senator CARDIN. I thank you for that answer. I think it is important that you put together the coordinated strategy and be very open in presenting it so it gives confidence that you have indeed given achieving health equity the high priority it deserves.

One area related to that is Federally Qualified Health Centers. One of the great stories of the Affordable Care Act is the significant resources that are being made available to the FQHCs. I have visited most of our centers in Maryland. They have expanded prenatal care, and the number of low birth-weight babies being born now is down, and infant survival rates are up.

We now have dental services in the community that were not available before, mental health services have been expanded. All that is a result of the Affordable Care Act and the added funding for FQHCs. We are going to need your support to continue that as a priority, because the ACA is not just about more third-party coverage, it is about access to comprehensive quality care and prevention, and the health centers provide those opportunities.

I want to ask you one more question dealing with dental care, which is another problem in low-income and minority communities across America. In Maryland, we experienced the tragedy of 12-

year-old Deamonte Driver, who died in 2007 because he was unable to get access to needed oral health care. The CHIP Act, the Children's Health Insurance Program, as well as the Affordable Care Act, provided for pediatric dental coverage.

However, in the ACA, exchanges can offer stand-alone dental insurance plans. We talked about this previously, and I just really want to get your response. We have to make the pediatric dental benefit as seamless as possible. That is, because it is an essential benefit, families need to have access to pediatric dental without separate deductibles and without additional out-of-pocket limits.

Will you look into how we can make pediatric dental a seamless benefit, as Congress intended under the Affordable Care Act?

Ms. BURWELL. Senator, this is an issue I know you have provided leadership on, and Senator Rockefeller actually brought it up in his comments as well. Having had the opportunity to actually work a little bit on the issue of dental, both pediatric and adult, in my foundation work, it is something that I would look forward to working on, figuring out how we can get those services delivered to people in a way that works for them, both in terms of how they can access it and use it, in ways that actually prevent the kinds of problems that you have described with the 12-year-old that actually extend through adulthood for many.

Senator CARDIN. Absolutely. I look forward to working with you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Cardin.

Senator Isakson is next.

Senator ISAKSON. Thank you, Mr. Chairman.

Ms. Burwell, congratulations on your nomination, and congratulations to your family, or condolences to your family, one way or another, for their loyal support. We appreciate the time you are donating to let her serve us, the United States.

At the hearing before the HELP Committee, I opened with an apology to the committee for bringing up a parochial issue, and I have already discussed with the chairman that I was going to do it one more time. But in that meeting I told you I had no more important responsibility as a member of the U.S. Senate, including your confirmation, than bringing about a resolution to the Savannah Harbor Expansion Project and that we had hit a bump in the road upon the submission of the President's budget by OMB earlier in the year and I did not know a way forward. I wanted to bring about clarity on a way forward, because I wanted to see to it, before you were gone from OMB, that we had a road forward to see that project through to reality.

To confirm what Dr. Coburn said about competence and responsiveness, within an hour of that hearing you contacted, or your staff contacted, our office, arranged an appointment on Tuesday of this week, which was yesterday, with your Chief Legal Counsel, your Deputy Director, your Chief of Legislative Liaison, and the Under Secretary of the Army, Jo-Ellen Darcy, over at the Corps of Engineers, where we reached an agreement on a way forward which I want to just memorialize with your concurrence at this hearing today, which was: (1) we need to pass the authorization for the 902, for the authorization of SHEP, which is in the final conference agreement—I have seen that; (2) the Corps has to initiate

and begin a partnership agreement negotiation with the Port Authority of Savannah and with OMB; and (3) the State needs to agree to forward-fund initial construction money for which it will receive credit towards its required match during the course of the expansion project.

Do I have a correct representation of the steps forward to complete this project?

Ms. BURWELL. Senator, you do. I am very hopeful that WRRDA* will pass quickly and we can get on our way with this important project.

Senator ISAKSON. Well, I want to thank you for responding to my question that day, and thank you on behalf of the people of Georgia, and really the trade of the United States of America and Ambassador Froman's responsibilities to expand and improve our exports around the world. But thank you very much for the responsiveness on that.

I was a real estate guy, but I had a little insurance agency in my company. We sold some small group health policies back in the good old days for which our agents, who were independent agents, received commissions. When the Affordable Care Act passed, it put in place a medical loss ratio threshold for small group plans and large group plans at 80 and 85 percent.

Your department, which you were not the head of then, determined that commissions were a part of the administrative costs of the plan, which meant you would have to pay the commission and administer the program out of the 15 percent, which basically put all the independent agents selling health insurance out of business and was a reason why we had to hire navigators to help people find their way through the exchanges.

I would like, when you become head of the Department, for you to look at that decision and revisit it, in terms of the efficiency for the plan, to allow small group salespeople and large group salespeople to get back in the business of selling insurance.

It will save costs for the government in terms of not having to have as many navigators, and it will put people back in business who were, I think, unintentionally put out of business by the Affordable Care Act.

Ms. BURWELL. Senator, if I am confirmed, I look forward to looking into and understanding that, thinking about it both from the perspective of insurers—having had the opportunity to have been on the board of an insurance company, I understand the independent agent issue—as well as the issue of how we think about premium issues, which are some of the issues that a number of people have brought up today, and how those two things interact. So I look forward to, if I am confirmed, learning more about how to think about that issue.

Senator ISAKSON. And I appreciate that.

On the SGR—which was brought up by the chairman and some of the other members—on the question of our need to finally fix it now that we have a window opening, I had the occasion to watch you in action for eight successive weeks at the White House when our little group of eight had dinner with the President, Dennis

*The Water Resources Reform and Development Act of 2014.

McDonough, and yourself, trying to find a way forward on deficit and debt reduction. We talked about ways in which we could reduce obligations over time.

I do not want to get into a long question, but I would like for you to just consider leaving all options on the table in terms of fixing the SGR, in terms of where we find the money to do so. As you will remember in our discussions, some structural reforms to Medicare in the out-years can bring about tremendous savings without hurting beneficiaries, and we talked about those in those meetings.

That could be a part of the equation that helps us to find a way to pay for the SGR, permanently fix it, and never again be stuck in these 1-year renewals over and over again. So I would appreciate your leaving all opportunities on the table, not committing yourself to every opportunity, but leave them all on the table for discussion.

Ms. BURWELL. Senator, I welcome the idea of leaving all opportunities on the table. I think as we reflect in our budget, we have a wide range of opportunities that range from the type you are talking about to revenue as well. So, all on the table—I hear you.

Senator ISAKSON. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Roberts?

Senator ROBERTS. Thank you, Mr. Chairman.

Ms. Burwell, when we spoke during your hearing before the Senate HELP Committee, I asked you questions about the Independent Payment Advisory Board, IPAB—

Ms. BURWELL. Yes, sir.

Senator ROBERTS [continuing]. That is the acronym for it—and what could happen with Medicare rationing if they in fact came into being. In response, you stated that you are hopeful that IPAB “never needs to be used” and, by your estimates, during your time as HHS Secretary “would never get triggered.”

With the outstanding comments about your ability and leadership by Senator Rockefeller and Senator Coburn, as a follow-up, since you do not believe IPAB will have to be activated, with your leadership, would you just simply support its repeal?

Ms. BURWELL. Senator, with regard to IPAB, first, I think it is important to reflect that IPAB as currently written would not affect beneficiaries. That is a very important part of the law with regard to, if it is implemented.

With regard to the repeal and that question, I think, Senator, one of the things that is hopefully a helpful thing is having belts and suspenders in place to help us all get to the place we need to with regard to reducing health care costs.

Senator ROBERTS. I do not know about a belt and suspenders. Maybe barbed wire would be a better way to put it.

I would echo my colleagues’ comments to you regarding your responsiveness and willingness to work with this committee and all members of Congress. I would also like to add relevant Medicare stakeholders to that list. Just this past week, I had the Kansas Hospital Association in my office sharing their frustrations about the lack of responsiveness from HHS. Here is a copy. That is not their letter, these scratchings are mine, but this is the same letter

they sent your predecessor in January. They have yet to receive a response regarding the Medicare Recovery Audit Contractors, what we lovingly call in rural America the RAC. They do not like to be put on the RAC.

On the Office of Medicare Hearings and Appeals' 2-year moratorium on assigning new cases to the administrative law judges, they are still waiting a response. Now, I know the RACs have returned savings to the Medicare trust fund. It is vital that these local hospitals, suppliers, and other Medicare providers, however, have access to timely appeals of these audits.

We are talking about 65 administrative law judges and now 357,000 claims for Medicare services, which I understand is the reason for the delay or the suspension. It is rather incredible. We have gone from pending appeals, in just 2 years, of 92,000 claims to 460,000 claims.

Then the weekly receipts in the Central Operations Division went from about 1,250 to 15,000 per week. The reason is obvious, and that is, hospitals win 70 percent of the time, which means these independent contractors come into a hospital, many times they have never seen them before, and they are being fined for regulations they do not know anything about. If you are in a small hospital, you really have a problem trying to figure out whether you are going to appeal or not, and now we find that the appeals are suspended.

So I would add to my list, what can be done to better balance the need to recover improper payments—and we are all for that—while not imposing undue administrative burdens on providers, particularly those in our rural areas?

Ms. BURWELL. Senator, with regard to this issue of the RACs, as well as the balancing of having hospitals be able to process things quickly at the same time that we are trying to prevent abuse of Medicare, those are the principles we need to balance.

If I am confirmed, this is an issue that I think is going to require a quick look, a fresh look, and we will need to think about how we get the balance and what processes can be used to balance the two interests, because I think you are appropriately reflecting, in terms of the speed and the processing, it is not where we want to be in terms of the system.

Senator ROBERTS. In last year's Inpatient Prospective Payment Systems rule, that is the IPPS rule—a rule, by the way, which you signed off on at OMB—HHS implemented a payment clarification that requires that physicians admitting a patient into a critical access hospital certify that the patient must be discharged or transferred within 96 hours.

This payment clarification, which is not in line with the critical access hospital's condition of participation for Medicare, in my view and in their view, is crippling the ability of many of these facilities to provide care in their rural communities. It is inhibiting doctors' abilities to confer with their patients. One doctor in Dodge City told me, "I usually met 12 minutes, now just 3 minutes because of the 96-hour rule, and then I decide on the best course of action for their care." It is another example, in my opinion, of having to tell CMS, if it is not broken, then there is no need to fix it.

If confirmed, will you do all you can to see if we can reverse this payment issue so that our rural seniors can continue to receive care in their local community?

Ms. BURWELL. Senator, the issue of critical access hospitals and care in rural communities is something, because of my background, that I consider very important. The issue of the 96-hour rule, which we discussed a little bit before, is one that we clearly need to get the right input on in terms of, how do we get to a place where the original objectives of the rule can be achieved in a way that they do not have the unintended consequences that you are articulating?

Senator ROBERTS. Thank you very much. My time has expired.

The CHAIRMAN. Thank you, Senator Roberts.

Senator Warner?

Senator WARNER. Thank you, Mr. Chairman.

Let me say, Ms. Burwell, thank you again for your service. It looks like you are coming around the bend here and close to being done. I have a number of things I want to get on the record. First of all, I want to add my voice to comments made by Senator Isakson and Senator Roberts. I think the displacement of agents and brokers was a challenge and a mistake, and I hope you will re-review that process.

Let me also add my voice to what Senator Roberts said. I hear repeatedly from particularly my rural hospitals, but all hospitals, about the RAC audits. We do need to make sure we avoid waste and fraud, but I hope you will take a fresh look at that.

Let me move to three or four other items very quickly that I want to get in. One, the Treasury Department recently finalized reporting rules that will deal with the employer and individual mandates. There are a lot of complexities about these rules, and some of these complexities were highlighted by the American Bar Association's Section of Taxation.

This is not just a Treasury/IRS issue. HHS also plays an important role in administering these subsidies. The way the rules are currently issued, there is a potential end-of-year contentious debate between business and the IRS, with the IRS kind of being a referee. I raised this with you before.

I have introduced legislation, S. 2176—we have eight co-sponsors, and it is endorsed by a number of employer groups—which would basically allow employers to report prospectively or forward-leaning rather than having this monthly reporting requirement that, for particularly small entrepreneurs, is a burden.

Now, this approach we are taking would not give a complete safe haven, but it would require the kind of up-front collaboration between HHS and Treasury that might remove one of the administrative burdens that we hear enormous amounts about around ACA. My hope is that, if you are approved, and I hope you will be, that you will help work with us on either this legislation or other ways that we can improve this reporting requirement and, again, look at this prospective action rather than simply doing it retroactively.

Ms. BURWELL. Senator, if I am confirmed, as the administration and the President have said, we welcome the opportunity to think about ways, legislatively and otherwise, that we can improve the implementation of the Affordable Care Act.

Senator WARNER. I will take that as a "yes."

It is also my understanding that CMS signed agreements with a number of web-based entities that were to allow private exchanges to enroll tax subsidy individuals pursuant to regulations issued by HHS in March of 2012, again, something we talked about. This effort was stymied due to inefficient technology integration with these entities.

I understand there have been some small steps taken by HHS, but not a lot has really taken place. To my mind, this should be a no-brainer if we can get some of these sites that are perhaps more user-friendly as an additive effort to *Healthcare.gov*. I hope that you will work with me and these web-based entities to ensure that there is better technology integration in this area.

Ms. BURWELL. Senator, I welcome the opportunity to think about the best way to do distribution. It is hearkening back to Senator Isakson's question and your comment in terms of that question of a distribution mechanism, in terms of how people can easily access and receive health care, and I think the web-based model is a very promising approach.

Senator WARNER. And clearly there are certain sites that may have been private-sector sites that have a better reputation, perhaps, than the Federal exchange. If we can find ways to utilize that and integrate that technology, to me it seems like we want to expand the sign-ups. I hope that we can work together on this.

Again, I would like to discuss an issue that I raised with you, which is a little more complicated, about CMS's recently issued changes in the hospice benefit. I think, as this is being rolled out, it is confusing and placing a lot of unnecessary burdens on hospice patients' families and the hospice provider community.

The guidance says that Part D plans should reject prescription drugs billed to them after a patient has enrolled in hospice unless the hospice provider submits a prior authorization form to justify why a drug is unrelated to the terminal illness and should be covered by the Part D plan.

Obviously, if it is related to the terminal illness, we understand, but if you have glaucoma and a terminal illness, glaucoma is not related, and shouldn't the hospice provider be able to get reimbursed for that? Now, obviously there are some major problems with the implementation on this. My hope would be that as we dig down—there are two or three other layers of difficulty with this issue—that you will work with me and CMS to see if we can get this resolved in a way that these hospice providers are not unduly penalized.

Ms. BURWELL. Senator, I look forward to working on that issue in terms of how we can figure out how we are paying for the right things, and doing it in a way that is implementable.

Senator WARNER. In a lightning round with 4 seconds left, as a former Governor, let me just say that one of the things that we often try to do as States is look at innovative programs to try to get a waiver, whether it is with Medicaid or CHIP.

Yet a lot of these programs, they never move from kind of innovative test models to actually become permanent parts of a State's program. This, to me, again, is an area that is ripe for some administrative review, and at some point you ought to either be proving

your case and be accepted as part of the State program or be rejected. Again, I hope you will work with me on this.

Ms. BURWELL. I will, Senator.

Senator WARNER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warner.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

Ms. Burwell, thank you for your willingness to step forward for what will be a very challenging task. As a former OMB Director and part of that fellowship of folks who have had the honor to have the worst job in Washington, I congratulate you on seeking a promotion. [Laughter.]

But I do think you come at it, therefore, with a different perspective than other HHS Secretaries have had in modern times, which is that of a budget cutter and somebody who has had responsibility for oversight and trying to find efficiencies. I think that is really important right now. I hope you will continue to have that attitude at HHS.

I am going to focus on Medicare because I think you would agree with me that, when you look at not just the health care issues, but also the fiscal issues, if we do not figure out a way to reform this incredibly important but unsustainable program, we will have a difficult time ever getting our fiscal house in order.

And, as you found out when you were at OMB, this is not an easy task, because there is obviously a lot of difficulty in touching any aspect of Medicare. But the reality is that the trust fund, which is the Part A trust fund covering hospital care, skilled nursing, and so on, is expected to be insolvent by 2026 according to the most recent trustees' report.

Even if that were not true, we know that Medicare as a program currently offers about \$3 in benefits for every \$1 in taxes that a retiree contributes. That is your typical family in Cincinnati or here in Washington, DC. So it is a program already that is heavily subsidized by general revenues and heading toward, again, this insolvency, even with the significant general revenue contribution.

So my question to you is this. In this confluence of OMB and HHS that may well come together here with your confirmation, what are your thoughts about it? Let me ask you a very specific question that I think you should be able to answer in the affirmative.

In the President's budget over the last couple of years, he has included a change in the way in which the recipients of Part B and Part D benefits pay their premiums. He said there ought to be additional premiums paid for folks who make over a certain amount, 170,000 bucks roughly per couple in retirement. Some have called that affluence-testing or means-testing. In the President's proposal, he saves \$56 billion, as you will probably recall since it was in your budget, over a 10-year period. But interestingly, all the analysis indicates, it is well over \$400 billion over the next 10 years. In other words, it is one of those changes on the mandatory side of the budget, which is now the largest and fastest-growing part of the budget, that has significant out-year changes, which is really what we ought to be focusing on here in Congress and with the administration.

So my question to you is: (1) I assume you support the President's budget proposal, but (2) would you support it as a stand-alone? In other words, would you be willing to work with us on means-testing under Medicare to be able to deal—and Johnny Isakson talked about SGR, and my question is really with regard to deficit reduction and how we come together—with a problem that has been difficult politically for us to handle over the last few years here in Congress? Would you support that proposal as a stand-alone measure?

Ms. BURWELL. Senator, I agree with you. I think one of the real benefits of the income-testing for premiums has to do with the fact that it is a structural change and you get those large benefits in the out-years that are important to the over-arching numbers in the deficit space.

When I think about the deficit issues in my role at OMB, one of the things that I think is important is understanding that the drivers are both the issue of health care costs in the Medicare system and also our demographics.

Because of that, the magnitude of the problem, when one gets to the specifics of what you are going to do to resolve that issue, I think it actually takes a combination of things to do that. I think it takes things, as you are discussing, that are on the beneficiary side. I think it takes things that are on the provider side.

Senator PORTMAN. Well, we certainly—

Ms. BURWELL. I think it takes things like revenue.

Senator PORTMAN. But, as you know, we have certainly done a lot on the provider side already. My question for you is, it is in the President's budget. I assume you support the policy. Would you be able to support that as a policy initiative, whether it is in the context of SGR, in the context of deficit reduction, or in the context of tax extenders, or whatever it is? Do you support the proposal?

Ms. BURWELL. I support the proposal in the context in which the President's budget presented it, and it returns to what Mr. Isakson said: all things on the table. As we suggest, these things are on the table, but we also believe revenue has to be a part of the conversation.

Senator PORTMAN. Tell me why revenue has to be part of the conversation with regard to means-testing.

Ms. BURWELL. With regard to the question that I think we are addressing specifically, it is the issue of deficit reduction in the long term. When one looks at the numbers overall, actually getting the specifics, when you get to the specifics of what you need to do from a premium perspective, from a beneficiary perspective, from the perspective of providers, there are other parts that you need. That is where I was going with the issue of immigration as well.

Senator PORTMAN. I only have a few moments left. So you were saying that, with regard to means-testing on premiums, that there have to be tax increases. Let me just ask you this. When someone pays a higher premium, are they not paying the government more? Is that not in essence a taxpayer over a certain income paying the government more for a benefit than they would otherwise have to pay?

Ms. BURWELL. Senator, these are both things that do affect high-income people. But I think what is important is, when one is look-

ing at or talking about a package, I think one needs to see what is in the package, what it is that we are paying for, and what are the offsets you use.

Senator PORTMAN. Yes. Let us just look at this logic just for a second. Mr. Chairman, please indulge me. So you are saying that you would insist on raising taxes on wealthier individuals in order that wealthier individuals could pay more to the government in a way, by the way, that the Congressional Budget Office says is also revenue, which is premiums being paid to the government. Is that the logic?

Ms. BURWELL. Senator, as the President's budget is presented, it has a number of different elements that do everything from corporate tax reform to other things. That is why I actually think it is important to look at a package in its entirety to understand those ramifications for whether it is high-income people or other beneficiaries.

Senator PORTMAN. I know my time is expiring here. Let me just make the obvious point that it is going to be very difficult for us to take even the baby steps forward on deficit reduction if we cannot even agree that, when people have to pay more to the government, that that is something that can be done outside of them having to pay more to the government. In other words, the logic does not seem to fit for me.

I hope we can begin to make progress on these issues. I am hopeful that, given your background at OMB, that, despite what you have said here today, that you would be willing to work with us on that and other issues to make some steps in the right direction to deal with these long-term deficit problems.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Portman.

Senator Schumer?

Senator SCHUMER. Thank you, Director Burwell. I am delighted you are here. You are just a fabulous OMB Director, and I think you will make a great Secretary. I am in enthusiastic support, and I predict you are going to get passed by a large bipartisan majority. The only person's superlatives I could not exceed were my good friend Senator Coburn's in praising you for this nomination.

I have two questions on immediate issues of concern to me. The first is about something called Palcohol, powdered alcohol. Recently, in April, the Treasury Department's TTB, the Trade and Tax Bureau, approved the labels for a new product called Palcohol. It is not in stores yet.

It is just as it sounds. Powdered alcohol can be mixed with water, sprinkled onto food, even snorted. TTB rescinded its original approval for the labels, but only due to an issue with the amount of powder in each package.

So once this is resolved, Palcohol makers have indicated they will seek labels for their product to be reapproved. It is on track to be on the shelves in the fall. It is really troubling to me. Obviously, you can drink a lot more alcohol in powdered form than in liquid form just because of the volume.

You can put it on food. Kids can sneak it into dances, concerts, sporting events, in their pockets and their shoes. It is really troubling. The only hope we have of stopping Palcohol from getting on

the shelves—and Mothers Against Drunk Driving is very concerned with this—is the FDA. You will oversee the FDA, so I believe that the FDA should get involved. It is our premier consumer agency.

I hope they can investigate this new substance, just as they did with Four Loko, which was alcohol and caffeine mixed, which they banned. I would hope they could do the same thing here because that was proven unsafe. I believe this will be also. So all I am asking you is, will you commit to having the FDA look into this new alcohol product for health and safety reasons?

Ms. BURWELL. Senator, if I am confirmed—this is a new issue. This is one that I would want to understand better and understand exactly which jurisdiction is appropriate and why it is currently at Treasury, as you described, in terms of being a tax issue, I understand that, but why it has not previously been looked at by FDA.

Senator SCHUMER. Yes. They have not looked at it, and I hope you would urge them to do so.

Ms. BURWELL. I will investigate it further, if I am confirmed.

Senator SCHUMER. All right. Thank you.

Next is another issue that I care about, which is Zohydro, where the FDA has been worse, and it is not such a new issue. We have opiate abuse all over the country, all over. It is in urban areas, suburban areas, rural areas. In 2013, October, a pure form of the powerful painkiller hydrocodone was approved by the FDA to go to market without the same tamper-proof protections aimed at curbing abuse that are in place for drugs that are less potent: Vicodin, Oxycontin.

FDA approved this, despite the recommendations of an advisory panel against it and in opposition of many Senators. It is a serious issue that has physicians, addiction experts, and law enforcement officials from around the country alarmed.

There are ways to make it tamper-proof; there are ways to make it so you cannot turn it into a powder and snort it or inject it. You know the scourge of prescription drug abuse that we face in every part of the country. Will you review the decision by the FDA on Zohydro once you get into office?

Ms. BURWELL. Senator, the issue of prescription drug abuse is one, being from a rural community in southern West Virginia, where I have seen the issues first-hand in terms of how damaging they are to both health as well as the economy, so these are things I take very seriously.

With regard to engagement with FDA, one of the things I want to do, if I am confirmed, is make sure that I work with FDA on science-based decisions. If I am confirmed, this is a case where I will want to understand how the decision was made.

Senator SCHUMER. Again, I hope you will be actively involved. I realize the necessary caution when you are sitting at that table, but I know who you are, and I think you will get involved.

Medicare Advantage. Senator Crapo talked about this, so I do not want to get into details. I only have 27 seconds left. All I would ask you is to look at the difference. There are some Medicare Advantage plans that are abusive, take advantage, rip off the Federal Government. There are some that are great, many of which are in upstate New York. We have a ton of them in Rochester.

I think 65 percent of all Medicare recipients are on Medicare Advantage, and most of them are very happy. You do not have to—I just would urge you to separate the wheat from the chaff. Some people on my side of the aisle, the minute they hear Medicare Advantage, they say it is terrible. It is just not true, not in my experience in my State. They are all across the board. I just hope that, when you look at Medicare Advantage, you will give it a careful look and not take one broad brush and say programs are all bad, because they are not.

Ms. BURWELL. Thank you, Senator.

Senator SCHUMER. Thank you.

The CHAIRMAN. Thank you, Senator Schumer.

Let's see. Next is Senator Carper, then Senator Toomey.

Senator CARPER. Thank you, Mr. Chairman.

Ms. Burwell, nice to see you. Congratulations on your nomination.

Ms. BURWELL. Thank you.

Senator CARPER. It is one of those deals where I have mixed emotions. I chair this committee that has a very close relationship with OMB, and, if you are confirmed for this position, it means we lose you at OMB. I was kidding with some of my colleagues. I said, you know, if Sylvia is confirmed for Secretary of HHS, the President is going to nominate Tom Coburn to be head of OMB. Two of my colleagues said, well, we cannot vote to confirm her. [Laughter.] So I just want to make it clear, that is not the plan. That is not the plan. We love working with you at OMB, love working with the team that you have put together.

One of the things we focused on, as you well know, is how do we get better health care results for less money? For most things, in terms of being successful in government, in academia, in business, whatever it might be, the key is leadership, leadership.

One of the reasons why the Department of Health and Human Services, which for years was kind of the laughingstock when it came to being a manager of finances, actually last year, wonder of wonders, they actually were auditable, but they got a clean audit. After 20-some years, the Department of Defense still has not done that, but DHHS has done that. The key is leadership, leadership. In terms of actually making further progress in reducing improper payments—what were they last year, \$50 billion in Medicare and probably \$20 billion in Medicaid—the key is leadership.

Talk with us about leadership, what you have learned, what you have brought with you to OMB, what you have learned there about how we can make further progress at the Department of Health and Human Services. What have you learned in your current job that will enable us to get better results for less money in some of these very expensive programs where we need to save money?

Ms. BURWELL. I think one of the things I have learned is being very specific about what you are trying to achieve in the space and very quickly getting to what are the most important levers. I think in our conversation today there have been a number of things where, actually, there are conflicting interests.

I think what is important is, as the leadership, to be able to quickly get to the problem-solving in terms of articulating, what are those conflicting interests and how do you weigh how you go

forward? It will be imperfect. In order to make the progress we need on Medicare fraud, it comes back to the issue we were discussing with regard to RACs and what tools are we using.

Some of those tools will be effective, but there will be places where they are not, so you have to be continuously thinking through where is the place you are going to focus on, what is the core objective, and how are you going to continuously improve?

Those are some of the elements that I think are making a difference in the results we have seen in improper payments, which have gone from 5.3 percent down to 3.5 for the entire Federal Government and which this Medicare and Medicaid issue will be a large portion of.

Senator CARPER. Dr. Coburn, after he introduced you, he and I left and we went off to meet at a secure briefing from the Secretary of Homeland Security. We talked about border security, we talked about all the folks who are coming up across the border now, not from Mexico, but Honduras, El Salvador, Guatemala. The reason why is because they are living hellish lives in those countries and they want to get out of there, and they will do almost anything to get out of there and to try to get up here.

I said to Secretary Johnson and to Dr. Coburn, it is not enough just for us to build bigger walls, stronger walls, more border patrols. We have to figure out the underlying causes, the underlying causes that are compelling all those people who want to risk life and limb to get up here to this country for a better life.

I want to talk about underlying causes with respect to obesity, underlying causes with respect to medication adherence. We know that obesity is a huge driver for medical costs in our country. Look at diabetics, all the money that we spend on that sort of thing. If you look at the medical adherence, where folks are actually able to afford their medicines and take their medicines, comply with their medication as they are directed, you see how much money we could save.

Talk to me in terms of helping to get better results for less money with respect to those kinds of things, the Program of All-inclusive Care for the Elderly, where we treat our dual-eligibles, folks that are Medicaid-eligible and Medicare-eligible, a very thoughtful approach. It is a little more expensive at first, but actually we save money in the long run. Would you just talk about how medication adherence programs like the PACE program actually are going to be helpful or can be helpful?

Ms. BURWELL. I think it comes down to the fact that prevention is such an important part of reducing costs. If we can get in front of these things, it is actually a similar concept to what we were talking about earlier with regard to, instead of pay-and-chase, you get in front. Things are generally cheaper, better, and easier if you can get in front of them.

I think some of the things that we need to do are, we need to help make sure we have the analytics that show what works in terms of whether it is obesity or diabetes prevention. I think there are models. We need to make sure those analytics are rigorous.

The second thing we need to do is make sure we are educating and communicating. Whether that is in the space that we are talking about with regard to prevention or in the space of making sure

people understand the rules of the road with regard to Medicare, the question is one of educating and making sure people have the right information.

The last thing is about tools. In my experience, at least in working on some of these issues at the WalMart Foundation, with regard to how people use healthy eating, you can provide the food. So the company would reduce the cost of fruits and vegetables—the goal was \$1 billion—taking those costs out. But with the communities and populations, it actually took educational programs to teach people. When you are shopping and you are a mother or a father and you are in the grocery store for a very short period of time, you need to get home, you need to fix that meal, in terms of serving and using things you have never used before, there is an educational component in order that you can actually use the tools. Share Our Strength is an organization that did that.

So I think working through all the elements of first the proof, the education, and then the tools, are all three elements that I think are necessary to make the kind of progress we need, especially on the prevention and diabetes front.

Senator CARPER. Great. Thanks for your service so far. Good luck, Godspeed. Thank you.

Ms. BURWELL. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Carper.

Senator Toomey?

Senator TOOMEY. Thank you, Mr. Chairman.

Director Burwell, thank you very much for being here and for very open and cooperative discussions that we have had leading up to this. I have a couple of questions for you.

First is about Alzheimer's. We talked about this a little bit in my office. It is estimated that over 5 million Americans have been diagnosed with Alzheimer's. My understanding is that about 11 percent of all Americans over the age of 65 and something like a third, 33 percent of all Americans over the age of 85, have Alzheimer's.

It seems that if you live long enough, chances are very, very high you are going to get Alzheimer's. It is 100-percent fatal. We have no cure. We have no meaningful treatment really, even. Yet in fiscal year 2013, only 1.7 percent of the NIH budget went to Alzheimer's research. Does that strike you as proportionate to the challenges that Alzheimer's presents?

Ms. BURWELL. With regard to the budget and Alzheimer's, our overall plan on Alzheimer's, there were increases. But I think you know, on the discretionary side, for anything to get increases in the current budget environment was a very difficult thing to do.

Senator TOOMEY. No, I am talking about within the allocation that goes to NIH, the \$30 billion that they get, they then control where that goes. That does not get appropriated by Congress specifically. Does 1.7 percent sound about right?

Ms. BURWELL. I think that the question of what is the right percentage is something that I actually, if I am confirmed, would want to spend time with Francis Collins on, to find out how they think about distribution. It is one of the issues you and I discussed, and I did follow up to try to find out exactly how it is done. A lot of it is done based on history. When one does something based on history and there are changes, one may need to reexamine.

Senator TOOMEY. Well, I appreciate that, and I hope you will revisit that, because the history has changed. Alzheimer's has become ever more serious and grave a threat.

I want to follow up briefly on Senator Portman's discussion with you, because I have to say I do find it troubling, at least what I understood you to be saying. If the idea seems to be that Republicans and the President's budget have both broadly felt that it is appropriate to ask very wealthy Americans to pay more for the Medicare benefits they get, it is disconcerting to hear that the price for getting an agreement to ask wealthy Americans to pay more for their Medicare is to raise taxes on wealthy Americans. It is going to be hard to reach agreement if something as common-sense as asking wealthy Americans to pay more for their Medicare has to come at the price of, in addition, raising taxes.

Ms. BURWELL. Senator, I think when one thinks about it, and why I talked about an entire package, is some of the revenue raisers and things in the President's budget are not like that. There are elements of the President's budget on the revenue side that are actually in the Camp plan in terms of what has been proposed on the House side, but have been proposed by Republicans. There is overlap.

That is why I actually think what is important in most of the issues that we are talking about today, whether on the health care side or on the deficit side, is actually to look at the specifics, to actually put together pieces and plans. I think when we all try to take a piece out, that that becomes difficult. If we can look at it in its entirety, I think we can make progress.

Senator TOOMEY. Well, look, I am in favor of a broad, comprehensive reform, but if that remains as elusive as it has been, a simple idea of asking the wealthiest Americans to pay more for the benefit they get strikes me as a very reasonable thing in and of itself. I would hope we do not have to raise taxes on people to get there.

But I want to follow up on a separate issue which you and I discussed, and that is the budget reclassification of the risk card or payment. So my understanding is that the payments that will go to insurers or come from insurers now that the Federal Government is in partnership financially with the health insurers, that that has gone from what would have been its own account to a CMS general program management account.

As you and I have discussed, my interest is just to ensure that we will have transparency in this account. I am hoping that you can commit that, for whatever reason that was done, and at least on an annual basis, we will be able to know how much money came from insurers or goes to insurers through this account, what the source was, whether it is a surplus or whether it is an expense.

Ms. BURWELL. Senator, as you and I had the chance to discuss, this is part of a larger rulemaking at OMB, it is part of 12866, which is an executive order which says I cannot discuss specifics. In general terms, what I would like to say is, Senator, this is something I want to work with you on with regard to the question of transparency.

I hear what it is about, which is knowing the numbers of what comes in and what goes out. I think that is the fundamental question you are asking and one that I would look forward to working

with you on. Having been at OMB and worked on budgets and accounts, I think that is something I would like to work—

Senator TOOMEY. Does the rule that restricts you from commenting on rules forbid you from making a commitment to having transparency in this account?

Ms. BURWELL. With regard to the commitment to transparency, that is something that I think we have talked about throughout this hearing, which is, transparency and accuracy are the two things that I want to do in a timely fashion. This committee has my commitment on that.

Senator TOOMEY. All right. Thank you, Mr. Chairman.

The CHAIRMAN. Staying in the State of Pennsylvania, Senator Casey.

Senator CASEY. Mr. Chairman, thanks very much.

Director, I know we are getting to the end, so we are rounding—whatever the baseball analogy is—we are getting close to home plate. So we are grateful for your patience, we are grateful for your testimony and your willingness to serve, again in very difficult public service, so we are grateful for that. I know we had a chance to discuss some children's health insurance issues in the Health, Education, Labor, and Pensions Committee.

I was noting that we do not have a lot of time for questions beyond maybe the two that I have, but just some of the numbers in Pennsylvania on enrollment have been pretty significant. I know we have all heard the national numbers, 8 million enrolled, almost 5 million in the Medicaid Children's Health Insurance Program area. I know that Senator Rockefeller has done so much work on both programs for so many years.

In Pennsylvania, the marketplace plan selection is a little more than 318,000 in Medicaid, CHIP enrollment is almost 41,000, a little shy of that. So almost 360,000 people, so some big numbers.

But I will move from ACA to at least two children's issues. One is title IV-E waivers regarding child welfare. We have in our State, as many States do, counties taking advantage of that waiver, where they are working to make sure they are trying to invest in evidence-based programs and incentives to reduce the long stays in what we used to call group homes in Pennsylvania to try to get children into better settings, but also to make sure that, as we do that, we are using the evidence-based strategies.

We have five counties in our State, five out of 67, that have used that waiver—two big ones, Allegheny and Philadelphia, among the five. But I would ask you to work with us on, I guess, two aspects of this: working for comprehensive reform of child welfare, number one, and also, as we do that, to help all children in that system; and secondly, to promote as best we can better outcomes and evidence-based practices.

So I would just ask for your commitment to work with us on that, and I would welcome anything you would want to say about it.

Ms. BURWELL. Senator, I would like to work with you on that. These issues are issues that I think are very important. Even in my current role at OMB, in terms of evidence-based practices and these issues, one of the things that I was very interested in and highly supportive of was the psychotropic drug provision that is

part of the President's budget, which is analytically based. Whether you use the numbers that the administration has, which are that 17 percent of all children in the system are on psychotropic drugs, or up to 34 percent in terms of some of the other studies, we should be using data to understand where things are going right or where things can be improved. So I would look forward to working with you across the range of issues for children in this space.

Senator CASEY. I appreciate that.

Secondly and finally, one of the areas of policy which probably does not get a lot of national attention but is showing some promise is the so-called CCMI program, where you have the Centers for Medicare and Medicaid Innovation. I know a lot of the innovation is focused on Medicare, and appropriately so.

What I hope, though, is that through both Medicaid and CHIP, through both of those programs and within the rubric of CCMI, we can have enough testing of new models so that we can get some of the benefits of that innovation for children in addition to the results that have prevailed for Medicare, and I would ask for your help on that.

Ms. BURWELL. Yes. I think we do want to get the benefits for both systems. Both systems are important. We actually have examples in our own budget, the President's budget, where we actually are taking things that are working in Medicaid and trying to have those shift to Medicare in terms of things that are working, in terms of effective health care that is cost-effective.

Senator CASEY. Well, I appreciate that. I know I am out of time, but I wanted to just make one final point. We know that anyone who has had anything to do with child advocacy over many years would tell us that children are not small adults, so we need specialized strategies and approaches for kids that may be different from how we treat or care for adults. But we are grateful for your commitment.

Ms. BURWELL. Thank you. My 6½- and 4½-year-old prove that every day.

Senator CASEY. Thank you.

The CHAIRMAN. Very good.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

Director Burwell, thank you very much for your willingness to serve and thank you for your time in the Pacific Northwest: 10 years as the head of the Bill and Melinda Gates Foundation for Global Development and then on the board at the University of Washington Medical Center. I am sure that time on the board will come in very helpful here in this post.

I wanted to ask you about two things as they relate to the Affordable Care Act and priorities, and see how you plan to manage them. One, section 3007—I do not expect you to know that section, but, knowing Sylvia Burwell, she actually might know that section—but we are talking about altering the payment formula by adding a quality-to-cost ratio that will reward providers for low-cost quality and penalize providers that do not—essentially, it moves the Nation out of our current model to an outcome-based model.

Now, we had some discussion—this is part of the implementation. I think the Secretary was required to start a process this year or the beginning of the formulation of the regulation this year, and probably it had to be published next year, and then the SGR bill that we were recently looking at had a provision in here that reformed that.

So what steps do you plan to take on implementing that value-based payment system? Are you for what was in the SGR bill? Are you planning on just proceeding with the rule? Do you think that that is a better process? Tell me your philosophy on the implementation of this provision.

Ms. BURWELL. With regard to the specifics of implementation that are currently at HHS, that is something, if confirmed, I want to look at. But with regard to the question of philosophy, I believe that the question of how we are going to be able to articulate quality and connect payment to quality will be a very important part of transitioning the entire system; that is, transitioning the system in terms of government and how we pay, but also the private sector.

I think what we will have to do is work on it from the perspective of the government side and how we do it. It is a complex thing in terms of, is the quality of your hip surgery because the surgeon did the front surgery versus the back? Is it the anesthesiologist? How do we determine those things? But I think what we need to do is work to get measures in place and start making progress. I also think that we can turn to the private sector, because, in some cases, they are already doing that as well.

Senator CANTWELL. Well, that is my point. The Pacific Northwest has already done this, already shown great results.

Ms. BURWELL. Yes.

Senator CANTWELL. So now the debate here in Washington seems to be, can we overturn the Affordable Care Act or ignore this, or can we put a provision in? I did support the SGR proposal, but should we put a provision in that gets the rest of the country to start doing this but in a very slow, incremental way, or do we go with the results that we know all across the country are working and get it implemented and push people to implement it in a more rapid fashion, given what we are looking at from a population bubble, and retirement, and everything else?

We need to make these reforms. So I hope that you understand you are going to hear a lot from me and from people from the Pacific Northwest. We do not want to go slow, we want to go faster. We do not want to see proposals that some of my colleagues are proposing on Social Security or Medicare to privatize them instead of doing these important outcome-based, better performance reforms.

I will note, even in the Affordable Care Act, there were a lot of States that took us up on rebalancing from nursing home care to community-based care, saving lots of money. These are States and Governors that said they did not even like the Act, and now they are implementing one of the biggest cost savings that exists. So, I hope we will run faster on that.

The second issue is on the implementation of the basic health plan, which was an option in the legislation to assist those people

who earn too much to qualify for the Medicaid coverage. But the private coverage struggle to make marketplace premiums—this was something that we gave States an option on, so I want to know what you will do.

The Department was very late in getting those rules developed. They finally came out in September. They were supposed to be done previously, so I want to know what you will do to make sure that States who choose that option will be fully operational by January 1, 2015.

Ms. BURWELL. Senator, if I am confirmed, one of the things I want to do is quickly find out about the sequencing of all the things that need to get done and the information that States need to have, as well as the technology we need to get in place to make sure that the next year runs smoothly. That is something, if I am confirmed, that would be one of the first things to do, to understand who needs which information when and how we are going to work to implement.

Senator CANTWELL. If you do not know enough about it right now, you do not need to discuss it, but you can write it. But I need an answer from you whether you support the basic health plan as an option for States as written in the statute. The agency has ignored that program for a long time, finally got it together, yet has put States behind. So I want to get a firm answer from you, so you can do that for the record.

Ms. BURWELL. Certainly. I would be happy to, Senator.

Senator CANTWELL. All right. And then, just the last thing. Well, I guess I am 16 seconds over.

The CHAIRMAN. Go for it.

Senator CANTWELL. Maybe I can have a little bit of extra time, being the last member.

The CHAIRMAN. You can.

Senator CANTWELL. I do not know, Mr. Chairman, if anybody brought up GME, but on graduate medical education and paying for graduate medical education, I do not know what role you think the agency is going to play in helping identify the need for filling that gap of primary care physicians that we need. Obviously we are not going to get there if we do not have a graduate medical education expansion.

Ms. BURWELL. So I think the President's current proposal in the budget does some of that expansion, in terms of making sure that we do two things: that we increase our providers, and that we target the help to primary care as you suggested and where we have shortages in specialties. In addition, expanding the National Health Service Corps is another means by which we hope to improve and push on getting more providers out in the field.

The other thing is that some of the proposals in the budget also expand what certain government programs can benefit in terms of, not just the physicians themselves, but also other physicians' assistants and nurses, in terms of some of the primary care needs we have. It is a place where I think we have to focus and use all the tools.

The other thing I think we have to do is to make sure that the money is going against what one is trying to do when one is doing GME and focus it on the right kinds of issues, which is why the

proposal is focused mainly on primary care, in terms of the new GME proposal.

Senator CANTWELL. Yes. We think it is a good start, but hopefully we will have a discussion about how big the need is as it relates to implementing a medical home for people and why we need to focus on moving forward on graduate medical education. But thank you.

Ms. BURWELL. Thank you.

Senator CANTWELL. And thank you for your willingness to serve.

Ms. BURWELL. Thank you.

The CHAIRMAN. Thank you, Senator Cantwell.

Just a couple of additional matters, and then we are going to liberate you, Director Burwell. This is your second nomination hearing in less than a week, and we appreciate your answers today.

We have focused for the most part on the agency's very extensive health care portfolio, and that is why I thought it was very good that Senator Casey began to touch on the human services aspect of the agency's work, and particularly programs like foster care and Temporary Assistance to Needy Families. You all have a very extensive workload there. Can you give us some sense of what your priorities would be on the human services side of your budget?

Ms. BURWELL. Senator, with regard to setting those priorities in those areas, in a number of my conversations with the members of this committee and the HELP Committee, they have articulated some of those priorities.

I would want to, as we discussed, also hear from the stakeholders and from the Department itself before setting exactly what those priorities are, but they are broad and they are numerous, and they include everything from an issue that is in the news today—which is bio-security in terms of the MERS issues and issues like that—to some of the issues that we have been talking about in terms of FDA.

The Administration for Community Living, I think, touches on some of the issues that we talked about today with regard to hospice and how we think about care for people in communities. How long can we keep people there? Is it both cost-effective and better in terms of quality? So I think the range of those issues is something I want to hear about and then quickly set priorities.

The CHAIRMAN. And by way of wrapping up, just a couple of comments. First, on the Medicare Advantage issue, I think you know that the Pacific Northwest has some of the highest rates of utilization in Medicare Advantage. It is good, Medicare Advantage.

We have been at it for decades in my hometown and Senator Cantwell's hometown. Obviously, we heard Senators on both sides of the aisle touch on it. I just want to walk through what I heard, because it was very constructive.

You made the point that the premiums are down, the coverage is up, and a number of the questionable operators have been squeezed out. I think that is very good, because I remember some of the tremendous abuses we saw in the early days of Medicare Advantage. We had oversight hearings on it in this committee, and it was just really gross, some of those practices. That has really been driven out of the field.

In response to the Senators' questions, Senator Crapo, Senator Schumer, and others, you essentially said—and I think this is where the Senators were going—that we ought to proceed carefully and get the latest data and work through these various issues to essentially continue on the track. That is what I heard the Senator say, and I think that is how you addressed it, and I think that is very welcome and very constructive.

The last point I want to mention is a reflection on the last 2½ hours and watching you also in the other committee that held a hearing on your confirmation. We have been at it for something like 2½ hours or thereabouts, and from the beginning, where you had this extraordinary bipartisan send-off from Dr. Coburn and Chairman Rockefeller, who I would note has not budged for the last 2½ hours, your ultimate loyalist I think it would be fair to say—

Ms. BURWELL. Thank you.

The CHAIRMAN [continuing]. What you have done is, in my view, tried to respond to important questions about a landmark law and big health care challenges in a way that ought to bring people together. That is why I referenced your point with respect to Part D, because a lot of the stories in the early days about the ACA resembled the early stories about Part D. Part D, we now know, has come in at 30 percent-plus in terms of cost reduction beyond what CBO projected, and the satisfaction among seniors has been enormous.

Senators, no matter how they voted on Part D, came together and said, we are going to try to make this work, and we are going to try to do that on this committee. I think you can be a very powerful agent, once you are confirmed—and we are going to do everything we can to make that possible quickly—in terms of trying to bring people together and to get us to that point that you touched on, post the enactment of Part D, of trying to bring people together regardless of how they voted.

So that is my take-away from the last 2½ hours: that you can be that kind of member of the Cabinet to really help us cut through some of the polarization we have seen over the last few months. I think that it will be an extraordinary service to the country.

Senator Rockefeller, is there anything you would like to add?

Senator ROCKEFELLER. Only that, in a Senate so full of toxicity and partisanship, I think your sort of attitude, your listening, your energy, your knowledge, your ability to defer properly things which you have not yet done because you are still in another job but are anxious to get at, is in a sense what the chairman is saying. That is, how do you begin to take down the walls on a subject so enormously important as the provision of health care, such an enormous piece of legislation with such vast implications for the country? I think it is very interesting, just in your performance this afternoon, that also obviously, in your position that I am sure you are going to have, you seem to just fit very comfortably.

Ms. BURWELL. Thank you, Senator. Thank you.

The CHAIRMAN. Director Burwell, let me just close by thanking my colleagues on the other side of the aisle, led by Senator Hatch. They have been very helpful in terms of allowing us to move forward. They have indicated that members could have until 6 p.m.

on Thursday to submit questions for the record, so clearly we are moving ahead.

It is my intent to work very closely with Senator Hatch and all committee members to report your nomination promptly after the answers to the questions are received. We thank you for your patience.

With that, the Finance Committee is adjourned.

[Whereupon, at 4:56 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Testimony of
Sylvia M. Burwell
Nominee for Secretary
United States Department of Health & Human Services

Before the
Committee on Finance

May 14, 2014

Chairman Wyden, Ranking Member Hatch, Members of the Committee, thank you for inviting me to discuss my nomination to be the Secretary of Health and Human Services. I am honored that President Obama has nominated me for this position, and it is a privilege to be considered by this Committee.

I want to thank the Members of this Committee and your staff for taking the time to meet with me over the course of the last few weeks and for continuing to share your views. If confirmed, I look forward to working together closely on our shared priorities for the Department of Health and Human Services.

I am especially grateful for my husband and children for their tremendous support, especially as I seek to take on this new role. And while my parents could not be here with us today, I also want to recognize them for instilling within me the enduring value of public service.

As a second-generation Greek immigrant, I was raised to be thankful for the gifts that this great nation gave to me and to my parents before me. Throughout my childhood in Hinton, West Virginia, my father, an optometrist and small business owner, and my mother, a teacher, were both engaged in service through our community and church.

And so, with this core commitment to service and passion for impact, I am humbled and excited by this next challenge. If confirmed, I look forward to working alongside the remarkable men and women of the Department to continue to ensure that children, families, and seniors have the building blocks of healthy and productive lives.

These issues are fundamental to all of us – whether it is the chronic condition of a child we love, the safety of the food we eat every day, or improving quality, lowering cost and expanding access in our healthcare system – so I respect and appreciate the importance of the challenges before us. I am committed to an open dialogue on priorities for the Department and our shared goal of delivering impact for the American people.

Commitment to Impact

As the Director of the Office of Management and Budget, and throughout my career in both the public and private sectors, I have had the opportunity to lead large and complex organizations and work across a range of issues. In each of my roles, I have focused on building strong teams, forging relationships, and delivering results. As Chief Operating Officer and later President for

Global Development at the Gates Foundation, I had the opportunity to work on some of the world's most pressing challenges, from agricultural productivity to healthcare in the developing world. As the President of the WalMart Foundation, I led our efforts to fight hunger in America, leveraging Walmart's presence in local communities to reach millions of people across the country to best maximize our impact. And as a member of the board at a university hospital and Fortune 50 insurance company, I gained firsthand experience into healthcare delivery and insurance markets – and how both can work better for businesses and families.

In my role as OMB Director, I have worked closely with members of this committee and others – both Democrats and Republicans – to support efforts to return to a more orderly budget and appropriations process. The enactment of the Bipartisan Budget Act of 2013 and the Consolidated Appropriations Act of 2014 represented important steps toward replacing damaging sequestration cuts with sensible long-term reforms and investing in key areas of innovation, education, and infrastructure to help grow our economy, create jobs, and strengthen the middle class. Throughout my tenure, I have made responsiveness to and engagement with Congress a priority – working with members on both sides of the aisle to drive towards progress on the issues we all care deeply about.

The Work of the Department of Health and Human Services

The Department of Health and Human Services touches Americans at every age, from every background, in every part of our country. As we meet here today, scientists and researchers at the National Institutes of Health are working to find cures for some of our world's most serious diseases – and experts at the Centers for Disease Control and Prevention are working to prevent them from spreading. The Food & Drug Administration is protecting the safety of the food we eat and the medications our doctors prescribe us. The Agency for Healthcare Research and Quality is researching ways to improve the care we receive and identify causes of racial and ethnic disparities in health so we can work to eliminate them. These talented men and women are not only among the best in their fields, they are among the best in the world.

Our parents and grandparents rely on the Centers for Medicare & Medicaid Services, and millions of our children benefit from Head Start and the work of the Administration for Children & Families. Meanwhile, millions of Americans are living with dignity in their own communities, thanks to the Administration for Community Living.

Throughout our country, one in five adults experiences mental illness. Our neighbors are supported by the behavioral health and substance use services provided by the Substance Abuse and Mental Health Services Administration. And the largest expansion of behavioral health coverage in a generation is finally delivering on parity between mental and physical health coverage.

Tens of millions of people living in underserved communities – from rural America to Indian Country to America's inner cities – are accessing quality care, regardless of their ability to pay, thanks to the Health Resources & Services Administration and the Indian Health Services.

The Department's work to ensure accessible, affordable, quality healthcare through the implementation of the Affordable Care Act (ACA) is making a positive difference in the lives of our families and our communities, while strengthening the economy. Because of the law, millions of Americans now have new benefits, new protections, and new health coverage. The Congressional Budget Office recently affirmed that the ACA is working to lower healthcare cost growth, make individual market premiums affordable, increase coverage, and reduce the Federal deficit.

Together, all this work forms the foundation of a stronger middle class, a more prosperous economy, and healthier communities.

Conclusion

If confirmed, I will work to continue to build on this progress. Understanding the complexity and significance of the challenges that lie ahead, I will approach my work at the Department with three guiding tenets – driving solutions for the issues we all care deeply about; building teams with the talent and focus we need to implement against our objectives; and strengthening relationships to make progress on the wide variety of issues at the Department that transcend parties, and will ultimately transcend our generation.

Mr. Chairman and Members of the Committee, thank you again for the invitation to speak with you today. I have valued the conversations we have had to date, and I am hopeful that we will have the opportunity to continue to work together closely to engage on some of the most pressing issues this nation faces today and to best support the health and wellness of the American people.

With that, I would be pleased to answer your questions.

**SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE**

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)
Sylvia Mathews Burwell, Sylvia Mary Mathews
2. Position to which nominated:
Secretary of the U.S. Department of Health and Human Services
3. Date of nomination:
April 11, 2014
4. Address: (List current residence, office, and mailing addresses.)
5. Date and place of birth:
June 23, 1965
Hinton, WV
6. Marital status: (Include maiden name of wife or husband's name.)
7. Names and ages of children:
8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

Harvard College, Bachelor of Art (9/1983–6/1987)
Oxford University, Worcester College, Bachelor of Art (10/1987–6/1990)

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)

Director, Office of Management and Budget, Washington, DC (04/2013-Present)

President, Walmart Foundation, Bentonville, AR (12/2011-04/2013)

President Global Development, Bill and Melinda Gates Foundation, Seattle, WA (04/2001-11/2011)

Deputy Director, Office of Management and Budget, Washington, DC (est. 1998-01/2001)

Assistant to the President and Deputy Chief of Staff, The White House, Washington, DC (est. 1997-1998)

Chief of Staff to the Secretary, U.S. Department of Treasury, Washington, DC (est. 1995-1997)

Staff Director for the National Economic Council and Special Assistant to Robert Rubin head of the National Economic Council, The White House, Washington, DC (est. 1993-1995)

Economic Policy DC Office Manager, Presidential Transition, Washington, DC (11/1992-01/1993)

Deputy Economic Policy Director, Clinton/Gore for President, Little Rock, AR (07/1992-11/1992)

Associate, McKinsey and Company, New York, NY (08/1990-07/1992)

Administrator, Oxbridge Academic Resources, New York, NY (07/1989-08/1989)

Researcher, Dukakis/Bentsen Presidential Campaign, Boston, MA (06/1988-11/1988)

Research Associate, The LEK Partnership, Boston, MA (06/1987-09/1987)

Governor's Aide, State of Massachusetts, Boston, MA (06/1986-08/1986)

Executive Education Reunion Coordinator, Harvard Business School, Boston, MA (01/1986-06/1986)

LBJ Intern, Congressman Nick Joe Rahall, Washington, DC (06/1985-08/1985)

Waitress, Kirk's Home of the Hungry Smile, Hinton, WV (06/1983-08/1983)

10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

Member, President's Global Development Council, January – April 2013

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

President, Walmart Foundation (01/2012-04/2013)

Director, MetLife (01/2004-04/2013)

Director, Council on Foreign Relations (06/2007-04/2013)

President Global Development, Bill and Melinda Gates Foundation (3/2001-11/2011)

Advisory Group Member, Peter G Peterson Foundation (03/2005-04/2013)

Advisory Group Member, Nike Foundation (03/2005-04/2013)

Board Member, Alliance for a Green Revolution in Africa (2007-2011)

Professional Advisory Board Member, ALS Evergreen Chapter (01/2008-04/2013)

Member Advisory Group for Managing Global Insecurity, Brookings Institution (2007-2008)

Smart Power Commission Member, Center for Strategic and International Studies (2007-2008)

Governing Council Member, Miller Center of Public Affairs (2000-2008)

12. Memberships: (List all memberships and offices held in professional, fraternal,

scholarly, civic, business, charitable, and other organizations.)

Member, Aspen Strategy Group (2001-2013)

Member, Trilateral Commission (2007-2013)

Young Global Leader, World Economic Forum (2004-2009)

Member, Pacific Council on International Policy (2003-2009)

Henry Crown Fellow, Aspen Institute (2005-2007)

Director, MetLife, Inc. (2004 – 2013)

Board Member, University of Washington Medical Center (2002-2005)

Advisory Board Member, Pete G. Peterson Foundation (2009 – 2013)

Advisory Group, The Nike Foundation (2005 – 2013)

Member, Council on Foreign Relations (2002-present)

Founding Member, The Next Generation Initiative (2003-present)

Member, St. John's (2013-present)

Member, St Paul's (2012-2013)

Member, St. Mark's Cathedral (2001-2011)

Member, Wasatch Group (2013)

Board Member, Alliance for a Green Revolution in Africa (2007 – 2011)

Professional Advisory Board Member, ALS Evergreen Chapter (2008 – 2013)

Member Advisory Group for Managing Global Insecurity, Brookings Institution (2007 – 2008)

Smart Power Commission Member, Center for Strategic and International Studies (2007-2008)

Governing Council Member, Miller Center of Public Affairs (2000-2008)

Member, Women's Forum of Washington (1998)

Member, Oxford Union (1987-1990)

13. Political affiliations and activities:

- a. List all public offices for which you have been a candidate.

None

- b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

My husband and I were listed as co-hosts of an Obama fundraiser at my 25th college reunion in May 2012.

- c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of \$50 or more for the past 10 years.

John Kerry \$1000 (2004)

Thomas Andrew Daschle via New Leadership for America PAC \$250 (2004)

Joe Torsella \$300 (2004)

Chris Gregoire \$100 (2004)

Cleo Mathews \$250 (2005)

Maria Cantwell via Friends of Maria \$250 (2006)

Democratic Congressional Campaign Committee \$250 (2006)

John Tester \$250 (2006)

Judy Feder \$200 (2006)

Obama for America \$500 (2007)

Jim Himes \$50 (2007)

Hillary Clinton \$50 (2007)

Carlos Del Toro \$150 (2007)

Anne Barth \$500 (2008)

Susan Craighead \$250 (2008)

Obama for America \$1300 (2008)

Clinton for President \$500 (2008)

Obama Victory Fund \$2000 (2008)

Obama for America \$1000 (2008)

DNC Services Corporation/Democratic National Committee \$1000 (2008)

Alan Khazei \$3000 (2009)

Democratic Senatorial Campaign Committee \$250 (2010)

Patty Murray \$250 (2010)

Joe Manchin \$250 (2010)

Alan Khazei \$500 (2011)

Holton for AG \$1000 (2012)

Jon Tester \$100 (2012)

Obama Victory Fund \$1500 (2012)

Obama for America \$1500 (2012)

Nancy Soderberg \$250 (2012)

Washington United \$500 (2012)

Walpac \$5000 (2012)

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

2014 Youth Leadership Spirit of the Mountains Award

Distinguished West Virginian Award
Rhodes Scholar
Institute of Politics Fellow, Harvard University
UCLA School of Public Policy Senior Fellow
Honorary Degrees: West Virginia University, Doctor of Humane Letters (2003)
and Northeastern University, Doctors of Philosophy (2011)

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

I have done my best to identify all titles, publishers, and dates of books, articles, reports, or other published materials, including a thorough review of my personal files and searches of publicly available electronic databases. Those I identified are listed below.

In my role as Director, I have authored blog posts and penned an op-ed for placement in regional papers across the country regarding information and activities of the Office of Management and Budget. The blog posts and op-ed are available at www.whitehouse.gov.

Mother's Day Every Day, Huffington Post Blog (May 11, 2012)

Better Crops = Better Lives, Bill & Melinda Gates Foundation Blog, www.gatesfoundation.org (April 13, 2011)

Leading Thinkers Series: Aid in the 21st century, The Globe and Mail (March 3, 2011)

Aid in the 21st Century, Bill & Melinda Gates Foundation Blog, www.gatesfoundation.org (March 3, 2011)

Fortify Lives with Agriculture and Nutrition, Bill & Melinda Gates Foundation Blog, www.gatesfoundation.org (February 10, 2011)

Addressing the Needs of Smallholder Farmers, Bill & Melinda Gates Foundation Blog, www.gatesfoundation.org (May 6, 2010)

The Policy Wonk in the War Room, Huffington Post Blog (October 4, 2011)

Building a Better World, Huffington Post Blog (May 25, 2011)

Keeping Promises and Delivering Hope to Poor Farmers and Their Families, Huffington Post Blog (December 17, 2010)

Banking on Savings for the Poor, Huffington Post Blog (November 11, 2010)

A Green Revolution growing in West Africa, Huffington Post Blog (September 14, 2010)

Hope on a Hillside, Huffington Post Blog (August 17, 2010)

Big Action for Small Farmers, Huffington Post Blog (June 25, 2010)

Security and Development at a Time of Global Economic Turmoil, Article from The Global Economic Crisis and Potential Implications for Foreign Policy and National Security, Aspen Strategy Group (2009)

Making Progress/Les champs du progress, Jeune Afrique, Op-ed (June 13, 2009)

If you improve agriculture, you improve life for millions, DesMoinesRegister.com (October 13, 2008)

Building Public-Private Partnerships: a condensed case study, Aspen Strategy Group (2008)

Financing for Global Health, Article from Transforming the Development Landscape: The Role of the Private Sector, The Brookings Institution (2006)

Chapters Play Important Role in Keeping Nation Connected, The Navajo Times (March 11, 2004)

Libraries Open Digital Window, Albuquerque Journal (March 13, 2004)

Computers Connect People, Charleston Gazette (February 14, 2004)

American Economic Policy in the 1990s, In J.A. Frankel & P.R. Orszag (Eds.)
The Role of Institutions in the White House: The Process of Economic Policy-Making During the Clinton Administration (pp. 1034-1038) (2002)

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

In my official capacity at Walmart and the Bill and Melinda Gates Foundation, I delivered speeches that focused on global development (e.g., increasing productivity for small holder farmers) and philanthropy, not relevant to the position for which I am being nominated. During my tenure as OMB Director, I have not delivered any formal speeches, but have made remarks at White House press conferences, open press events and congressional hearings.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

During my time at OMB, and throughout my career in both the public and private sectors, I have had the opportunity to lead large and complex organizations and work across a range of issues- from increasing agricultural productivity in the developing world to tackling hunger in the United States. In each of my roles, I have focused on building strong teams, forging relationships, and delivering results. As Chief Operating Officer and later President for Global Development at the Gates Foundation, I had the opportunity to work on some of the world's most pressing challenges, including improving access to financial services, sanitation and healthcare in the developing world. As the President of the WalMart Foundation, I worked on a range of issues from community giving to women's economic empowerment. As a member of the board at University of Washington Medical Center and MetLife, I gained firsthand experience into healthcare delivery and insurance markets – and how both can work better for businesses and families. And as the Director at the Office of Management & Budget, I have had the opportunity to work with agencies across the Federal government and our partners in Congress to manage complex issues, address challenges and deliver impact for the American people.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

If confirmed, I will continue to serve as a government employee, including working with the Office of Management and Budget on official government business.
2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No
3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

No
4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

Yes

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

I have engaged in no such activity.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's designated agency ethics official to identify potential conflicts of interest. Any

potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.
6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

No. As a member of the MetLife Board, I may have been named in individual matters, however, to my knowledge, none of these cases involved allegations of wrongdoing by me in my official or individual capacity. Walmart as a company has various proceedings and litigation; however, I was not involved in any of these matters.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

No

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

None to my knowledge.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes

United States Senate Committee on Finance
Public Hearing
“Hearing to Consider the Nomination of Sylvia Mathews Burwell to be Secretary of the
United States Department of Health and Human Services”
May 14, 2014

Questions Submitted for the Record

Senator Orrin Hatch:

Questions for the Witness:

1. CMMI

With regard to demonstrations being conducted by the CMS Innovation Center, please provide the process by which you intend to convey results from the programs to Congress. Do to the significant financial resources devoted to the CMS Innovation Center, it is imperative to have regular and consistent status reports from the Administration. Will you outline a process to communicate the results to Congress on a regular basis?

With regard to the expansion authority granted to CMS through the CMS Innovation Center, what are the plans for rolling out using the authority for expansion of testing of the model?

Answer: I understand that HHS is committed to communicating results from testing Innovation Center models to Congress and to the general public. As required by Section 1115A of the Act, the Secretary must publicly report the results of the evaluation of each model. These evaluation reports may be published on the Innovation Center’s website or communicated through other avenues. Additionally, the Innovation Center is required to issue a biannual Report to Congress describing the models tested, including the number of individual participating in the models, payments made, models chosen for expansion, and the results from any evaluations. I recognize this is an issue of interest and, if confirmed, I look forward to communicating further on it.

2. Partnership for Patients.

CMS has dedicated up to \$1 billion over three years to test care models to reduce hospital-acquired conditions and improve transitions in care. How much of the \$1billion has been spent to date? Please provide specific answers to who has received the funds and what the expenditure has achieved. CMS has said these efforts have the potential to save 60,000 lives and reduce millions of preventable injuries and complications in patient care over the next three years and save up to \$50 billion over 10 years.

What is CMS’ progress to date with regard to the stated target of \$50 billion in savings.

How is CMS differentiating between this effort and the multitude of other policy efforts aimed at similar outcomes?

How is CMS ensuring that these funds are being well spent and not duplicating efforts?

Answer: I understand that the Partnership for Patients is achieving early promising results, demonstrating the potential to accomplish national patient safety goals through collaborative improvement. In particular, improvements are being seen across nearly all hospital-acquired conditions targeted by the Partnership. CMS is in the process of analyzing results to date, as well as savings, and if confirmed, I look forward to working with CMS to share this information when it becomes available.

3. 340B Program

In your testimony before the Committee you stated that the 340B program had “expanded beyond its bounds.” One area of significant growth in the program has been the number of disproportionate share hospitals (DSH) participating in the program. As noted by the GAO in its September 2011 report, while the law specifies that hospitals must meet certain requirements that are intended to target those facilities that offer a higher proportion of care to uninsured indigent patients, there is little guidance or oversight to enforce these requirements. As recognized in the GAO report, hospitals with contracts that that provide small levels of care to low-income individuals not eligible for Medicare or Medicaid could claim 340B discounts. This does not seem to be consistent with the law’s intent.

In its upcoming mega-rule, will HRSA be offering further guidance on the eligibility criteria that hospitals must meet – including, guidance on what it means to be “formally delegated governmental powers by a unit of state or local government” as well as guidance on what constitutes a “under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare”?

Answer: I do not recall stating the 340B program had “expanded beyond its bounds” at my nomination hearing before the Committee. HHS recently submitted a rule on the 340B program for OMB review. It is OMB’s longstanding policy not to comment on rules under review. That said, we would welcome you or your staff to come in and share your views on the rulemaking with us, and updated information on the status of any review can be monitored at: www.reginfo.gov.

4. 340B Program

Another area of growth in the 340B program appears to be the number of “child sites” that are eligible for the program as a result of being listed on a hospital’s Medicare cost report. Over the past decade or more, there has been considerable consolidation in the health care market. As a result, many hospitals have acquired clinics that had previously been community-based clinics, such as community oncology centers. With those acquisitions, hospitals eligible for the 340B program have been able to access 340B discounts for those acquired child sites. Other than being required to be listed on a hospital’s Medicare cost report, are “child sites” required to provide a certain level of care to low-income vulnerable patient populations? In other words, is the expectation that if a hospital lists a

child site, such as oncology clinic, on its cost report, that the site is expected to provide treatment to uninsured or low-income patients the same way that the hospital is required to treat an uninsured patient that walks into its outpatient facility of the 340B hospital?

Answer: HHS recently submitted a rule on the 340B program for OMB review. It is OMB's longstanding policy not to comment on rules under review. That said, we would welcome you or your staff to come in and share your views on the rulemaking with us, and updated information on the status of any review can be monitored at: www.reginfo.gov.

5. 340B Program

Another driver of growth in the 340B program is the contract pharmacy program that has seen significant growth over the past 3 ½ years. In 2010, HRSA fundamentally changed the 340B program through guidance that allowed 340B covered entities to contract with an unlimited number of contract pharmacies. Since that time, there has been over 750 percent growth in the number of contract pharmacies. As of November 2013, covered entities collectively maintained over 30,000 pharmacy arrangements. While HRSA has recently stated that the vast majority of 340B covered entities do not utilize contract pharmacies, it is clear that the growth that has occurred far exceeds the estimates HRSA previously had with regards to the number of contract pharmacy arrangements that they predicted would develop.

While the original goal HRSA articulated in its 2010 guidance permitting such an expansion was laudable, it is unclear whether the current policy is helping vulnerable patients access discounted medicines. The unstated premise of the 2010 policy was that contract pharmacies would pass through 340B prices to covered entity patients. However, a recent report by the U.S. Department of Health and Human Services Office of Inspector General found that with regards to the DSH hospitals it interviewed, only 1/3 of those hospitals provided the discount to uninsured patients in at least one of their contract pharmacy arrangements.

If discounts are not passed onto needy patients through contract pharmacy arrangements, what is the direct patient benefit of permitting unlimited contract pharmacies?

Answer: HHS recently submitted a rule on the 340B program for OMB review. It is OMB's longstanding policy not to comment on rules under review. That said, we would welcome you or your staff to come in and share your views on the rulemaking with us, and updated information on the status of any review can be monitored at: www.reginfo.gov.

6. Physician Ownership Issues

I know you're familiar with my work on physician owned distributorships and inappropriate financial arrangements that appear to exist between physicians and certain vendors. I was also involved in the recent pharmaceutical compounding legislation passed by Congress. Where these two issues overlap has become a matter of concern to me.

I have been hearing of compounding pharmacies nationwide offering investment opportunities to referring physicians around the country and this I find troubling. These offers are often promoted as entitling physician-investors to a share of the revenue generated from the prescriptions they send to a compounding pharmacy they have an ownership stake in. This is concerning on many levels, including inappropriate prescribing, patient safety and potential anti-kickback violations.

Have you heard of such arrangements to date? Will you commit to examining this area to determine if there is a potential problem here?

Answer: Although this is not an issue I have been involved with as Director or OMB, I understand that if physicians are entering into the type of business arrangements you describe with compounding pharmacies, it raises questions about patient care, and potential violations of laws governing inappropriate physician referrals as well as the False Claims Act and Anti-Kickback Statute. I also understand that the Social Security Act authorizes the Secretary of HHS to deny payment and seek refunds, civil monetary penalties, assessments, and exclusion for many types of conduct, including violations of the Stark physician referral rules and the Anti-Kickback Statute. The Secretary of HHS has delegated many of these authorities to the Office of Inspector General, which works closely with the Centers for Medicare & Medicaid Services and the Department of Justice to investigate allegations of wrongdoing and pursue appropriate remedies where violations are found. If confirmed, I will examine this area and will support efforts to ensure that the Department uses its available authorities to identify, deter and prevent fraud and abuse.

7. EITC Improper Payments

The Treasury Inspector General for Tax Administration (TIGTA) recently reported that, according to IRS estimates, 22 to 26 percent of Earned Income Tax Credit (EITC) payments were issued improperly for Fiscal Year 2013, with an associated dollar value estimated to be between \$13.3 billion and \$15.6 billion. The EITC remains, according to TIGTA, as the only revenue program fund to be considered at “high risk” for improper payments. TIGTA also identified recently that “...the IRS stated that it had received guidance from OMB that will allow it to resolve the non-compliant areas identified by TIGTA.”

A March 31, 2014 TIGTA report (Reference Number: 2014-40-027) identifies that “For the third consecutive year, the IRS did not publish annual reduction targets or report an improper payment rate of less than 10 percent for the EITC.” The report identifies that “The IRS did not provide the Department of Treasury or TIGTA with quantifiable improper payment reduction targets for the EITC as required by the IPERA for a third consecutive year. IRS management has indicated that the IRS and the Department of the Treasury are in continued discussions with the Office of Management and Budget to obtain its approval to develop supplemental measures that are appropriate to gauge the impact of EITC compliance and outreach efforts in lieu of developing error reduction targets.” The report also identifies that “...the IRS has made little improvement in reducing EITC

improper payments since being required by the Improper Payments Information Act of 2002 to report estimates of these payments to Congress.”

Please provide a copy of whatever guidance from OMB to IRS was issued with respect to its EITC improper payments.

Please also identify whether that guidance requires any concrete steps by IRS to reduce EITC improper payments, aside from requirements or suggestions that IRS seek additional administrative funding.

Please explain why the IRS, Treasury, and OMB have been in discussions to develop measures in lieu of developing error reduction targets and how long those discussions have taken, especially in light of years of IRS noncompliance with requirements of the law.

Please also provide a time frame for the development of whatever supplemental measures are under consideration, what those supplemental measures might be, and how they satisfy requirements of existing law.

According to the March 31, 2014 TIGTA report, at the time the report was compiled, “...the IRS and the Department of the Treasury are continuing to meet with the Office of Management and Budget to determine the best way to address improper tax refunds, including which revenue refund accounts to include in the annual risk assessment process.”

Why, in your view as OMB Director, has it taken so long for OMB to offer compliance guidelines with respect to the Improper Payments Elimination and Recovery Act of 2010, especially given the large amount of improper payments estimated to have been associated with the EITC and given that the IRS, for the third consecutive year, did not publish annual improper payment reduction targets or an improper payment rate of less than 10% for the EITC?

Answer: Agencies with high-priority programs, such as the Earned Income Tax Credit (EITC), are required to establish supplemental measures for reducing improper payments. Supplemental measures are intended to provide information on high-risk areas and report on root causes of errors that agencies can resolve through corrective actions. Supplemental measures are developed to tackle the specific challenges of each program and therefore vary in the frequency that the data are collected and reviewed. The EITC supplemental measures do not serve as a replacement for all the concrete steps already being taken by the Internal Revenue Service (IRS) to reduce EITC improper payments, or as a replacement for the improper payment rate reported annually. Rather, the supplemental measures will serve as an additional indicator of the EITC improper payment rate.

Approving supplemental measures is a multi-step process. Original discussions about supplemental measures began with all high-priority programs in 2010, when OMB issued implementing guidance for Executive Order (EO) 13520. More concrete discussions with IRS about proposed supplemental measures for EITC began late last year, when IRS provided a few

proposed supplemental measures. OMB reviewed them, provided feedback, and in the last few months we received a new version. A few weeks ago, we agreed on two preliminary measures, and we are currently waiting for IRS to submit a final version, which we anticipate receiving shortly.

OMB issued implementing guidance to all agencies for the Improper Payments Elimination and Recovery Act (IPERA) in April 2011—issued as OMB Circular A-123, Appendix C, Parts I and II. While the guidance applies to all agencies in the executive branch, OMB often works individually with agencies, as needed. Given the uniqueness of each program, OMB works with agencies on any specific issues that may arise or to respond to questions regarding specific requirements.

The particular guidance to IRS mentioned in the question acknowledged that the Department of the Treasury (Treasury) is developing supplemental measures for EITC as required by EO 13520 and the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA). By establishing supplemental measures and reporting them along with the annually reported EITC improper payment estimates, Treasury and IRS will fulfill specific requirements found in EO 13520 and IPERIA. OMB also requested that Treasury continue to report on IRS compliance and outreach activities that are expected to reduce the estimated improper payment rate for EITC.

More generally, OMB works closely with the IRS to monitor EITC improper payments and to bring down the improper payment rate through a number of different approaches. The IRS currently engages in aggressive EITC enforcement, including conducting 500,000 EITC audits and is constantly improving its data analytics to target likely errors and problematic tax preparers. These measures have slowly but steadily reduced the improper payment rate in recent years.

The President's 2015 Budget proposes a number of additional measures that would help ensure the integrity of the EITC, as well as the rest of the tax code. Most importantly, the Budget provides adequate funding for the IRS to fulfill its enforcement responsibilities, including through a proposed program integrity cap adjustment for IRS enforcement activities. The Budget also proposes to provide explicit authority for the IRS to regulate paid preparers, who prepare about 60 percent of EITC returns; to change the timing of information returns so that the IRS can do more data matching in real time, resulting in savings, including for the EITC; to extend existing EITC due diligence requirements for tax preparers to the Child Tax Credit; and to provide IRS with additional math error authority. Each of these proposals would generate savings from refundable credits.

The Administration takes EITC improper payments very seriously and is committed to reducing them. At the same time, the Administration believes that the EITC has been exceptionally effective at both reducing poverty and encouraging work for families with children. This success is directly connected to the fact that the EITC is administered through the tax system, which results in high take-up relative to many other programs—as well as exceptionally low administrative costs (less than 1% of program dollars).

8. Continuing Disability Review

As my questions and comments during your confirmation hearing revealed, there is significant concern and frustration by many on the Senate Finance Committee around lack of communication and transparency from several departments, offices, and agencies, including HHS, Treasury, and others. The Committee has oversight responsibilities that are stymied when Member's questions go unanswered, or are received well past deadlines, or do not receive serious and complete responses.

My staff recently shared an inquiry that was made of OMB regarding funding for Continuing Disability Review activities of the Social Security Administration. The inquiry was in regard to a proposal in the President's budget and relates to possible bipartisan work toward enhancing program integrity in the Disability Insurance (DI) program. Unfortunately, without having received a response from an inquiry in mid-March, I am not able to determine whether the administration shares a common understanding of certain data related to the DI program. Such a shared understanding, it seems to me, would be necessary to consider the President's budget proposal seriously. As this example shows, lack of communication by agencies, offices, and departments in this administration hampers progress, even toward goals of the President's budget.

In your confirmation hearing, you identified that your preferred solution to instances in which Members of the Committee receive no, delayed, or incomplete responses to questions posed by them to agencies, offices, and departments like HHS or Treasury, would be for Members to call you. It seems, however, that such a solution would likely not be efficient given the large number of instances in which there has been lack of responsiveness from the administration.

Therefore, I wonder whether you have any other suggestions as to what Members of the Senate Finance Committee should do when responses from agencies, offices, and departments of the administration are not forthcoming, or are repeatedly delayed, or are repeatedly inadequate and incomplete. Evidently, the current structure of deadlines and incentives does not seem sufficient to ensure anything close to responsiveness from agencies, offices, and departments that is necessary for Members of the Finance Committee to be fully informed and to exercise the oversight responsibilities it has to provide transparency and accountability to the American people.

Please provide any suggestions that you have to change from the existing lack of responsiveness to an administrative structure in which departments such as OMB and HHS become responsive to requests for information from Members of Congress.

Answer: During my tenure at OMB, I have worked hard to respond to requests for information from Members of Congress. With regard to the specific questions that you had about program integrity activities at the Social Security Administration, Budget Control Act program integrity funding is used to cover the costs associated with conducting Continuing Disability Reviews (CDRs) in the Disability Insurance and the Supplemental Security Income (SSI) programs, as well as redeterminations of eligibility in the SSI program. "Direct marginal costs" refers to all

spending related to conducting these reviews except for overhead costs. Overhead costs are costs that remain fixed (or generally stable) regardless of how many reviews are conducted and are budgeted for within the regular Limitation on Administrative Expenses (LAE) account (whereas the costs funded through the BCA program integrity base and cap adjustment, such as labor costs, increase as the number of reviews increase). When calculating the projected ROI for program integrity funding proposed in the Budget, SSA excludes overhead costs. This is because SSA is required to conduct CDRs and redeterminations using regular LAE funds under current law, even absent a cap adjustment, so SSA would incur these overhead costs regardless. Nothing has changed with the way the ROI is calculated for purposes of the President's Budget or in the Inspector General's approach to documenting program integrity costs and ROI in their annual report. However, in 2014, a portion of the funds provided through the program integrity cap adjustment were used to pay for overhead costs. As a result, if the ROI were re-calculated for 2014 using the same approach as is used in the Budget for proposed funding, we would see a small dip in the ROI for that year. The President's Budget proposes to return to the normal approach of covering overhead costs fully with regular LAE funds in 2015 and beyond.

With respect to your broader concerns about responsiveness to inquiries, if confirmed, I will work to put into place an administrative structure at HHS with the goal of making sure requests for information from Members of Congress receive more timely responses. I believe that my time at OMB has shown a strong commitment to transparency and responsiveness in working with Congress, and I look forward to continuing this approach at HHS, if confirmed.

9. Federal Statute Changes

Director Burwell, the Obama administration has—without consulting Congress—made more than 20 unilateral changes to the timing and applicability of various Obamacare provisions. Both conservative and liberal legal scholars agree that many of these executive actions are unlawful and contradict the plain statutory language passed by Congress and signed by the President. I'd like to ask you a series of *clear and direct* questions, and ask that you respond to them in a *clear and direct* manner—yes or no.

- a. First, does HHS have authority to refuse to enforce a duly enacted federal statute based on policy considerations—yes or no?**
- b. Second, does a general grant of rulemaking authority afford HHS the power to ignore an explicit enforcement deadline specified in statute—yes or no?**
- c. Third, does HHS, or any of its sub-entities, have authority to offer *transitional relief* from the enforcement of duly enacted federal law—yes or no?**

Answer: As the Affordable Care Act is implemented, the Administration is committed to ensuring as smooth a transition as possible for consumers, issuers, providers, and businesses and has taken commonsense steps within the law to achieve that goal. I agree that HHS has the duty to enforce the law and that general rulemaking authority does not confer the power to ignore deadlines in statute. I would note that courts have affirmed that agencies have some latitude in implementing statutes in order to ensure that congressionally authorized programs are properly effectuated.

10. Employer Mandate

The delay of the employer mandate—a major unilateral policy change that many believe lacked lawful authority—was announced in a blog post that offered no legal justification for the administration’s action.

- d. If confirmed, will you commit both to consult with Congress and to offer a substantial legal justification prior to any contemplated non-enforcement action?
- e. Will you likewise commit that HHS will not seek to implement policy through a blog posting (or a hashtag or selfie or anything else of the sort)?

Answer: The Administration has focused on implementing the Affordable Care Act in a common sense manner consistent with the law. Ultimately, final actions on implementation efforts rest with the relevant agencies. For the issue identified above, the final decision was made by the Department of Treasury. The legal basis for such decisions may be described in rulemaking, guidance, or other relevant documents. I would respectfully refer you to the Department of Treasury for any information about the relevant legal determination not contained in those documents.

11. HHS Program Integrity

In terms of recoveries, HHS has had a historically successful program integrity operation aimed at Medicare fraud and other types of improper payments. But there is much more to be done. Are you committed to increasing resources and enhancing policies to further strengthen the Medicare program integrity organization?

Are you committed to also increasing and enhancing support for Medicaid program integrity operations?

Answer: If confirmed, supporting fraud prevention and the reduction of improper payments in Medicare and Medicaid will be one of my top priorities. I support the President’s FY 2015 Budget, which would invest a total of \$428 million in new Health Care Fraud and Abuse Control Program (HCFAC) and Medicaid program integrity funds. Together, the program integrity investments in the Budget will yield \$13.5 billion in gross savings for Medicare and Medicaid over 10 years. The Budget also proposes legislative changes to give HHS important new tools to enhance program integrity oversight; cut fraud, waste, and abuse in Medicare, Medicaid, and Children’s Health Insurance Program (CHIP); and generate an additional \$1 billion in program savings over 10 years.

12. Fraud Partnership

Along with partners at the Department of Justice, state governments and private payers, HHS presided over an unprecedented public/private health care fraud partnership. For the first time, private payers and HHS exchanged claims data and identified potential fraud and other improper payments. The partnership stands at a crucial moment, with plans to

expand beyond the demonstration stage, to a robust exchange of data using a Trusted Third Party contractor. Are you committed to taking the next steps of expanding the partnership and awarding the Trusted Third Party contract?

What are your plans to evaluate other currently available pooled data resources and analytic solutions that would be valuable for solving FWA, quality of care, and other problems driving healthcare costs in our nation?

Answer: It is my understanding that the Healthcare Fraud Prevention Partnership (HFPP) is designed to share information and best practices in order to improve detection and prevent payment of fraudulent health care billings. The partnership currently has 35 partner organizations from the public and private sectors, law enforcement, and other organizations combatting fraud, waste, and abuse.

CMS has been collaborating more with the private sector, law enforcement, and our state partners to harness best practices in our fight against health care fraud. In the past year, CMS collaborated with key partners in unprecedented and exciting initiatives. CMS plans to improve and look for ways to reduce fraud, waste, and abuse, as well as to use innovative tools to further enhance our collaboration with the private sector, law enforcement, and other key partners in detecting and preventing fraud.

13. FDA

Will you provide me in writing with a detailed update on the FDA's plans for implementation of the Biologic Price Competition and Innovation Act (BPCIA)? I am concerned that the FDA is not engaging in a transparent, inclusive process for developing policies that implement this important law.

Answer: While I have not been engaged in this process in my role as OMB Director, I understand from HHS that, to date, FDA has held public hearings and issued five draft guidances, inviting public comment, on implementation of the Biologics Price Competition and Innovation Act of 2009. A November 2010 public hearing provided a forum for interested stakeholders to provide input regarding the agency's implementation of the BPCI Act. FDA reviewed these numerous and extensive comments in developing the draft guidances issued in February 2012 following FDA's Good Guidance Practices. A second public hearing in May 2012 to receive input on these guidances and in obtaining public input regarding the Agency's priorities for development of future policies regarding biosimilars. FDA issued their most recent draft guidance in May 2014. FDA will take into consideration all received comments as they move forward in finalizing the draft guidance documents and developing future policies regarding biosimilar products and interchangeable products.

FDA listed a number of draft guidances related to biosimilars that are under development on the Center for Drug Evaluation and Research (CDER) Guidance Agenda for 2014.

The public will receive an opportunity to comment on these new guidances. FDA continues to actively engage with prospective biosimilar sponsors, including holding development-phase meetings and providing written advice on ongoing development programs for proposed biosimilar products.

14. 340B

The 340B program was established in 1992 to give certain safety net providers discounts on outpatient drugs. When it was established in 1992, the vast majority of the clinics and hospitals that participated in the program were true safety net facilities dedicated to serving vulnerable patient populations, including the uninsured and indigent as well as patients who were afflicted with specific conditions and diseases that raised public health concerns or were expensive to treat. However, the program has evolved over the past two decades. The program has experienced accelerated growth and has moved from a program involving only about 90 hospitals in the early 1990s to about 2,000, which accounts for one-third of all hospitals today. This growth in size combined with growing evidence of compliance concerns calls into question if the program is operating as it should. A recent government report issued by the OIG suggests that critical ambiguities in the 340B program elements are creating potential opportunities for diversion in the program. The Health Resources and Services Administration's (HRSA) own audits are revealing substantial adverse findings. HRSA is currently working to formalize 340B program guidance through a regulation. This rule presents an opportunity for HRSA to take a comprehensive review of the program and provide regulatory clarity, establish guardrails and improve transparency in the program. This program has helped to contribute to the valuable and important safety net program that serve many communities across this country. If HRSA fails to take this opportunity to address the problems that exist in the program today it may not be sustainable for those who need it in the future. Will you make it a priority to ensure the HRSA rule provides clarity in the program protocols and standards and establishes appropriate guardrails?

Answer: HHS recently submitted a rule on the 340B program for OMB review. It is OMB's longstanding policy not to comment on rules under review. That said, we would welcome you or your staff to come in and share your views on the rulemaking with us, and updated information on the status of any review can be monitored at: www.reginfo.gov.

15. Medication Management

As the US healthcare system shifts from fee-for-service to value and outcomes, medications are increasingly viewed in the context of overall clinical impact and ability to reduce non-prescription medical costs. Appropriate medication use has risen as a top priority for ACOs/PCMH/ and coordinated care initiatives in the ability to reduce avoidable hospitalizations and achieve patient and clinical goals of therapy. However, comprehensive medication management approaches in high-risk patients has been lacking and poorly funded by HHS.

Will your administration support and expand comprehensive medication management approaches which directly link to closing clinical gaps in therapy and optimizing patient outcomes?

Answer: I agree that improved medication adherence can help reduce health care costs, improve quality, and protect patient's health. If confirmed, I will work across the Department to improve our strategies to promote appropriate use of medications.

16. Medication Management

Given the role chronic disease plays in impacting patient outcomes and overall healthcare costs, a systematic approach to medication management is needed to close the gaps in care and optimize patient outcomes. However, our current delivery and payment models have failed to integrate a comprehensive medication management service, despite evidence that "appropriate medication use" could save at least 1 million lives and over \$300 billion dollars annually. Would you be willing to prioritize a comprehensive approach to medication management as a key objective for HHS?

Answer: I agree that improved medication adherence can help reduce health care costs, improve quality, and protect patient's health. If confirmed, I will work across the Department to improve our strategies to promote appropriate use of medications.

17. Medicare Advantage Rates

Can you explain the final rates for the year, and your perspective on how they will impact seniors? Can you provide us with an explanation as to how you could say there is an increase, when in fact all independent experts, could see it as over 3% cut? What assessments have you done about disruption that seniors are likely to experience this fall? Finally, all of these rate cuts we have been discussing are all due to CMS actions. Can you talk about the disruption for seniors that is likely to occur this fall due to the provisions in the ACA relating to MA?

Answer: The Medicare Advantage program is strong. Since the Affordable Care Act was passed in 2010, Medicare Advantage premiums have fallen by nearly 10 percent and enrollment has increased by 38 percent to an all-time high of more than 15 million beneficiaries. Today, nearly 30 percent of Medicare beneficiaries are enrolled in a Medicare Advantage plan. Furthermore, enrollees are benefiting from greater quality as over half of enrollees are now in plans with 4 or more stars, a significant increase from 37 percent of enrollees in such plans in 2013.

The April 7, 2014 rate announcement sets a stable path for Medicare Advantage and implements a number of policies that ensure beneficiaries will continue to have access to a wide array of high quality, high value, and low cost options while making certain that plans are providing value to Medicare and taxpayers.

CMS estimates that the overall net change to plan payments between 2014 and 2015 to be +0.4 percent, compared to the estimated overall net change to plan payments of -1.9 percent for the proposals in the Advance Notice. Individual plan payments will vary by plan based on, but not limited to, its location and star rating.

18. State-Federal Relations

In your opinion, what is the role of the states in the Medicaid partnership? How will you incorporate state by state best practices in HHS policy? Do you believe that HHS has a role in dictating process to states if the outcome is the same?

Answer: The states are the federal government's partners in the administration of the Medicaid program. The federal government and the states share the responsibility to ensure that the program is operated in the best interest of its beneficiaries and in keeping with the statutory requirements. CMS should continue to support learning amongst states and consider how state-based experiences can influence broader Medicaid policy. If confirmed, I will continue the work already ongoing at CMS to maintain and enhance the federal-state Medicaid partnership.

19. Exchange Insurance Plans

President Obama pledged that "if you like your coverage, you can keep it." Do you concur with this statement? I ask the question because I'm concerned about the law's long-term effect on Americans with employer-sponsored insurance. I've noticed several trends with exchange plans: narrow provider networks, restrictive formularies, and integrated medical and drug deductibles.

With the government's stamp of approval on these plans, what would you say to Americans who may see their employer switch to a plan that looks more like an exchange plan?

Answer: The Affordable Care Act ensures that new health plans offered in the individual and small group markets, both inside and outside of the Health Insurance Marketplace, offer a comprehensive package of items and services, known as essential health benefits and include certain other consumer protections. Additionally, it is important to remember that all qualified health plans (QHPs) must maintain a provider network that ensures that all services are available without an unreasonable delay. I understand that Network Adequacy is a very high priority for CMS, and that they intend to closely monitor the market for any complaints involving enrollee access to covered services.

20. Meaningful Use

We've heard from many hospitals both large and small, as well as physicians that the Meaningful Use program for health information technology simply isn't working. CMS and ONC, both of which you will oversee, has great discretion to make changes to ensure that the federal dollars spent on this program are not wasted.

Can you please give us your commitment that the success of this program will be a priority for you and your tenure as Secretary?

Answer: I am aware that HHS has been listening to providers, health care associations, EHR vendors, and its partners in the health care industry. In December 2013, HHS announced that it would engage in rulemaking to extend Stage 2 of meaningful use for one year and allow Stage 3

to begin in 2017. In addition, ONC issued a 2015 Edition EHR Certification Criteria Proposed Rule as part of its new regulatory approach to provide more frequent updates to the certification criteria. This approach is designed to provide more time for public input on policy proposals, enable the certification processes to more quickly adapt to include newer industry standards that can lead to greater interoperability, and add more predictability for EHR technology developers.

By extending Stage 2 until 2017, HHS would have an additional year of Stage 2 implementation data to help inform any program changes. An extension also allows CMS and ONC to better align quality performance measures across federal programs and to consider effective Stage 3 approaches to advance interoperability and clinical decision support capabilities that will help drive improved health outcomes.

In response to stakeholder concerns that providers were having difficulties meeting the requirements of Stage 2, CMS and ONC announced in February 2013 that additional flexibility would be provided that would allow eligible professionals and hospitals to request a hardship exception because they are unable to control the availability of Certified EHR Technology (CEHRT) at a practice location or a combination of practice locations.

If confirmed, I look forward to engaging with CMS and ONC to continue this important work.

21. Recusal from MetLife

Ms. Burwell, from 2004 through 2013 you were a director of MetLife. On April 15, 2014, an article was published in the Washington Times regarding a lawsuit that MetLife is currently defending itself against which alleges the company used the Social Security Death Master File to stop making payments when beneficiaries died, but did not use the file to track deaths for the purpose of paying claims when a death would trigger a payout.

As a director of MetLife I understand you are named in the lawsuit.

Have you had any personal involvement in this lawsuit, and as a Director did you make decisions pertaining to when MetLife would stop making payments to beneficiaries, or start making payments to policyholders?

Answer: I am named as a defendant in my capacity as a former Board Member of MetLife in the case of City of Westland Police and Fire Retirement System v. MetLife, Inc. and others. I am not involved in the defense of this litigation. I believe decisions pertaining to the practices and procedures for making payments to beneficiaries or policyholders would have been handled by management of the appropriate operating division at MetLife. I do not recall making any such decisions as a MetLife Board Member.

32. Legal Basis for Welfare Work Requirement Waivers

On July 12, 2012, the Obama Administration released an "Informational Memorandum" (IM) to states granting this and presumably future Administrations vast waiver authority, not previously contemplated by any preceding Democrat or Republican Administration.

After the release of the IM, the Department of HHS (The Department) released a “Legal Basis” for this expanded waiver authority.

In this “Legal Basis,” the Department refutes the argument, put forward by Chairman Camp and myself in our letter dated, July 12, 2012 that authority under Section 1115 of the Social Security Act (SSA) only extended to Section 402 of the SSA, a section requiring states to describe how a state will do a number of things and NOT to the actual work requirements in Section 407 of the SSA.

In the “Legal Basis” the Department argues that, because Section 1115 (a) (1) refers to Section 402 and “the plain text of section 402 incorporates the requirements of section 407 *by reference*,” then the Secretary, under 1115 may waive Section 407, even though Section 1115 (a) (1) never refers to Section 407.

A number of additional sections are referred to in Section 1115 (a) (1). Of particular interest is Section 1902 of the SSA, the State Plan for Medical Assistance. Please provide an additional “Legal Basis” on whether or not the logic of the 2012 “Legal Basis,” extends to Section 1902 and *by reference*, any section of the SSA mentioned in Section 1902?

Answer: I understand from HHS that, consistent with the analysis in the document referenced above, the authority under section 1115(a)(1) has consistently been read to permit waiver of section 1902(a) requirements, even when those requirements are described in more detail elsewhere in the Medicaid statute. Numerous demonstration projects include waivers based on this position, and Congress has repeatedly recognized the position by specifying certain Medicaid requirements that cannot be waived under such authority. I also understand that this has been the Department’s longstanding position and predates the position on sections 402 and 407 of the Social Security Act discussed in your question.

22. Child Welfare Waivers

P.L. 112-34 amended Section 1130 of the SSA to permit the Secretary to authorize demonstration programs designed to test innovative strategies in state child welfare programs. Authority to approve these demonstrations expires this year. The Secretary may extend existing waivers, but under the terms set by Congress, no demonstration project may be conducted after September 30, 2019. Do you believe that the Secretary of HHS has the authority to extend demonstration programs after 2019?

Answer: While I have not been engaged in this issue as OMB Director, it is my understanding from HHS that the statute states that the authority expires on September 30, 2019, and that all waiver demonstration projects must end by that date accordingly.

23. State Interest in Flexibility

In responding to criticism from Republicans that the welfare work waiver IM undermined key features of welfare reform, the Obama Administration argued that this action was taken in response to state concerns about the need for additional flexibility. In a letter to

Chairman Camp and Senator Hatch, then Secretary Sibelius wrote that, “For years, Republican and Democratic Governors have requested more flexibility in implementing welfare reform so they can meet their states specific needs.” (Letter to Senator Hatch, July 18, 2012).

Please describe these “state specific needs.”

Many Members who worked on the 1996 welfare reform bill believe that the inherent nature of a block grant implies a great deal of state flexibility.

Please describe in detail how the current block grant structure and the current federal work requirement which permits at least 50% of adults on assistance to engage in full time college work, mental health or substance abuse treatment or any other activity deemed relevant by the state is insufficient to addressing “state specific needs.”

Answer: When the Temporary Assistance to Needy Families (TANF) program was established in 1996, it was intended to give states flexibility to design effective programs to help parents move from welfare to work. Over time however, subsequent statutory and associated regulatory changes have significantly diminished state flexibility with respect to designing innovative welfare-to-work programs. These rules have often discouraged innovation and focused state efforts on meeting process requirements rather than increasing employment outcomes.

In response to the Presidential Memorandum “Administrative Flexibility, Lower Costs, and Better Results for State, Local, and Tribal Governments”, the Administration for Children and Families (ACF) engaged in a dialogue with state TANF stakeholders across the country during the summer of 2011. ACF also received written comments from a total of 28 states and territories and one county. The information below summarizes the issues that were raised.

- States have said they need greater flexibility to focus on employment and job retention outcomes that improve the lives of recipients, but that their workers were spending a large share of their time simply documenting compliance with administrative requirements.
- States expressed interest in providing subsidized employment, but expressed concern that such placements would not help them achieve a higher participation rate if the subsidized jobs provide wages sufficiently high to remove participants from assistance.
- States need greater flexibility to serve vulnerable populations or other groups with specific needs such as those facing domestic violence or facing barriers related to substance abuse and mental health.
- The durational limitations on counting job search/job readiness assistance create disincentives to serving families with a longer-term need such as substance abuse or a mental health issue.
- The various limitations on counting educational activities create disincentives to placing individuals in the most appropriate activity, such as vocational education related to a career path or English as a Second Language (ESL) for a refugee.

24. State Application for Waivers

In correspondence between the Department and Committee staff on February 22, 2013, Committee staff were told that, “HHS has not received any formal applications but we have received expressions of interest in exploring the possibility of waivers from the following states: CT, CO, MN, PA, and WA.”

Have any of the states that expressed interest in exploring the possibility of a waiver applied for a welfare work wavier?

Answer: It is my understanding from HHS that while several states have informally expressed interest through communications with Regional and Central Office staff, HHS has not received any formal waiver requests.

Have any other states expressed interest in exploring the possibility of a welfare work wavier?

Answer: As OMB Director, I have not been engaged on this issue. It is my understanding from HHS that in addition to the states mentioned in your question, two states – Utah and Nevada – submitted written comments that specifically identified waivers as one mechanism for testing new approaches to promoting employment and self-sufficiency, and a number of other states – including California – asked about the potential for waivers.

Has any state applied for a welfare work waiver?

Answer: It is my understanding that, to date, HHS has not received a waiver application in the TANF program.

Currently, Congressional staff are examining whether or not it is possible to extend the Family Connection Grants for up to three years but have only been able to agree on approximately \$15 million in offsets, enough for only one year of funding.

If no state has applied for a waiver of TANF work requirements and no state has expressed recent interest in applying for such a waiver, would you support legislation rescinding the HHS IM on waiving the TANF work requirements and target the resulting \$30 million in savings from doing so towards extending Family Connection Grants for the full three years proposed in legislation that has passed the House and the Senate Finance Committee?

Answer: I appreciate the work that you, your colleagues, and the Congressional staff have done to advance important bipartisan legislation to improve the outcomes for children in the foster care system and to support relative caregivers in the Family Connection Grants Program. As I have not been engaged on this issue as OMB Director, I am not fully aware of all of the specifics of the TANF waiver at this time. If confirmed, I will evaluate this issue and will work with you and your colleagues on strategies that will help low-income families move to self-sufficiency and support at-risk children and families.

25. 2009 Memo to Mark Greenberg

On February 8, 2013, after repeated requests from Chairman Camp and myself, Republican Ways and Means and Senate Finance Committee staff traveled to HHS to review internal HHS staff e-mails and legal memoranda pertaining to the Department's deliberations over the TANF waiver policy. The Department eventually released a December 15, 2009 Memo to Mark Greenberg, Deputy Assistant Secretary for Children and Families from the Chief of Litigation.

26. The Greenberg Memo and Section 408

The Greenberg Memo includes a series of questions about the scope of this current and future Secretaries. One of these questions was, "Can the Secretary permit a state to extend assistance to a family for which assistance would otherwise be prohibited under Section 408? Answer: Yes."

Can you confirm that under the authority as contemplated, this current or any future Secretary may therefore permit TANF funds to support the following individuals and activities –

1. Adults collecting federal TANF checks for more than 5 years (the federal time limit);
2. Fugitive felons;
3. The cost of medical services, including abortion services;
4. Families without children;
5. Parents who refuse to cooperate in establishing paternity or obtaining child support;
6. Teen parents who don't attend high school;
7. Non-citizens (by reference)?

Answer: The issue you raise is not one on which I have been engaged as OMB Director. It is my understanding from HHS that the Secretary has broad authority to allow states, as part of an approved demonstration project, to pay for costs that would not otherwise be permissible uses of funds under Title IV-A of the Social Security Act. The legality of each proposed demonstration project would have to be evaluated on a case-by-case basis, and would include consideration of the legal standards in Title IV-A, and all other legal standards applicable to HHS and the use of federal funds. Also, it is my understanding that the Secretary has discretion as to whether to grant a demonstration project. If confirmed, my goal would be to ensure that all approved demonstration projects are consistent with the law and reflect the sound use of federal funds.

27. The Greenberg Memo and "Reasonable Cause"

In addition to vast authority to waive much of what Congress passed in PRWORA, the Greenberg memo seeks to confirm additional authority of the Secretary. The memo stipulates that even if the Secretary does not have the authority to "waive" certain provisions, the Secretary is essentially permitted to disregard them through the application

of “reasonable cause,” in not applying certain penalties. Can you provide the Committee with a definitive list of the provisions under which the Secretary may apply “reasonable cause” relative to the lack of penalties?

Answer: It is my understanding that section 409(b) of the Social Security Act prohibits the Secretary from imposing a penalty if the Secretary determines that a grantee has reasonable cause for failing to comply with certain requirements. These requirements include those to ensure the proper use of funds, to submit required reports, to satisfy minimum work participation rates, to participate in the income and eligibility verification system, to comply with paternity establishment and child support enforcement requirements under title IV-D, to comply with the 5-year limit on assistance, to maintain assistance to an adult single custodial parent who cannot obtain child care for a child under age 6, to reduce assistance for recipients refusing without good cause to work, to establish or comply with work participation verification procedures, and to enforce spending policies.

28. Congressional Review Act

Director Burwell, many Members of Congress believe that the welfare work waiver IM constituted an excessive and unwarranted over reach of executive authority. The Government Accountability Office agreed and determined that the IM is in fact a “rule,” under the Administrative Procedures Act and, as such, should have been submitted to the Congress for review. Since the TANF work waiver rule was not submitted to Congress, the rule is subject to a joint resolution of disapproval under the Congressional Review Act (CRA).

On December 12, 2012, a letter was sent to President Obama, asserting my decision to withdraw my right to call for a vote a Resolution of Disapproval under the Congressional Review Act (CRA) of the July 12, 2012 “Rule.” I took this action in good faith in order to facilitate a collegial pathway towards a robust reauthorization of the TANF programs. I asked President Obama to instruct then Health and Human Services Secretary Kathleen Sebelius to withdraw the welfare waiver rule and submit a five year TANF reauthorization to the Congress.

I have not received a response to my letter from the White House or the Department. In the interest of moving forward on making needed improvements to TANF, will you agree to withdraw the welfare work waiver rule and submit a five year reauthorization of TANF to the Congress to being bipartisan, bicameral work on this important issue?

Answer: I recognize this is an area of deep concern for you and some other Republican members of the Finance Committee. As the Administration has stated in its Budget submission, when Congress takes up TANF reauthorization, the Administration will be prepared to work with lawmakers to strengthen the program’s effectiveness in accomplishing its goals. This effort should include using performance indicators to drive program improvement and ensuring that states have the flexibility to engage recipients in the most effective activities to promote success in the workforce, including families with serious barriers to employment.

If confirmed, I look forward to learning more about the specifics of the TANF waiver issue and would like to work with you to initiate a bipartisan discussion of ways to fight poverty.

29. Social Services Block Grant (SSBG)

During his inaugural address, President Obama asserted, “The question we ask today is not whether our government is too big or too small, but whether it works... Where the answer is yes, we intend to move forward. Where the answer is no, programs will end.” Contrary to the President’s promise, the Social Services Block Grant has almost no accountability for results – and no way to tell whether it achieves its goal of helping States reduce dependence on welfare.

Previous budgets, Republican and Democrat, from current and former Congresses, have recognized SSBG’s lack of accountability, and urged defunding it:

From President Clinton’s Fiscal Year 1999 Budget (February 2, 1998): “The budget targets funding to programs that can better demonstrate positive performance. The Social Services Block Grant supports a broad range of social service programs, but without statutory performance goals or measures of progress.”

SSBG has been criticized for having no state match, no clear program goals, no accountability structure in place and no requirement to coordinate with other programs serving at risk populations.

**Do you believe that SSBG is sustainable from a policy and political perspective?
Are you willing to engage with the Congress in efforts to reform or repurpose SSBG
to support evidenced based policies and programs to improve outcomes for
vulnerable populations?**

Answer: My understanding is that officials at HHS believe that the Social Services Block Grant (SSBG) is sustainable and, if confirmed, my goal would be to engage in conversations about ways to strengthen the program to ensure improved outcomes for vulnerable populations.

SSBG makes valuable contributions to state social services and addresses critical needs not currently met through other funding sources.

I share your view that it is important to have accountability for federal funds. If confirmed, I would ensure that the Department seeks consultation and input from states that rely on these funds before making any changes to this program. I would also welcome additional input and would be glad to work with Congress on this program.

30. Group Homes

Do you believe that non-family foster homes, otherwise known as “group homes” or congregate care facilities produce the best outcomes for children and youth? Do you

believe that group homes are appropriate for children under the age of 6 years? Do you believe that the federal government, with some appropriate exemptions for very ill youth, should put limits on the reimbursement rate under IV-E for non-family foster homes?

Answer: Children are best served when they are raised in permanent families, and I fully support the federal position that when children must be removed from their homes and placed into foster care, they should be placed in family-like settings. In some cases, group home or institution may be the most appropriate setting to meet the needs of certain children, such as those with serious physical or mental health needs. It is my understanding that states are currently undertaking efforts to make appropriate placements that take into account a child's presenting issues. If confirmed, I will continue the work underway at HHS to promote community-based care models for children with social and emotional needs, for example through the demonstration to address the over-prescription of psychotropic medications for children in foster care outlined in the President's FY 2015 Budget. I also would like to work with you to discuss new strategies for addressing this issue.

31. Child Welfare Financing Reform

Director Burwell, according to recent estimates from the Congressional Budget Office, the federal outlays for foster care under Title IV-E of Social Security Act is projected to decrease every year from 2013 to 2023. Do you believe that an ongoing erosion of federal dollars is sustainable over the next decade? Do you believe that comprehensive child welfare financing reform is needed? Will the Administration put forward any principles or guidance relative to child welfare financing reform?

Answer: I understand that there is bipartisan interest to address the comprehensive financing reform in the child welfare program and that you have been very involved in those discussions. An initiative such as the demonstration to address the over-prescription of psychotropic medications for children in foster care outlined in the President's FY 2015 Budget is one strategy that would increase federal investments for this vulnerable population, though I recognize that a more comprehensive approach may be needed. If confirmed, I would welcome the opportunity to work with you to examine this issue more closely and develop principles and strategies to address child welfare financing reform.

32. Healthy Marriage Grants

The Deficit Reduction Act of 2005 established the Healthy Marriage Promotion Initiative. This initiative currently provides \$75 million in grant dollars to organizations that promote marriage, encourage the value of marriage and provide individuals with relationship and marriage skills, among other things.

I understand that recently, the administration has decided to renew the current grantees for at least one more year instead of opening up the grant program to competition.

Section 7103(a)(2)(A)(ii) of Public Law 109-171 -- clearly states that the Secretary “may not award funds on a non-competitive basis.” It appears that simply renewing current grantees for an additional year, if not more, is inconsistent with the law.

Can you elaborate on the rationale for allowing current grantees “to submit a non-competitive continuation application,” including legal authority in which that decision is based.

Answer: I have not been involved in this issue in my role as OMB Director and I look forward to learning more about it if confirmed. It is my understanding from HHS that the Healthy Marriage and Responsible Fatherhood grants were initially awarded in 2011 through a competitive funding process. These current grantees have been invited to apply for one-year continuation grants in order to resume the progress being made toward their goals and enhance the research evaluations currently underway. Because this year's continuation grants are for the competitively selected projects that had submitted applications meeting the statutory criteria in 2011, I have been advised the continuation grants comply with the Act. If confirmed, I will work with HHS Counsel to address any additional questions you have concerning the legal bases for this decision.

Does the Administration intend to continue the practice, in clear violation of the intent of Congress?

Answer: It is my understanding that the current one-year continuation grants will expire in September, 2015. If confirmed, I would ensure that all grants continue to be awarded consistent with the grants' authorizing statute and all other applicable laws.

Senator Brown:

Questions for the Witness:

1. Network Narrowing

Since the rollout of the Affordable Care Act (ACA) we have seen insurance plans narrow their marketplace provider and site of service networks in order to save money. This practice results in the exclusion of valued providers and sites of care from insurance networks across the country, and reduces access to preferred providers and locations.

I am generally pleased with the progress of ACA implementation at this stage. However, I have heard from many healthcare providers that insurance plans are excluding them from their networks, making it difficult for patients to remain with their preferred physicians or sites of care. I am concerned that Americans across the country are losing out on access to necessary providers, both primary care doctors and specialists, and important sites of service close to home. Worse yet, many Ohioans have told me they were unaware of the network narrowing at the time they selected a health plan because the marketplace website did not include a complete or

updated list of network providers. This is unacceptable. While I appreciate the work the Centers for Medicare and Medicaid Services (CMS) has done to help ensure sufficient networks, more needs to be done to ensure network adequacy to ensure access to care in marketplace plans.

- a) How do you plan on ensuring robust networks in the future?**
- b) By cutting out expensive hospitals and negotiating with certain doctors, insurers believe they can keep their premiums down. How can we balance cost with adequate coverage?**
- c) How will you ensure that networks are adequate for all individuals, including children and individuals with rare diseases?**

Answer 1a-c: All qualified health plans (QHPs) must maintain a provider network that ensures that all covered services are available without an unreasonable delay. Ensuring that individuals have access to an adequate network of providers is a very high priority for this Administration and would be for me if confirmed. It is my understanding that CMS intends to closely monitor the market for any complaints involving enrollee access to covered services. I also understand that CMS has strived to implement Marketplace and QHP regulations creating a strong federal floor, but allowing states and issuers flexibility to innovate. Thus, while issuers must adhere to new network sufficiency and essential community provider standards, they still have room to make business decisions that work for them.

It is my understanding that in Federally-facilitated Marketplace states, CMS will now assess provider networks using a “reasonable access” standard, and will identify networks that fail to provide access without unreasonable delay, as required by federal regulations. In order to determine whether an issuer meets the “reasonable access” standard, CMS will focus most closely on those areas which have historically raised network adequacy concerns (e.g. hospital systems, oncology providers, primary care providers and mental health providers).

- d) Beyond robust networks, we must make sure that consumers have access to complete, accurate lists of providers and facilities before and during the enrollment process. Consumers should be able to see a full list of providers in a plan’s network before signing up for insurance. How will CMS ensure this consumer protection?**

Answer: I understand from HHS that as part of the 2015 plan certification process in the Federally-facilitated Marketplace (FFM), CMS requires issuers to provide up-to-date provider directories for publication online and use by consumers comparing qualified health plans in the Marketplace.

If an issuer has multiple provider directories, it should be clear to consumers which directory applies to which QHP(s). Further, CMS expects the directory to include location, contact information, specialty, and medical group, any institutional affiliations for each provider, and whether the provider is accepting new patients.

2. Tobacco Deeming Regulations

At the end of April, the FDA finally issued deeming regulations that will allow the agency to regulate e-cigarettes and related products. Thank you for your work at Office of Management and Budget (OMB) in reviewing and releasing the tobacco deeming regulations.

It has been four years since the passage of the Tobacco Control Act. In those years, the tobacco industry has been tirelessly morphing new products to addict Americans. We cannot afford any more delays in regulating these new products.

- a) Will you commit to finalizing these proposed tobacco regulations before the end of the year?**

Answer: If confirmed, I assure you that finalizing the deeming rule after a thorough review of the comments will be a priority.

- b) As Secretary of the Department of Health and Human Services (HHS) you will have to juggle many competing priorities. Recognizing that several of your responsibilities will include coordination between agencies and other stakeholders, how will you ensure timely review and minimal delays when multiple important priorities are before you?**

Answer: It is my understanding that the FDA is currently receiving comments on the deeming proposed rule. Given the importance and significance of this proposed rule, if confirmed, I will ensure a thorough and expeditious review of public comments and issuance of a final rule as quickly as possible.

3. CMMI Primary Care Demonstration

The ACA created an Innovation Center at CMS to help test “innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care” for individuals who are insured through Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP). One of these projects is a Comprehensive Primary Care Initiative, or CPCI, which is testing ways to foster collaboration between public and private health care payers with a focus on strengthening primary care. The Cincinnati-Dayton region is one of 7 participating localities where Medicare is working with commercial and state health insurance plans to offer bonus payments to primary care doctors who better coordinate care. The idea here is that primary-care practice transformation can’t occur if only one payer (e.g. Medicare or Medicaid) changes the way it pays for health care—payment reform must be aligned across multiple payers.

- a) I understand that CMS will report Year One results soon. What can you tell us about these findings?**

Answer: It is my understanding that the Comprehensive Primary Care initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. As the model is relatively new, unfortunately results are not yet available, but if I am confirmed, I will ensure that additional information is shared when these findings are complete.

b) What conclusions can be drawn from the demonstration so far?

Answer: It is my understanding that as the model is relatively new, results are not yet available. If I am confirmed, I will ensure that additional information is shared when these findings are complete.

c) If the actuarial analysis demonstrates that this primary care demonstration reduces costs and / or improves quality, would you work to expand them beyond their current test markets?

Answer: If I am confirmed, I will ensure this model is appropriately evaluated to determine whether it is appropriate for expansion.

4. Biologics Price Competition

Biologic drugs represent the cutting edge of biomedical research and the future of treatments for diseases like multiple sclerosis, arthritis, and numerous other chronic diseases and illnesses. Unfortunately, of the biologics that exist today, many of these drugs remain inaccessible and unaffordable for the patients who need them most. Four years ago, Congress enacted the Biologic Price Competition and Innovation Act (BPCIA) to help protect and ensure access to safe, effective, and affordable biologic medicines. Since the BPCIA was enacted, the Food and Drug Administration (FDA) has done very little to consult with other stakeholders to implement the BPCIA.

While I am aware that the FDA has participated in more than 60 formal meetings with prospective biosimilar manufacturers, I am concerned that the FDA is not engaging in a transparent, inclusive process for developing policies to implement this important law. Patients, health care professionals, manufacturers with expertise with biologics, other stakeholders, and policy makers should also have an opportunity to provide meaningful input on the BPCIA implementation process.

- a) Can you please provide me with a detailed update on the FDA's plans for implementation of the BPCIA?**
- b) Can you ensure that the FDA will request input from other stakeholders in this space throughout the remainder of BPCIA implementation?**

Answer: While I have not been engaged in this process in my role as OMB Director, I understand from HHS that, to date, FDA has held public hearings and issued five draft guidances, inviting public comment, on implementation of the Biologics Price Competition and Innovation Act of 2009. A November 2010 public hearing provided a forum for interested stakeholders to provide input regarding the agency's implementation of the BPCI Act. FDA reviewed these numerous and extensive comments in developing the draft guidances issued in February 2012 following FDA's Good Guidance Practices. A second public hearing in May 2012 to receive input on these guidances and in obtaining public input regarding the Agency's priorities for development of future policies regarding biosimilars. FDA issued their most recent draft guidance in May 2014. FDA will take into consideration all received comments as they move forward in finalizing the draft guidance documents and developing future policies regarding biosimilar products and interchangeable products.

FDA listed a number of draft guidances related to biosimilars that are under development in the Center for Drug Evaluation and Research (CDER) Guidance Agenda.

The public will receive an opportunity to comment on these new guidances. FDA continues to actively engage with prospective biosimilar sponsors, including holding development-phase meetings and providing written advice on ongoing development programs for proposed biosimilar products.

5. Drug Shortages

In February, the U.S. Government Accountability Office (GAO) published a report entitled *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability*, which concluded that drug shortages remain a serious problem in the United States. Although the overall number of shortages has decreased, the total remains high, representing a direct threat to patient care. While I am pleased with the significant steps the FDA has taken to prevent these devastating shortages, I continue to hear from doctors, patients, and pharmacists in Ohio about new and existing shortages that represent a direct threat to the health of Americans. More must be done to combat existing and future drug shortages.

- a) If confirmed as Secretary, what will you do help decrease the number of existing drug shortages and prevent additional drug shortages in the future?**

Answer: If confirmed, I will support the FDA's efforts to prevent and mitigate drug shortages and protect the public health.

While I have not engaged directly on this issue in my role as OMB Director, I understand that FDA has a number of tools it can use to prevent or mitigate potential shortages:

- Work with manufacturers to resolve manufacturing and quality issues contributing to short supply;

- Expedite FDA inspections and reviews of various submissions from manufacturers to alleviate shortages;
- Identify and work with manufacturers willing to initiate or increase production
- Exercise temporary enforcement discretion for new sources of medically necessary drugs; and
- Exercise temporary enforcement discretion in appropriate circumstances to permit the distribution of a product in shortage, if this would not cause undue risk to patients (e.g., by allowing a product with particulate matter to be distributed with a filter that would be used to eliminate the particulates).

6. Temporary Assistance for Needy Families Program

Child poverty in the United States is at a 20-year high, with 21.8 percent of children living below the poverty line. Poverty is a particularly serious problem for children as those who live in poverty even for a short time suffer lifelong negative effects.

Programs, such as the Temporary Assistance for Needy Families (TANF) program, are an essential part of the social safety net. As you know, a significant number of TANF cases are “child-only cases,” yet reduction of child poverty is not an explicit goal of TANF. As Secretary, how would you prioritize and support reforms that focus on the reduction of child poverty?

Answer: I understand that while child poverty reduction is not an explicit goal of TANF, the four purposes of TANF reflect strategies to promote economic self-sufficiency and reduce child poverty, including providing temporary cash assistance so needy children can remain in their homes or the homes of relatives, engaging low-income parents in work, reducing out-of-wedlock pregnancies, and promoting two-parent family formation. Also, to clarify, while it is correct that “a significant number of TANF cases are ‘child-only cases,’” all TANF assistance cases must include a minor child living with a parent or relative caretaker.

At the same time, there is a concern that the percentage of poor children who are receiving TANF has diminished over time. The President’s FY 2015 Budget contains several recommendations that would strengthen the TANF program both as a temporary safety net for poor children and families and as a program to help move poor families toward self-sufficiency. This includes repurposing the current TANF contingency fund to provide subsidized employment opportunities for needy parents. The recent experience with the TANF Emergency Fund created under American Recovery and Reinvestment Act (ARRA) suggests subsidized employment can provide individuals with a critical foothold into the workforce. Additionally, the budget proposes that the spending of all TANF funds should be limited to needy families and children. Currently, expenditures under some of the purposes of TANF are not limited to families in need, thus diverting critical resources away from poor families and children.

Senator Cantwell:

Questions for the Witness:

Director Burwell, as you may know, I worked to include the Federal Basic Health Plan in the Affordable Care Act, which is based on Washington State's successful program. This option enables states to better utilize federal dollars to negotiate directly with health insurers, which will help provide more affordable and more stable coverage to individuals making between 133 and 200 percent of the Federal Poverty Level.

The Basic Health Plan would also save money. According to a 2011 Urban Institute analysis, states could save up to \$1.3 billion each year by shifting certain adults from Medicaid to Basic Health coverage. This study projected that if fully implemented, the Basic Health Plan will reduce annual health care costs for low-income adults by an average of \$1,456.

Under the statute, the Basic Health Plan should have been made available to states concurrent with the Affordable Care Act's exchanges and Medicaid expansion in 2014. Unfortunately, the Centers for Medicare and Medicaid Services (CMS) failed to implement the Basic Health Plan on time. Instead, CMS decided to delay the operational date of the Basic Health Plan by one year, to 2015, a decision the agency did not inform me of. This past March, CMS issued the final rule and payment methodology.

1. Do you support the Federal Basic Health Plan as a way to provide more efficient and affordable coverage to individuals who earn between 133-200 percent of the Federal Poverty Level?

Answer: I look forward to working with you as this provision of the Affordable Care Act continues to be implemented. As you know, CMS issued the final rules establishing the standards for the Basic Health Program on March 7, 2014 and is working with states that are interested in implementing the program beginning in 2015. HHS is committed to working with states that are interested in participating and I look forward to continuing this work if confirmed.

2. Given CMS's previous failure to implement the Basic Health Plan on time, and the agency's previous lack of responsiveness to Congress, what specific assurances can you give me that the provision will not be delayed or ignored again?
3. What will you do as Secretary to assist interested states in making the Basic Health Plan operational by January 1, 2015?

Answer 2&3: If confirmed, I will work with states to help make sure that the first year of implementation runs smoothly.

I understand that CMS is moving forward with the program and issued the final rules establishing the standards for the Basic Health Program earlier this year that set forth a framework for Basic Health Program eligibility and enrollment, benefits, delivery of health care services, transfer of funds to participating states, state administration and federal oversight. Additionally, CMS also published the 2015 payment notice providing states the final funding methodology for the Basic Health Program and information about the 2015 payment rates.

If confirmed, I look forward to working with any state that might be interested in offering this option to its residents.

Senator Cardin:

Questions for the Witness:

1. **Section 10334 of the Affordable Care Act requires the Director of the National Institute on Minority Health and Health Disparities (NIMDH) to coordinate “all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities” and “to plan, coordinate, review and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health.” Are you committed to ensuring that NIMDH has the resources to fulfill its Congressionally-mandated mission and that it does so?**

Answer: If confirmed, I will work with Dr. Collins to ensure that the National Institute on Minority Health and Health Disparities (NIMHD) is able to fulfill its congressionally-mandated mission in coordinating all of the minority health and health disparities research and activities at the National Institutes of Health (NIH). The NIMHD has an important role in NIH’s planning, reviewing, coordinating, and evaluation of minority health and health disparities research activities conducted at and supported by NIH’s 27 Institutes and Centers.

2. **Beyond coverage and access, what do you consider to be the five most significant impediments to eliminating health disparities in the United States?**

Answer: Eliminating health disparities is an important priority of not only HHS but the entire Administration. As such, the Administration recognizes that factors such as poverty, access to quality education, economic, and job opportunities, safe and affordable housing, and availability of community-based resources and social supports have an important role to play in efforts to eliminate health disparities. For example, through greater investments in early childhood education, increasing access to healthy food, creating pathways to jobs, and supporting a raise in the minimum wage, every department is playing a role in advancing health equity. Initiatives such as Ladders of Opportunity strive to better coordinate such work and align efforts to improve the well-being of Americans.

3. **Please share with the Committee your vision for achieving health equity in this nation. What specific initiatives and strategies do you plan to implement toward this goal? If confirmed, are you willing to appear before the Committee to discuss the progress the Department is making toward achieving this goal?**

Answer: Achieving health equity is a priority for me, the Administration and HHS. If I am confirmed, the Department will continue to promote integrated approaches, evidence-based programs and promising models to reduce disparities through the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*, the most comprehensive federal commitment to reducing health disparities. The HHS Disparities Action Plan’s goals address (1) transforming health care,

(2) strengthening the nation's health and human services infrastructure and workforce, (3) advancing the health, safety, and well-being of the American people, (4) advancing scientific knowledge and innovation, and (5) increasing efficiency, transparency, and accountability of HHS programs.

Through further implementation of the Affordable Care Act, millions more Americans will have access to quality, affordable health coverage. As such, millions more will have access to preventive services and medical care to lead healthier lives and reduce disparities in access to coverage. Health centers and the important services they provide will remain an important component of the implementation of the Affordable Care Act. If confirmed, I will continue the work that is underway at the Department to support health centers and their work to provide comprehensive, high-quality preventive and primary health care to over 21 million people annually, of which nearly two-thirds are racial and ethnic minorities. The Department will continue to invest in initiatives to increase the number of providers practicing in vulnerable and underserved communities; provide assistance to individuals from disadvantaged backgrounds to become health care professionals; and enhance cultural competency training among health care providers to strengthen the health care workforce. The Department will continue to promote data collection and research focused on disparities in health and health care to better understand the causes of health disparities and further develop effective interventions to reduce disparities.

4. How do you plan to employ the Offices of Minority Health at HHS to implement these initiatives? How do you plan to ensure that the Directors of the Offices of Minority Health are involved in the key policymaking processes at HHS?

Answer: The establishment of Offices of Minority Health in HHS Operating Divisions (Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, and Substance Abuse and Mental Health Services Administration), was called for by the Affordable Care Act.

Furthermore, I understand that the HHS Health Disparities Council is comprised of senior-level representatives from Operating and Staff Divisions across HHS, with the purpose of (1) coordinating the efforts of HHS operating and staff divisions on a cohesive set of health disparity reduction strategies, creating synergy and efficiencies where appropriate; (2) providing a forum for sharing information related to progress on health disparity reduction plans, successful strategies, and new opportunities to reduce health disparities; (3) serving as a resource to the HHS leadership and operating and staff divisions, providing guidance and support on the development and implementation of policies, programs, and strategic plans that address racial and ethnic health disparities; and (4) leveraging the policies, programs, and resources of HHS agencies in support of health disparity reduction goals.

The Deputy Assistant Secretary for Minority Health serves as the principal advisor to the Secretary for health program activities that address minority populations, develops policies for the improvement of health status of minority populations, and coordinates across Public Health Service minority health activities. In this capacity, the Deputy Assistant Secretary for Minority Health and HHS Office of Minority Health serve as an important liaison for the agency Offices

of Minority Health to the Office of the Secretary. I look forward to continuing the ongoing efforts of these components if confirmed.

- 5. In 2011, HHS launched its Action Plan to Reduce Racial and Ethnic Health Disparities and National Stakeholder Strategy for Achieving Health Equity. In addition to HHS, eleven other federal cabinet-level departments collaborated and provided guidance. Are you committed to implementing the Action plan? What will be your first steps in doing so?**

Answer: Yes, if confirmed, I will be committed to continuing to implement the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*. I understand that the HHS Disparities Action Plan charges all HHS Operating and Staff divisions to heighten the impact of HHS policies and programs in reducing health disparities. It complements the *National Stakeholder Strategy for Achieving Health Equity*, a product of the National Partnership for Action to End Health Disparities that was developed based on the input of thousands of individuals and organizations across the country. The HHS Disparities Action Plan and the *National Stakeholder Strategy for Achieving Health Equity* will continue to serve as the framework for HHS' efforts to address health disparities.

- 6. A National Quality Forum (NQF) expert panel recently released draft recommendations to begin risk-adjusting quality measures to account for poverty and other socio-demographic factors. This type of risk adjustment would ensure that health care providers – particularly safety net providers – are not unfairly penalized for treating vulnerable patients, while still pushing these providers to improve. It would also ensure patients continue to have access to care, particularly in lower-income communities.**

Based on the nearly unanimous recommendations of the NQF panel and MedPAC's long-standing call for risk adjustment, I believe that this type of risk adjustment can be done in a way that ensures high-quality care for all patients. Given this, I urge you to make risk adjustment for socioeconomic status and other social determinants of health a top priority when you take the helm at HHS. Will you commit to working with this Committee on this critical issue?

Answer: I agree that this is an important issue. I understand that, as you point out, NQF has been reexamining this issue and recently issued a draft report about adjusting for sociodemographic factors. If confirmed, I will work with CMS to examine NQF's work in this area, review the evidence basis, and consider appropriate adjustments.

- 6. Section 220 (i) of the recently enacted Protecting Access to Medicare Act of 2014 (PL 113-93) entitled "Disclosure of Data Used to Establish Multiple Procedure Payment Reductions" states that "The Secretary of Health and Human Services shall make publicly available the information used to establish the multiple procedure payment reduction policy to the professional component of imaging services in the final rule published in the Federal Register, v. 77, n. 222, November**

16, 2012, pages 68891–69380 under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).”

Will you commit to publishing this data before July 1, 2014? If not, why not?

Answer: As you point out, this provision was just enacted and requires making publicly available the data used to establish the multiple procedure payment reduction policy for imaging services. As I indicated when I appeared before the Committee, the two principles that will guide me with regard to information are transparency and accuracy. If confirmed, I will see that this data is made available as soon as practicable, consistent with my commitment to accuracy.

Senator Enzi:

Questions for the Witness:

1. **More than \$450 million in federal taxpayer dollars has been spent developing failed Obamacare exchanges in four states, and exchanges in at least two other states are at risk. If confirmed, will you try to recoup these funds from the contractors who failed to deliver a working system?**

Answer: I believe that we need to determine what went wrong and why (and in states where things are going right understand that too). In those states where federal government and taxpayer funds were misused, I believe that we need to use all available avenues to get those funds back for the taxpayer. Finally, we need to make sure that ensure that those who should be receiving access to quality, affordable health care through those states receive that access.

2. **Earlier this year the Congressional Budget Office estimated that spending on Medicaid is expected to increase to \$574 billion by FY 2024, more than twice what was spent in FY 2013. Medicare spending will rise from \$585 billion in FY 2013 to nearly \$1.1 trillion in 2024.**

As the Director of OMB this year, you were responsible under OMB Circular A-11 for recommending a complete set of budget proposals to the President based on agency requests. The FY 2015 budget request made no real effort to sustain Medicare and Medicaid for the long term, and when you testified before the Budget Committee in March you only referenced some one-time savings your budget requested.

As HHS Secretary, you would be responsible for proposing Medicare and Medicaid budgets and reforms to OMB and the President. What real and long term savings will you propose to sustain these programs for future generations?

Answer: Over the last few years, health care spending growth has fallen to the lowest levels since the government started tracking these data in the 1960s. Data from the Centers for Medicare and Medicaid Services and the Bureau of Economic Analysis show that from 2010 through 2012, health care spending grew at an annual rate of just 1.1 percent in inflation-

adjusted per capita terms, compared to the 4.0 percent average annual rate over the first part (2000 - 2007) of the last decade. One notable structural factor contributing to the slowdown is the Affordable Care Act, which is lowering costs and improving quality by reducing excessive Medicare payments to private insurers and providers, deploying new payment models that encourage more efficient, higher-quality care, and creating strong incentives for hospitals to reduce readmission rates.

The President's 2015 Budget builds on the Affordable Care Act by including \$402 billion in Medicare, Medicaid and other federal health program savings to further bring long-term health care costs under control. For Medicare, the Budget addresses additional areas where experts have identified inefficient health care delivery practices and excessive payment with targeted modifications. Importantly, the Budget also includes reforms that improve program finances and encourage beneficiaries to seek high-value services through targeted changes in cost sharing, deductibles, and premiums. These proposals build a stronger foundation for Medicare's future and extend the Hospital Insurance Trust Fund's solvency by approximately 5 years. The Budget also includes targeted, sensible reforms to Medicaid, including reforms to help states and the federal governments improve financing and reimbursement policies, and enhance program integrity.

As Secretary, I will continue to look for ways to achieve efficiencies in Medicare and Medicaid and improve long-term sustainability without undermining health care quality and access to care within these programs.

- 3. In the enrollment report released May 1, HHS disclosed that only 28 percent of enrollees in the Exchange were part of the all-important 18-24 age group. This falls short of the 40 percent that was reported as necessary by the Kaiser Family Foundation to prevent surges in future insurance premiums and the success of the market.**

Since only 28 percent of the new enrollees represent the young, healthy population which is far shorter than the required 40 percent mentioned by industry experts, how will we avoid the so called "death spiral" or significant spikes in premiums in 2015?

Answer: Consistent with expectations, through the end of 2014 open enrollment, the proportion of young adults (ages 18 to 34) who have selected a Marketplace plan through the SBMs and FFMs has remained strong. We expect that the robust sign-up numbers we are observing in the Marketplace's first year—8 million at the close of 2014 open enrollment—will encourage insurers to compete on price for consumers during next year's open enrollment period. In addition, provisions of the Affordable Care Act including, rate review and the medical loss ratio rule, will help protect consumers against unfair rate hikes.

- 4. I understand that our colleagues on the Senate Appropriations Committee have been unable to secure Secretary Sebelius' attendance at a hearing on the FY15 HHS Budget Request, even though she committed to keeping – and doing – her job until a successor is confirmed.**

If confirmed, do you commit to honor this Committee's requests for your attendance at hearings as long as you hold the position?

Answer: I commit to respond to any reasonable summons to appear and testify before this Committee.

5. **A huge priority for my state is the Abandoned Mine Land program that was created to help clean up abandoned mines and to help states where mining takes place deal with the impacts of energy development. The Office of Surface Mining (OSM) sent the State of Wyoming a letter recently stating OSM will not make what would be an additional payment of \$21.2 million in AML funds to Wyoming in fiscal year 2015. This is in error, however, as the recent changes to Surface Mining Control and Reclamation Act (SMCRA) did not relieve OSM from its obligation to distribute the remaining prior balance funds owed to Wyoming, nor does it relieve OSM from its obligation to make a total of seven annual installments of prior balance funds to Wyoming. Consequently, SMCRA still requires OSM to make two more annual installments equaling a total of \$165,401,519 in prior balance funds to Wyoming. You and I talked about this when we met last week, and I gave you a copy of a letter the Wyoming delegation sent to you as the head of OMB.**

Before you leave OMB, will you work with OSM to reverse this decision and properly implement the law Congress adopted so Wyoming receives its rightful share under the law?

Answer: I very much appreciate you raising this important issue, and I know Wyoming and the Department of the Interior are currently engaging in dialogue about it. While OMB does not administer this statute or the payments in question, I understand that the particular issue raises a number of complicated legal and technical concerns, and stems in part from a number of recent amendments to this legislation. Given the fact that OMB does not administer this statute, I would defer to the technical expertise of the Department of the Interior in answering your specific questions. That said, I am encouraged that DOI and Wyoming are engaging constructively on this issue. I have reached out to the Secretary and offered any assistance OMB can provide.

6. **As you and I have discussed, OMB must review all major federal rules and regulations, and under your leadership approved the proposed New Source Performance Standard rule for new electricity plants developed by the EPA. EPA states that the standard it set for a new natural gas combined cycle power plant (1000 pounds of CO2 per megawatt hour) is being met by over 90% of those types of plants in operation today. How many coal power plants in operation today can meet the proposed standard (1100 pounds of CO2 per megawatt hour) for new coal power plant?**

If the answer is none, why did you allow the EPA to proceed with this rule?

Answer: EPA based the requirements of the rule on its determination of the Best System of Emissions Reductions (BSER) which is adequately demonstrated, as directed by the Clean Air Act. The 1100 lb/MWhr standard is based on the determination that sources such as natural gas combined cycle electricity generating units and coal fired electricity generating units that utilize partial carbon capture and storage technology would demonstrate BSER in order to meet this standard. The basis for EPA's determination that this technology is adequately demonstrated is explained in the preamble to the rule and accompanying technical support document.

In the preamble of the proposed rule, EPA cites several facilities that have deployed, or are in the process of deploying, partial capture and storage technologies for carbon sequestration that would demonstrate their ability to meet the BSER standard established in the proposed rule. For additional information, I would respectfully refer you to EPA.

- 7. In previous EPA testimony, the Agency says the proposed standards for a new coal power plant "reflect the demonstrated performance of efficient, low carbon technologies that are currently being used today." Are there any full scale coal power plants currently in commercial operation in the US that are using CCS technology?**

To be clear, CCS components have been developed. Is any electricity generating plant using them all in a fully integrated system – I'm not asking about gasification or EOR systems, but electricity generating units?

If not, how as OMB Director how can you allow the EPA to choose a standard without knowing whether it is achievable in practice?

Answer: As explained in the preamble of EPA's proposed rule, several coal fired electricity generating units are deploying, or are in the process of deploying, partial capture and storage carbon sequestration technologies that adequately demonstrate their commercial scale deployment. This analysis is explained in detail in the technical support document for the rule. For additional information, I would respectfully refer you to EPA.

- 8. The Department of Energy testified recently that early stage deployment of CCS for new power plants would increase the costs of wholesale electricity by approximately "70 to 80 percent." As Director of OMB, did you ensure the Department of Energy or OMB conducted a comprehensive economic and employment impact assessment of the EPA New Source Performance Standards for new EGUs?**

If so, where can I and the public find it, and if not, why did OMB not assess the economic consequences of a de facto permanent moratorium on the construction of new, highly efficient and cleaner coal electric power plants?

Answer: EPA provided a draft proposed rule and regulatory impact analysis that was reviewed by OMB and several agencies during the interagency review process that OMB conducted pursuant to Executive Orders 12866 and 13563. This proposed rule, along with supporting technical documents and a regulatory impact analysis, included a discussion of the potential

impacts of the rule, and was made available to the public for a 90-day public comment period which ended on March 10, 2014. As explained by EPA in these documents, several coal fired electricity generating units are deploying, or are in the process of deploying, partial capture and storage carbon sequestration technologies that adequately demonstrate their commercial scale deployment. You can find these various documents at: <http://www2.epa.gov/carbon-pollution-standards/2013-proposed-carbon-pollution-standard-new-power-plants>.

- 9. In February, several Senators asked CMS for specific answers about plans for testing the ICD-10 billing code system. While a delay was announced shortly after the letter was sent, the transition is still expected next year. Please provide a detailed explanation of the testing CMS plans to perform before transitioning to ICD-10 next year and specify which entities will be allowed to participate in such testing.**

Please outline, in detail, the testing CMS plans to perform before transitioning to ICD-10 and specify which entities will be allowed to participate in such testing.

Answer: HHS has announced that it intends to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD-9 through September 30, 2015. CMS plans to conduct end-to-end testing in 2015 and will release details about the testing later this year. I also understand that this past March, CMS conducted a successful ICD-10 testing week where testers submitted claims with ICD-10 codes to the Medicare fee-for-service (FFS) claims systems and received electronic acknowledgements confirming that their claims were accepted. If confirmed, I will work to ensure that the transition to ICD-10 incorporates sufficient pre-implementation testing and opportunities for stakeholders to provide feedback.

Senator Cornyn:

Questions for the Witness:

- 1. Recently, a number of state exchanges have seriously struggled despite the fact that four states alone spent almost half a billion dollars in taxpayer money developing their exchanges (Oregon, Massachusetts, Nevada and Maryland). This is a prime example of wasted money and a lack of oversight.**
 - a. What is your plan going forward for addressing these broken websites?**
 - b. If more states choose to follow Oregon's example and transition to the federally run HealthCare.gov, can the site even accommodate this additional burden?**

Answer: My understanding is that CMS is working with states on addressing the implementation challenges with their State-based Marketplace. I understand that CMS will be implementing contingency plans to smoothly and effectively assume the Marketplace functions

for any states that are unable to demonstrate readiness to continued operation of their Marketplace. If confirmed, I will support this work going forward.

2. **In December 2011, Texas received approval of its Section 1115 Medicaid waiver. Under this five-year waiver, almost 1 million Medicaid beneficiaries were moved to Medicaid managed care organizations. Plans have been ongoing since then and each regional health care partnership has developed programs that are meant to increase the quality of care provided to beneficiaries in the community. These programs are designed to target the specific needs of the patients in that area. As Texas prepares to renew this waiver, there is concern that HHS will treat a waiver renewal unfavorably given the state's decision not to expand Medicaid.**

- a. **Can you assure me that, if confirmed, you will ensure your agency works fairly with Texas as we seek to continue under a waiver?**

Answer: To the extent Texas pursues a renewal of their 1115 demonstration I am committed to ensuring that the Department evaluates the state's proposal fairly and in view of existing law and regulations if confirmed.

3. **Focusing in on access to care, in my home state of Texas, Medicare patients are already facing access issues. The Texas Medical Association conducted a survey in July 2012 and found that only 58 percent of physicians in the state were accepting all new Medicare patients. The outlook is even worse for Medicaid. Only 31 percent of physicians will accept all new Medicaid patients. This is part of the reason why I opposed Medicaid expansion in Texas. It is already broken.**

- a. **What reforms would you propose to ensure that beneficiaries truly have access to services?**

Answer: If confirmed, ensuring that beneficiaries continue to have access to the care they need will be one of my top priorities. A number of provisions in the Affordable Care Act were designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and certain services provided in underserved areas and investments in health professional training programs to increase supply. Additionally, the President's FY 2015 Budget includes a proposal to extend the Medicaid primary care payment increase through 2015 and expand eligibility to mid-level providers, including physician assistants and nurse practitioners. This proposal is designed to support providers as they accept new Medicaid beneficiaries and to accommodate the anticipated increase in demand for primary care services as a result of the Medicaid expansion, in states choosing to do so. These proposals support robust primary care provider networks for both current and new beneficiaries.

4. **In order to fund Obamacare the administration included deep cuts to the Medicare Advantage program. The majority of these looming cuts have yet to be implemented and promise to increase premiums and decrease choice and access for seniors.**

- a. **How will you ensure these cuts do not undermine a program that millions of seniors depend upon?**

- b. Do you feel that it is appropriate to continue funding other elements of Obamacare that have resulted in millions of wasted taxpayer dollars (e.g., broken exchanges) by making even further cuts to the benefits that we have promised to our seniors?**

Answer: I expect Medicare Advantage (MA) will continue its strong performance into the future. With enrollment at an all-time high and costs remaining stable, concerns that recent changes to the MA program would result in lower enrollment and higher costs have not come to fruition. Nationwide, over 15 million Medicare beneficiaries are now enrolled in an MA plan. This is a 30 percent increase in enrollment since 2010, and enrollment is projected to continue increasing. Plan participation continues to be robust with 99.1 percent of beneficiaries having access to an MA plan in their area. Since passage of the Affordable Care Act, average MA premiums are down by 9.8 percent. Robust access, growing enrollment, slow-growing premiums, and stable plan choices are all indications that the MA program can be expected to remain strong in the coming years. If confirmed, I will ensure that the Department continues to closely monitor the program to make sure it continues to provide access to Medicare benefits.

5. The Administration has unilaterally delayed provisions of Obamacare more than 20 times.

- a. Do you believe the Administration has the authority to delay these provisions without seeking Congressional approval?**
- b. As Secretary of HHS, would you consider issuing further delays?**
- c. How would you determine which provisions should be delayed and do you plan to consult Congress?**

Answer: The Administration has focused on implementing the Affordable Care Act in a common-sense manner consistent with the law. As we implement laws, I think it is important we do so in a way that protects the health, welfare, and safety of Americans while promoting economic growth, job creation, competitiveness, and innovation.

Ultimately, final decisions on implementation efforts rest with the relevant agencies. The legal basis for such decisions may be described in rulemaking, guidance, or other relevant documents. Should you determine those materials do not contain the information you seek, I would respectfully refer you to the relevant agency. If the relevant agency is HHS, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

The goals of the Affordable Care Act are to give millions of middle class Americans health care security, slow the growth of health care costs, and bring transparency and competition to the Health Insurance Marketplace. In implementing this law or any others, I think it is important to focus on accomplishing the goals of the law in the most effective, efficient way possible. As Secretary, I will work with Congress, policy experts, and stakeholder groups to ensure that there

is stability to in the health insurance market. I am committed to ensuring a smooth transition in accordance with the law as implementation continues.

6. If, in a given year, the IPAB does not submit recommendations to Congress for reducing Medicare expenditures according to the targets set forth in the ACA, the Secretary of HHS is required to develop and submit such proposals.

a. What type of recommendations would you make in order to cut spending, if you were required under the law to do so?

Answer: The Independent Payment Advisory Board (IPAB) serves as a backstop to protect against excessive cost growth in the Medicare program. IPAB may not propose increases in cost-sharing or beneficiary premiums, restrictions on benefits, rationing of health care, or changes in eligibility. According to analysis conducted by the independent CMS Actuary for the President's FY 2015 Budget, projected that per capita Medicare spending growth will not exceed the statutory-based target specified for IPAB until 2019, meaning that recommendations would not need to be submitted for Congressional consideration until at least 2018. The President's FY 2015 Budget, includes a package of legislative proposals that will save over \$400 billion over 10 years by more closely aligning payments with costs of care, strengthening provider payment incentives to promote high-quality efficient care and creating incentives for beneficiaries to seek high-value services. Enactment of these proposals would delay the date of IPAB required recommendations for years beyond 2018.

7. In the HHS budget proposal for FY 2015, the Administration once again doubles down on the IPAB and proposes to further limit Medicare growth by lowering the target growth rate from gross domestic product (GDP) per capita plus 1 percent to GDP per capita growth plus 0.5 percent. This is estimated to save \$12.9 billion. Obamacare specifically states that the IPAB's recommendations may not:

- Raise revenues;
- Raise Medicare beneficiary premiums;
- Increase beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or;
- Modify eligibility criteria.

a. What is left for the IPAB to propose?

b. The health reform law also specifically prohibits the IPAB from making recommendations that would "ration health care" or "otherwise restrict benefits." Would you agree that provider payment rates can be cut so low that this ultimately leads to rationing of care?

Answer: The Independent Payment Advisory Board (IPAB) serves as a backstop to protect against excessive cost growth in the Medicare program. IPAB may not propose increases in cost-sharing or beneficiary premiums, restrictions on benefits, rationing of health care, or changes in eligibility. According to analysis conducted by the independent CMS Actuary for the

President's FY 2015 Budget, projected that per capita Medicare spending growth will not exceed the statutory-based target specified for IPAB until 2019, meaning that recommendations would not need to be submitted for Congressional consideration until at least 2018. The President's FY 2015 Budget, includes a package of legislative proposals that will save over \$400 billion over 10 years by more closely aligning payments with costs of care, strengthening provider payment incentives to promote high-quality efficient care and creating incentives for beneficiaries to seek high-value services. Enactment of these proposals would delay the date of IPAB required recommendations for years beyond 2018. If confirmed, I look forward to working with Congress to achieve the savings necessary without affecting our seniors' access to the care and treatment they need.

- 8. During a hearing with Secretary Sebelius in November 2013, she agreed that there is no federal requirement that navigators undergo background checks. She also admitted it was possible for a criminal to become a navigator. Since then, this has proved to be true. In California, at least 43 of the navigators working in the state are convicted criminals. A navigator in Illinois turned out to be a convicted terrorist.**

a. Do you have any plans to address this problem?

Answer: It is my understanding that HHS is working to provide consumer assistance that balances the provision of high-quality consumer information with consumer protections. In addition to the rules set forth in the law, funding announcement, and regulations related to Navigators, recipients of Navigator grants in the FFMs, like other entities and individuals seeking to conduct business with the federal government, were subjected to a robust screening process before the grants were awarded.^[1] Awardees must also meet any licensing, certification, or other standards prescribed by the state or Marketplace, if applicable, so long as these state Navigator standards do not prevent the application of the provisions of Title I of the Affordable Care Act. As of April 2014, eighteen states with FFMs have set additional requirements for Navigators. If confirmed, I will continue to ensure that consumers are protected and the standards of these programs are adhered to.

Senator Portman:

Questions for the Witness:

Medicare Part D

- 1) Given the proven success of the Medicare Part D program, I was very concerned when CMS put out a proposed rule for the 2015 contract year fundamentally changing the program. As you know, in response to a letter my colleagues and I sent to Marilyn Tavenner, CMS agreed to withdraw the most problematic sections of the rule dealing**

^[1] Entities and individuals are not eligible for a federal grant, including a Navigator grant in an FFM, if they are on the General Services Administration's web-based System for Award Management containing the names of entities or individuals who have been suspended or debarred by any federal agency. Screening applicants using this system will help to ensure that individuals or organizations that pose a risk to the federal government are not awarded federal Navigator grants.

with Secretarial interference in plan negotiations with drug makers and with pharmacies; preferred pharmacy networks; protected drug classes; and reducing plan choices.

However, Ms. Tavenner's response stated that CMS does not plan to finalize these proposals "at this time." I am concerned that the letter's ambiguity would allow the agency to revisit these proposals in the future which would most directly be detrimental to seniors and to the program itself.

Can you provide assurance that if you are confirmed as Secretary you will not allow a rule or any subregulatory guidance to proceed that will interfere with the principles that have made for such a successful Part D program and have the effect of limiting beneficiary choice of plans and increasing premiums?

Answer: I understand that the proposed rule included many important provisions related to the Medicare Part C and D prescription drug program. During the rule's comment period, CMS received numerous concerns about some elements of the proposal from members of Congress and stakeholders. In particular, there were concerns raised about the proposals to lift the protected class definition on three drug classes, to set standards on Medicare Part D plans' requirements to participate in preferred pharmacy networks, to reduce the number of Part D plans a sponsor may offer, and clarifications to the non-interference provisions. Given the complexities of these issues and stakeholder input, I understand CMS' final rule will not finalize these proposals.

Delphi Retirees

- 2) Across the country there are thousands of families of Delphi Salaried Retirees who have already lost up to 70 percent of their earned pensions due to the Administration picking winners and losers during the GM bankruptcy. These families are in a very tough situation, after losing so much of their pensions, and now looking at challenging health care decisions. They are trying to deal with health care deadlines, while comparing rates with a website that simply does not work.

Many of these 20,000 Delphi salaried retirees and their families are unable to compare the health plans they are offered through the Delphi Salaried Retiree Association to coverage offered through the Exchange, because of the major technical issues of the Exchange. These retirees were required to sign up for benefits through their Association by November 6 of last year but due to the inability to compare coverage through Healthcare.gov many weren't able to make an educated decision.

If confirmed as Secretary, what will you do to ensure that these retirees and their families are able to make informed health care choices in the future?

Answer: I understand that since the initial months of open enrollment, HHS has made considerable improvement to HealthCare.gov, including vastly improved functionality that enables consumers to window shop for plans available in their local market. Consumers can use

HealthCare.gov to find important information on providers, formularies and cost-sharing that enables them to make an educated decision. As HHS prepares for the next annual open enrollment period this fall, lessons learned during the past year will enable the Department to further improve this consumer experience.

To the extent that any of your constituents need personalized assistance, I understand that the Marketplace Call Center continues to respond to consumer inquiries. The “Find Local Help” function on HealthCare.gov also provides up-to-date information about Navigators and other in-person assisters, so that all consumers and their families can get connected with the personalized help they need.

Medicare Advantage

- 3) **I was pleased that CMS decided not to move forward with their initial proposal to cut Medicare Advantage rates by 6% in the 2015 contract year. Over 15 million seniors have chosen to enroll in Medicare Advantage because of its higher quality benefits and improved care coordination.**

In CMS’ announcement of rates for the 2015 contract year, they stated that the final rates would represent an increase of .4%. Within days of that announcement, independent analysts examined the final proposal and found that it actually cuts MA by between 3%-4% in 2015. Even more concerning is that a final rate cut of 3-4% for 2015 in addition to cuts of approximately 6% in 2014, means that the program is facing around a double-digit reduction over just two years.

Can you provide us with an explanation as to how you could say there is an increase, when in fact all independent experts, could see it as a more than 3% cut?

Answer: I understand that the April 7, 2014 rate announcement sets a stable path for Medicare Advantage and implements a number of policies that ensure beneficiaries will continue to have access to a wide array of high quality, high value, and low cost options while making certain that plans are providing value to Medicare and taxpayers.

CMS estimates that the overall net change to plan payments between 2014 and 2015 to be +0.4 percent, compared to the estimated overall net change to plan payments of -1.9 percent for the proposals in the Advance Notice. Individual plan payments will vary by plan based on, but not limited to, its location and star rating.

Durable Medical Equipment (DME)

- 4) **The Durable Medical Equipment (DME) competitive bidding program, run by CMS, currently has 8 bidding areas in Ohio. Based upon analysis of public records from the state of Ohio, it appears that CMS selected multiple contractors that are not licensed in the state. It also appears that CMS has chosen contractors that are not appropriately accredited for the product for which they have a contract.**

During the Senate Finance Committee mark-up of legislation to repeal and replace the Sustainable Growth Rate, I, and a bipartisan group of my colleagues, led an effort to get language requiring that bidders prove that they are licensed in the state before they can supply equipment through the program. This lack of a state licensure requirement has continued to be an issue in Ohio and several other states.

In the President's FY 2015 budget he proposed to limit Medicaid reimbursement of DME to Medicare rates and expand the pricing determined through competitive bidding. If you are confirmed as Secretary, would you commit to clearly establishing a requirement that bidders prove state licensure prior to submitting bids?

Answer: I understand from HHS that suppliers submitting a bid for a product category in a competitive bidding area (CBA) must meet all DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) State licensure requirements and other applicable state licensure requirements, if any, for that product category for every state in that CBA.

Contracts are only awarded to suppliers that meet applicable state licensure requirements. I understand that failure to comply with these requirements is a breach of contract and may result in contract termination, the revocation of Medicare billing privileges, and other significant penalties.

- 5) On December 2, 2013, CMS published in the Federal Register a final rule containing a clarification to the grandfathering provision of the medical loss ratio (MLR), effective April 1, 2014. In the 2013 final rule, CMS committed that it "will continue to consider these issues and provide additional guidance if necessary." Will CMS provide guidance regarding which modifications to "grandfathered" DME products render them "new" products that are no longer grandfathered? If so, when does CMS plan to issue this additional guidance?**

Answer: As OMB Director, I have not been engaged directly in this issue. However, I understand that HHS issued a final rule in December that clarifies issues pertaining to grandfathered DME products and that CMS will respond to specific questions about the policy as they arise.

I understand from HHS that the 3-year minimum lifetime requirement (MLR) is designed to represent a minimum threshold for a determination of durability for a piece of equipment. The 3-year MLR is not an indication of the typical or average lifespan of DME, which in many cases is far longer than 3 years. In the final rule published in the Federal Register on December 2, 2013, CMS stated that the 3-year MLR is prospective only and does not apply to equipment classified as DME on or before January 1, 2012. CMS clarified that the 3-year MLR would not be applied to grandfathered items or products that are modified if modifications are merely refined or upgraded versions of the same product. However, if the modified product would now have an expected life shorter than the expected lifetime for that item covered as DME on or prior to January 1, 2012, then the modified product would be considered a new item and subject to the 3-year MLR requirement. CMS also clarified that a grandfathered "product" is a specific product (make, manufacturer, model, model number, etc.) that was covered and paid for as DME on or

prior to January 1, 2012. I understand that CMS will continue to respond to specific questions about the policy, and if confirmed, I look forward to learning more about whether additional guidance would be helpful and would welcome your views on the matter.

Comprehensive Medication Management

- 6) **Given the role chronic disease plays in impacting patient outcomes and overall healthcare costs, a systematic approach to medication management is needed to close the gaps in care and optimize patient outcomes. However, our current delivery and payment models have failed to integrate a comprehensive medication management service, despite evidence that “appropriate medication use” could save at least 1 million lives and over \$300 billion dollars annually. Would you be willing to prioritize a comprehensive approach to medication management as a key objective for HHS?**

Answer: I agree that improved medication adherence can help reduce health care costs, improve quality, and protect patient’s health. If confirmed, I will work across the Department to improve our strategies to promote appropriate use of medications.

- 7) **CMS has indicated it will likely publish the final rule on the new federal upper limit methodology for Medicaid AMP pricing in July 2014. However, Ohio, like most states, will need to file a State Plan Amendment (SPA) with CMS prior to implementing the Medicaid reimbursement methodology changes. This adds additional time to the process, especially if a state has other SPAs that were filed before the Medicaid drug reimbursement SPA, which they are waiting for CMS to approve.**

Does CMS intend to expedite the SPA process for Medicaid drug reimbursement SPAs? Has CMS considered providing states with a transition period to properly implement these reimbursement and dispensing fee changes and not interfere with beneficiary access to prescriptions?

Answer: I understand that in November 2013, CMS informed states that it intended to finalize the Federal Upper Limits (FULs) for multiple source drugs in July 2014. The finalization of the FULs is a separate activity from the publication of the final rules. If I am confirmed I will be happy to look into this issue.

Hospitals

- 8) **Congress originally intended the Medicare and Medicaid Electronic Health Records (EHR) incentive programs to support widespread adoption of interoperable technology to improve health care. A recent report from GAO (GAO-14-207) indicates that the first stage of the program has led to increased adoption, but noted that program changes make future participation difficult to estimate.**

Health care providers have expressed significant concerns about the readiness of EHR vendors to support the mandatory transition to the 2014 Edition Certified EHR in a

safe and orderly fashion. They also have concerns about the overly complex, rigid requirements of the meaningful use program.

How will the Administration take steps to address provider concerns about the challenges of adopting the 2014 Edition EHRs certified through the HHS program? If confirmed, what specific steps will you take between now and the end of the fiscal year to ensure that any provider making a good faith effort can meet the requirements, earn the promised incentives, and avoid future penalties?

Answer: I understand that HHS has been listening to providers, health care associations, EHR vendors, and its partners in the health care industry. In December 2013, HHS announced that it would engage in rulemaking to extend Stage 2 of meaningful use for one year and allow Stage 3 to begin in 2017. In addition, ONC issued a 2015 Edition EHR Certification Criteria Proposed Rule as part of its new regulatory approach to provide more frequent updates to the certification criteria. This approach is designed to provide more time for public input on policy proposals, enable the certification processes to more quickly adapt to include newer industry standards that can lead to greater interoperability, and add more predictability for EHR technology developers.

By extending Stage 2 until 2017, HHS would have an additional year of Stage 2 implementation data to help inform any program changes. An extension also allows CMS and ONC to better use data from Stage 2 to inform rulemaking for Stage 3, and to consider additional Stage 3 approaches to advance interoperability and clinical decision support capabilities that will help drive improved health outcomes.

In response to stakeholder concerns that providers were having difficulties meeting the requirements of Stage 2, CMS and ONC announced in February 2013 that additional flexibility would allow eligible professionals and hospitals to request a hardship exception because they are unable to control the availability of Certified EHR Technology at a practice location or a combination of practice locations.

Senator Isakson:

Questions for the Witness:

1. In 2012, the Supreme Court ruled that the federal government cannot force states to expand their Medicaid programs by threatening to withhold all existing Medicaid funding. Therefore, it is within the authority of each state, through its established policies and procedures, to determine whether to participate in the massive expansion of Medicaid authorized under the Patient Protection and Affordable Care Act (PPACA). I understand that this Administration supports Medicaid expansion and will make public statements encouraging states to participate. However, for those states that have made a determination that the budgetary risk of a significant Medicaid expansion is too large for them to take on, I want to get some assurance that the Administration is not going to try to exercise new means of unconstitutional coercion or to punish states that choose not to expand.

Can you commit to me that, if confirmed, you will not adopt policies that discriminate against states that have not expanded their Medicaid programs?

Can you further commit that HHS decisions on Medicaid flexibility waivers, grant allocations, and other matters affecting states will be made based on the merits, and not based on any effort to “reward” or “punish” states for their decisions on Medicaid expansion?

Answer: If confirmed, I will evaluate states’ proposals fairly and in view of applicable laws and regulations.

2. **Small businesses struggle every day to be successful. Small business owners are often forced to make hard decisions in order to keep their businesses afloat, subsidizing their businesses with personal savings and credit cards. Congress and the Administration should be doing everything they can to ease these burdens. Instead, small businesses are taking another blow in the form of PPACA’s health insurance tax (HIT). While this is nominally a tax on health insurance companies, its true burden will fall onto the backs of small businesses that provide health benefits to their employees. In fact, the National Federation of Independent Business (NFIB) projects private-sector employment through 2022 will be reduced by at least 146,000 jobs because of the health insurance tax, and perhaps as much as 262,000 jobs. This tax also hurts state Medicaid programs and seniors’ Medicare Advantage benefits.**

Proponents of PPACA have stated a goal was to bring down the cost of health insurance. I think the law has had the opposite effect and is leading to increased costs. Regardless of our differences on the overall impact of the law, how will taxing health insurance policies where the costs are passed through to individuals and small businesses lead to lower health care premiums?

Answer: The Affordable Care Act helps small businesses in several ways. First, by creating SHOP exchanges, small business employers have an easy way to provide health coverage to their employees, and, if eligible, can obtain tax credits to help cover the cost of premiums. By providing affordable health insurance options, the Affordable Care Act levels the playing field between small and larger businesses in the labor market, enabling small businesses to recruit talented employees. The exchanges also enable people to venture out on their own as entrepreneurs, without having to worry about not having health care coverage provided through their work.

For specific concerns regarding the implementation of the health insurance fee, I respectfully refer you to the Department of Treasury.

3. **According to data from the Altarum Institute, in recent months, year-over-year growth in health care spending has risen to the highest levels since before the 2007-08 recession. Do you believe this increase in the rate of health care cost growth is wholly or partially a result of the implementation of PPACA?**

Answer: National health expenditures have in fact been rising slower in recent years, not faster. Before the Affordable Care Act, consumers in the individual market frequently saw double digit rate increases for their health insurance. The Affordable Care Act is contributing to a slowdown in health care spending growth. The Marketplace is encouraging plans to compete for consumers, resulting in affordable rates. Average actual Marketplace premiums for 2014 were lower than those implied by initial Congressional Budget Office (CBO) projections. Additionally, CBO revised its projections for future premiums on April 14, 2014 and found that the Affordable Care Act's coverage expansion will cost \$104 billion less over than next ten years than it originally estimated, citing lower than expected premiums as a "crucial factor" in the new estimate.

The Affordable Care Act also contains many tools to keep large premium increases in check. For example, the Affordable Care Act requires insurance companies to justify rate increase of more than 10%, shedding light on arbitrary or unnecessary costs and protecting consumers from unfair rate hikes. The rate review program works in conjunction with the 80/20 rule or Medical Loss Ratio rule, which requires insurance companies to spend at least 80 percent (85 percent in the large group market) of premiums on health care, and no more than 20 percent (15 percent in the large group market) on administrative costs such as executive salaries, marketing, and profits.

The Affordable Care Act created several avenues to reform our delivery system and encourage increased quality and efficiency in health care, including demonstrations in the Center for Medicare and Medicaid Innovation, incentives to reduce hospital readmissions and health care associated infections, and initiatives to improve coordination of care for people with chronic medical conditions.

4. Some supporters of PPACA have claimed that increased spending on health care resulting from the law's implementation "saved" the U.S. economy from negative growth in the first quarter of 2014. If this trend toward higher health care costs continues, do you believe it is likely to have a positive or negative impact on the prospects for long-term economic growth?

Answer: By providing quality, accessible health care coverage through the Marketplaces, the Affordable Care Act creates additional job mobility, puts small businesses on a level playing field with large businesses in the labor market, and enables people to make employment decisions that better suit their needs. Affordable health insurance under the Affordable Care Act has a variety of economic benefits to businesses and workers. Access to health insurance outside the workplace allows people to structure their careers in ways that make sense for them, and reducing job lock encourages entrepreneurship - a critical ingredient for growth and job creation. The Affordable Care Act also benefits the bottom lines of small businesses by making it easier for them to find better, more affordable coverage options. And because small business owners will be joining a much bigger risk pool, they will no longer be vulnerable to sharp swings in their rates based on the health of a few employees.

As CBO Director Doug Elmendorf testified, the Affordable Care Act "spurs employment and would reduce unemployment over the next few years." Additionally, CBO estimates indicate that the Affordable Care Act will reduce the deficit by about \$100 billion over the budget window -- a

benefit for our nation's fiscal health. Since the Affordable Care Act passed into law, the private sector has added 8.1 million jobs as of February 2014. That is the strongest 45-month job growth since the late 1990s and contrasts with the 3.8 million private sector jobs lost in the decade before the Affordable Care Act passed.

5. **Last year, Secretary Sebelius dismissed reports that PPACA would increase premiums by saying, "Some of these folks have very high catastrophic plans that don't pay for anything unless you get hit by a bus. They're really mortgage protection plans, not health insurance." Should Americans have the option of purchasing less costly health insurance plans that protect them against catastrophic expenses, and using tax-free health savings accounts to pay for routine medical costs?**

Answer: Consumers have access to a wide variety of health insurance plans on the Marketplaces, ranging from low-cost, high deductible "bronze" plans to "platinum" plans with higher premiums, but more robust benefits. Young adults and those eligible for a financial hardship exemption can continue to purchase catastrophic coverage. High deductible plans paired with Health Savings Accounts (HSAs) remain an option for consumers. Furthermore, all of these plans must now provide consumers with basic protections, such as no annual or lifetime limits.

6. **A May 7 Kaiser Health News report highlighted that many employers are considering whether to discontinue their health benefits and shift their employees on to PPACA's health insurance exchanges. According to a new study, "silver" level exchange plans require enrollees to pay more than twice as much out of pocket for prescription drugs as compared to the average employer-sponsored plan. Additionally, multiple reports have described the exclusion of medical centers of excellence and key safety-net providers from the "narrow networks" featured in many exchange plans. Are you concerned that PPACA may create an incentive for employers to "dump" their employees onto taxpayer-subsidized exchanges? Could a shift from employer coverage to exchange plans have negative ramifications for medication adherence and access to high-quality providers?**

Answer: If confirmed, I would be happy to discuss concerns you may have on this range of issues. Federal standards require health plans in the Marketplace to include sufficient networks of providers as well as essential community providers. Issuers often alter provider networks and payments rates as a regular course of business, but must adhere to new network sufficiency and essential community provider standards.

To the issue of medication adherence specifically, I understand from HHS that qualified health plans (QHPs) are subject to standards to ensure adequate coverage of prescription drugs. I also understand that plans are required to have an exceptions process to allow enrollees to request and gain access to clinically appropriate drugs not on a plan's formulary.

7. **To date, the President has not appointed any individuals to serve in any of the 15 voting positions on the Independent Payment Advisory Board created by PPACA. If**

confirmed, you would hold IPAB's authority to unilaterally implement cuts in Medicare spending without Congressional approval, unless members of the Board are appointed and confirmed. IPAB is prohibited from proposing any changes to the Medicare program that would "ration health care." What is your understanding of the meaning of this prohibition? Could a proposal to reduce reimbursement for a particular medical service or treatment constitute rationing?

Answer: The Independent Payment Advisory Board (IPAB) serves as a backstop to protect against excessive cost growth in the Medicare program. IPAB may not propose increases in cost-sharing or beneficiary premiums, restrictions on benefits, rationing of health care, or changes in eligibility. These are important protections, and if confirmed as Secretary, I would work with Congress to look for ways to achieve efficiencies in the Medicare program and improve its long-term sustainability without undermining health care quality and access to care.

- 8. Section 1341 of PPACA provides for a temporary transitional reinsurance program funded through a tax on individual and group health insurance policies. The law specifies that the tax applies to plan years "beginning in the 3-year period beginning January 1, 2014." Do you believe that HHS has statutory authority to extend this tax and the associated reinsurance program beyond 2016?**

Answer: The reinsurance program is a critical premium stabilization program during the implementation of the new consumer protections and market reforms in 2014. If confirmed, I look forward to working with Congress on ideas to strengthen and efficiently implement this and other important Affordable Care Act programs.

- 9. A recent study from Avalere Health cited the "woodwork effect" of previously eligible individuals signing up for Medicaid, even in states that have not expanded eligibility. For example, in Georgia, nearly 100,000 new beneficiaries have signed up as of the end of March. States are receiving the standard Federal Medical Assistance Percentage (FMAP) to cover the cost of these previously eligible, but newly enrolled, beneficiaries – as opposed to the much higher FMAP for expansion states to cover newly eligible beneficiaries. Do you believe that maintaining different FMAPs for different classes of Medicaid enrollees is sustainable over the long run? Won't this structure give states an incentive to focus their resources on signing up higher-income people who are eligible for the more generous expansion FMAP, while neglecting to enroll the truly needy individuals and families for whom Medicaid was originally created?**

Answer: I am pleased that Americans across the nation are continuing to sign up for coverage through the Medicaid program and, if confirmed, I am eager to continue to work with all states to expand Medicaid so that they can take advantage of the federal funding provided. I will seek to ensure that all Medicaid beneficiaries across the country receive all of the protections afforded to them under the law and push to ensure that all individuals, regardless of income, that are eligible for Medicaid have the opportunity to enroll in the program.

- 10. State Medicaid agencies are voicing concerns about CMS's planned release this July of new Federal Upper Limits (FULs) for required use for pharmacy reimbursement. I am concerned that CMS may expect states to implement this new pharmacy matching rate limitation immediately, whereas due to the need for both legislative and regulatory changes, the reality is that Medicaid agencies will need up to one year to come into compliance after the final rule is issued. If confirmed, will you ensure that state Medicaid agencies are given a reasonable amount of time to implement this and other CMS regulatory changes?**

Answer: I have not been engaged on this issue as OMB Director. I understand from HHS that in November 2013, CMS informed states that it intended to finalize the Federal Upper Limits (FULs) for multiple source drugs in July 2014. The finalization of the FULs is a separate activity from the publication of the final rules. If I confirmed, I look forward to learning more about this issue and to working with you to address any additional concerns you may have.

- 11. Many children's hospitals around the country, including Children's Healthcare of Atlanta, have been working to address the challenge of coordinating care for children in Medicaid who have medically complex conditions and who often require services in multiple states. A number of members of this Committee have been engaged on their proposed concept for Medicaid pediatric care networks, anchored by entities that are centers of excellence for those children. I believe this framework has the potential to significantly improve the quality of care for these children while also saving money for the Medicaid program. In addition, it could achieve more budget certainty for state Medicaid programs and ensure more uniform collection of Medicaid quality data. Can you commit to work with Congress to move forward with this concept?**

Answer: I fully agree that everything possible should be done to ensure that children with medically complex conditions receive the highest quality care. If confirmed, I look forward to learning more about the proposed concept, and to working with Congress on efforts to improve care coordination.

- 12. I am very troubled by this Administration's continued proposals to cut the Medicare Advantage program. Nearly 400,000 Georgia seniors are enrolled in Medicare Advantage, and they appreciate the value-added benefits, care coordination, and choices that are available through MA. President Obama's health care law included devastating cuts to MA that are only in the early stages of being phased in. Furthermore, the Administration and CMS continue to put forward proposals for additional Medicare Advantage cuts, on top of the Obamacare cuts. Many of these proposals seem to be based on an assumption that Medicare Advantage plans are getting overpayments through gaming the risk adjustment system. However, a recent Milliman study found that MA plans are actually underpaid, relative to fee-for-service, for many of the highest-risk beneficiaries. The underpayment is 2 percent for dual eligibles, 7 percent for patients with chronic kidney disease, 20 percent for institutionalized beneficiaries over age 80, and so on. These are the very people who stand to gain the most from the improved care**

coordination that Medicare Advantage offers. While I appreciate that CMS pulled back its proposal to restrict MA plans' use of home risk assessments, the President's FY 2015 budget includes another proposal to cut Medicare Advantage by an additional \$31 billion by reducing risk adjustment payments for chronically ill beneficiaries.

If confirmed, will you commit to ensuring that risk adjustment formulas accurately reflect the cost of covering Medicare beneficiaries with multiple chronic conditions, and to rejecting efforts to modify risk adjustment solely to achieve budgetary savings?

Answer: The Medicare Advantage program is strong. Since the Affordable Care Act was passed in 2010, Medicare Advantage premiums have fallen by nearly 10 percent and enrollment has increased by 38 percent to an all-time high of more than 15 million beneficiaries. Today, nearly 30 percent of Medicare beneficiaries are enrolled in a Medicare Advantage plan. Furthermore, enrollees are benefiting from greater quality as over half of enrollees are now in plans with 4 or more stars, a significant increase from 37 percent of enrollees in such plans in 2013.

It is my understanding CMS announced in the Final Rate Announcement on April 7, 2014, that to provide for continued stability in the Medicare Advantage program, CMS will implement a new phase-in schedule for the Part C risk adjustment model introduced in 2014. Moreover, to improve payment accuracy, CMS has refined its risk adjustment methodology to account for the impact of the influx of baby boomers. In addition, for 2015, CMS did not finalize the proposal to exclude diagnoses from enrollee risk assessments. If confirmed, I will continue to ensure the Medicare Advantage program remains strong and the risk adjustment model helps maintain program stability.

13. Under the Medicare Advantage Star rating program, CMS plans to terminate contracts for plans that do not rate sufficiently high on a range of quality measures. While I support the goal of providing Medicare beneficiaries with information about which MA plans are achieving the highest quality standards, I am concerned that the Star rating system does not account for socio-economic factors such as income and education level of MA enrollees, which may affect health outcomes. I understand that a workgroup of the National Quality Forum has also raised concerns about the risk of failing to adjust Star rating calculations for these factors. In addition to the danger that 150,000 Georgians could lose their Medicare plan this fall, flawed quality measures could discourage plans from working to enroll minority, low-income, and/or medically complex patients. If confirmed, will you commit to looking at this issue and ensuring that CMS does not inappropriately terminate MA plans that serve the neediest beneficiaries?

Answer: The Medicare Advantage program is strong. Since the Affordable Care Act was passed in 2010, Medicare Advantage premiums have fallen by 10 percent and enrollment has increased by 38 percent to an all-time high of more than 15 million beneficiaries. Today, nearly 30 percent of Medicare beneficiaries are enrolled in a Medicare Advantage plan. Furthermore, enrollees are

benefiting from greater quality as over half of enrollees are now in plans with 4 or more stars, a significant increase from 37 percent of enrollees in such plans in 2013. If confirmed, I will listen to stakeholder's concerns and take them into consideration as we move forward with a goal of maintaining a strong Medicare Advantage program.

- 14. Earlier this year, CMS issued proposed regulations that would fundamentally change the successful Medicare Part D program. Following strong opposition from stakeholders as well as Congress, including most of the members of this Committee, CMS announced that they would not be proceeding with the changes "at this time." I am concerned that by simply choosing not to finalize certain portions of the proposed rule, as opposed to withdrawing the rule altogether, CMS could decide at any time to resume consideration of these extremely controversial changes. Will you commit to ensuring that these and any other changes to Part D do not move forward unless they are re-proposed through regular order, with full opportunity for the public and members of Congress to review and comment on them?**

Answer: It is my understanding that CMS has indicated they do not plan to finalize the following provisions of the proposed rule:

- Lifting the designation of antipsychotics, antidepressants and immunosuppressants for treatment of transplant rejection as drug classes of clinical concern;
- Requiring Part D sponsors to accept any willing pharmacy in their preferred pharmacy networks;
- Setting new limits reducing the number of Part D plans a sponsor may offer; and
- Clarifying the statutory non-interference provision in regulation.

In the event that CMS make these or similar proposals again, the agency would only do so as part of a new rulemaking process, during which it would solicit public comment once more before deciding whether to publish final regulations. If confirmed, I will ensure CMS continues to use the notice and comment rulemaking process before making changes to Part D regulations.

- 15. I am troubled by recent actions of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to restrict Medicare coverage of new life-saving medical technologies. To cite one example, the U.S. Preventive Services Task Force recently recommended the use of annual low-dose CT screening for patients at high risk of developing lung cancer. A clinical trial sponsored by the National Cancer Institute found that annual CT scans for patients age 55 to 74 with a history of smoking could reduce lung cancer mortality by 20 percent. Astonishingly, however, MEDCAC recommended on April 30 that Medicare should not cover this screening, with one panel member stating "If you look at the data, I'm not understanding where we're getting substantial benefit." Do you believe that a 20 percent reduction in death rates constitutes a "substantial benefit" that should be reflected by Medicare? Should Congress and CMS consider changes to the MEDCAC process to ensure that this little-known, unelected board does not become a de facto rationing agency for Medicare beneficiaries?**

Answer: Although I have not been involved in Medicare coverage policies during my tenure as OMB Director, it is my understanding that Medicare's national coverage determinations are based on a comprehensive, evidence-based, transparent process with multiple opportunities for public input. In some cases involving new or complex services, CMS may request an outside Technology Assessment and/or review by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). Each of these elements is just one part of a larger process aimed at assessing the best available evidence, and provides an opportunity for independent experts to supplement input from other sources. I appreciate your concerns about the MEDCAC's conclusions in this particular case, and understand that CMS will have a public comment period following release of a proposed coverage decision later this year.

16. Medicare's "Coverage with Evidence Development" (CED) process, under which Medicare beneficiaries can be covered for a treatment if they are enrolled in a clinical trial, is intended to drive innovation by allowing the program to reimburse for promising new technologies. I am concerned that CMS has increasingly been applying CED policies to FDA-approved products or well-established modes of treatment, including diagnostic tools for Alzheimer's disease. In this way, a policy that was intended to expand Medicare beneficiaries' access to treatment is actually being used to restrict access. What is your view of the appropriate use of Coverage with Evidence Development policies?

Answer: Thank you for your interest in diagnostic tools for Alzheimer's disease, which represents one of the greatest challenges facing the Medicare population and the nation as a whole. Although I have not been involved with policies related to Medicare's coverage with evidence development (CED) process in my role as OMB Director, I understand that CMS' evidence-based coverage decision-making process is not meant to replace or duplicate the FDA's determination of a product's safety and effectiveness; rather, it is designed to meet CMS' statutory obligation to ensure that Medicare covers only items and services determined to be "reasonable and necessary" for their beneficiaries. I also understand CED can be a useful tool in helping the agency meet that obligation while expediting access to emerging technologies; however, it is only one element of the overall "toolkit" to ensure the best care possible for beneficiaries.

17. Under current law, physicians who enter into private contracts with Medicare beneficiaries are barred from participating in Medicare for two years. According to CMS data, nearly 10,000 physicians who had previously accepted Medicare opted out of the program in 2012. Increasingly, Medicare beneficiaries, particularly those newly enrolled or living in rural areas, are reporting difficulty finding a primary care physician. Would you be open to working with Congress on a demonstration program in which a limited number of voluntarily participating states could test whether relaxing restrictions on private contracting, while ensuring that low-income beneficiaries are protected from higher out-of-pocket costs, could help to provide more choices and better access for beneficiaries?

Answer: Ensuring Medicare beneficiary access to primary care physicians is a high priority for the Department. A number of provisions in the Affordable Care Act were designed to strengthen

the health care workforce, such as Medicare payment bonuses for primary care providers and certain services provided in underserved areas and investments in health professional training programs to increase supply.

As you know, under current law a physician or practitioner can sign an affidavit to opt-out of Medicare for 2-years and privately contract with beneficiaries. If confirmed, I look forward to discussing any ideas you have to ensure that Medicare beneficiaries continue to have access to primary care physicians.

18. For the past several years, Congress and the Department have been addressing ways to reduce hospital readmissions and hospital-acquired conditions to improve patient care and to reduce overall Medicare spending. Expanding access to clinically appropriate care provided in a patient's home is one way to ensure that beneficiaries do not always have to rely on inpatient hospital care for particular treatments. Unfortunately, many Medicare beneficiaries are forced to receive infusion care in the hospital setting because of limitations in Medicare coverage of home infusion therapy. Home infusion, which is widely used outside the Medicare program, has the potential to save money and reduce complications from unnecessary hospital admissions. Would you work with Congress to ensure that Medicare beneficiaries will have the same access to these treatments in the home as non-Medicare patients have had for many years?

Answer: I agree that it is important that seniors and people with disabilities have access to care in clinically appropriate settings. It is my understanding that Medicare covers certain items and services for home infusion therapy but does not have a distinct home infusion benefit. It is also my understanding that adding a home infusion benefit to the Medicare program would require a statutory change. If confirmed, I will look into the issue and work to ensure the Department uses the full extent of its existing authorities to ensure that Medicare beneficiaries have access to care in clinically appropriate settings.

19. Last year, CMS issued a regulation implementing cuts to Medicare home health payments under PPACA. Under this regulation, Medicare home health services will be cut by 3.5% per year from 2014 through 2017. I am concerned that even though most home health providers are small businesses, CMS did not conduct an analysis of how the cumulative impact of four consecutive years of cuts would impact the sustainability of these businesses, as required under both the Regulatory Flexibility Act and President Obama's own Executive Order 13563. In fact, another federal agency, the Small Business Administration, filed its own comment letter with CMS expressing concern about the impact of these cuts and urging CMS to conduct additional economic analyses. If confirmed, what steps will you take to ensure that this and other CMS regulations comply with federal laws requiring a cost-benefit analysis of regulations affecting small businesses?

Answer: It is my understanding that the Calendar Year (CY) 2014 Home Health Prospective Payment System Rate Update final rule includes an assessment of the impact of the rule on small businesses. For the purposes of the analysis, CMS estimated that almost all home health

agencies are small entities. HHS's practice in interpreting the Regulatory Flexibility Act is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. Based on analysis of Medicare claims, CMS concluded that the policies finalized in CY 2014 rule will not result in an economically significant impact on Medicare payments to home health agencies. If confirmed, I will work with CMS to ensure that it continues to conduct robust analyses as part of its regulatory process.

20. CMS recently issued guidance on Medicare Part D claims for patients who have enrolled in hospice. Under this new guidance, no drugs can be covered for hospice beneficiaries, even if they are being used to manage conditions unrelated to the patient's terminal illness, unless the hospice has submitted a prior authorization form. This comes on top of numerous other regulatory and paperwork requirements that CMS has imposed on hospice providers in recent years. While some of these requirements may be necessary to prevent fraud, I cannot understand why CMS would want to send patients nearing the end of life, and their families, the message that enrolling in hospice could mean losing access to all of their prescription drugs. Will you commit to review this policy and take steps to ensure it does not harm patients' access to appropriate care?

Answer: It is my understanding that the CMS guidance requires Part D plans to speak with hospice providers to document why a drug is not related to a beneficiary's terminal illness. Beneficiaries will continue to have access through Part D for these unrelated drugs.

Additionally, CMS is soliciting comments on processes that Part D plan sponsors could use to coordinate with Medicare hospices in determining coverage of drugs for hospice beneficiaries and resolving disagreements between the parties in a proposed rule issued on May 8. In addition, through the rulemaking process, the agency is seeking comment on definitions of "terminal illness" and "related conditions" in order to strengthen and clarify the current concepts of holistic and comprehensive hospice care under the Medicare hospice benefit. I look forward to understanding and addressing the concerns raised by the comments received through this process if confirmed.

21. Is it currently OMB's official position that the Department of State's proposed Foreign Affairs Security Training Center (FASTC) project represents the most cost-effective use of taxpayer dollars for the enhancement of the federal government's diplomatic security training capacity? If the answer is yes, please provide the date on which OMB made this decision and include a timeline for the decision-making process.

Answer: OMB's role in reviewing the State Department's proposal for a new diplomatic security training facility was to ensure that due diligence was done in reviewing alternatives before final selection of a new facility. To that end, we worked with the State Department and FLETC to look for alternatives that could provide the quality of training that the State Department was seeking at lower cost. The State Department determines its diplomatic security

training needs, and the final decision on the location of the new training facility remained with the State Department.

- 22. Did OMB, at any point in its analysis of this issue, come to a conclusion that was different than the current official position relating to the proposed FASTC project (i.e., did OMB at any point determine that the Federal Law Enforcement Training Center (FLETC) or any other options were more cost-effective)?**

Answer: OMB's role in the project, as explained in the answer to the question above, was to facilitate the analysis of alternatives. The State Department believed that FASTC best met their training needs, and OMB relied on the State Department's expertise on security issues.

- 23. Did OMB receive any instructions or feedback, or experience any pressure, from either the White House Office (WHO), Executive Office of the President (EOP), Department of State, General Services Administration (GSA), or any other federal agency officials or personnel, to alter or disregard any internal analysis in order to approve the Department of State's proposed FASTC project?**

Answer: OMB did not receive any instructions or pressure from any officials in the executive branch to alter or disregard any analysis related to FASTC.

- 24. The Department of State has informed congressional personnel that they currently estimate the cost of the Department of State's proposed FASTC project to be approximately \$461 million. It is our understanding that the Department of State has current funding, accumulated during previous fiscal years that it could potentially apply to the design and construction costs of the proposed FASTC project. What is the specific dollar amount of this existing funding? Given that the Department of State does not currently have the total dollar amount necessary to fund the design and construction of the proposed FASTC project, is OMB at all concerned about the inherent risk in commencing construction in the absence of all necessary funding (and without an existing congressional commitment to supply additional funding)?**

Answer: According to the State Department, there is \$123 million currently available for use on the project. In general, Administration policy for the construction of facilities requires appropriations be fully available to pay for all usable segments of projects when construction begins. However, for this facility, the timing was not in sync to complete the review of alternatives and to prepare the FY 2015 Budget. Given that the Department has additional planning and study work to perform before it begins construction, it was important for the Department to move forward this spring with its final design steps rather than wait an additional budget cycle.

- 25. What is OMB's official assessment with regard to the Department of Homeland Security's proposal to expand an existing FLETC facility to accommodate federal diplomatic security training needs at an estimated cost of \$272 million?**

Answer: The staff at FLETC prepared an alternative training facility proposal for the State Department to consider. Ultimately, the State Department determined that the proposed FLETC facility did not fully meet their training needs.

26. Will you commit to having relevant OMB staff brief my staff on the Department of State's proposed FASTC project?

Answer: OMB's role in reviewing the State Department's proposal for a new diplomatic security training facility was to ensure that due diligence was done in reviewing alternatives before final selection of a new facility and OMB continues to work with State Department in helping it achieve its training needs. The State Department, however, has the expertise in the diplomatic security training needs addressed by its FASTC project. The State Department is the most appropriate agency to brief your staff on the issue of FASTC and OMB will work with the Department to set up a briefing.

Senator Burr:

Questions for the Witness:

- 1. What opportunities do you believe exist to streamline the review of states' Medicaid waivers? As OMB Director, what shortcomings with the current administrative waiver processes have you seen firsthand? If confirmed, will you take steps to implement administrative reforms within the Administration to ensure that states have timely decisions on pending waivers?**

Answer: I understand that HHS has taken steps to streamline the application process for section 1115 demonstrations and enhance transparency in the review process through rulemaking and other administrative actions. At the federal level, HHS and OMB are working to improve and streamline collaboration in the review of section 1115 demonstrations. If confirmed, I will work to ensure that review of demonstration applications will proceed in a timely and responsive manner.

- 2. I regularly hear concerns from my constituents regarding Medicare's audits and appeals processes. How do you think the audits and appeals processes could be administratively improved to ensure that the burden and costs associated with these processes strike a more appropriate balance? How will you ensure that providers are afforded fair and due appeals processes and not penalized during or prior to completion of their appeals process?**

Answer: While I have not directly worked on this issue in my role as OMB Director, if confirmed, I am committed to addressing this challenge. It is my understanding that the Department has formed an intra-agency workgroup tasked with developing recommendations to improve the audits and appeals process. I also understand that the Department is working diligently to identify short and long-term solutions that can be implemented expeditiously. If confirmed, I will support this effort.

3. The Congressional Budget Office estimated that the Affordable Care Act's risk corridor program could generate an \$8 billion surplus over the next three years. This surplus would be deposited into Treasury's general fund and used to pay down the debt. The President's Fiscal Year 2014 budget treated the program in similar fashion in that payments from insurers were deposited into Treasury's general fund. However, the President's Fiscal Year 2015 budget request reclassifies the risk corridor spending and payments from insurers so that the Secretary of HHS would be able to use any surplus generated from the program to finance the Administration's priorities without seeking Congressional approval.

A. Please explain why the Administration changed the budgetary classification of the risk corridor program in the President's latest budget submission and, with this proposed change, the full extent of how the Administration intends to use these funds.

B. What will happen in the event that risk corridor collections are insufficient to pay for all risk corridor payments? How will potential premium impacts be taken into consideration as the Administration weighs potential options in the event of this scenario?

Answer: The temporary risk corridor provision in the Affordable Care Act is an important safety valve for consumers and insurers as millions of Americans transition to a new coverage in a brand new Marketplace. For consumers, the program will play an important role in mitigating premium increases in the early years as issuers gain more experience in setting their rates for this new program. The FY 2015 Budget categorizes the program as discretionary offsetting collections and spending authority from those collections, consistent with other collections and spending activities in CMS's budget. HHS will implement the risk corridor program as a discretionary user fee program under the Centers for Medicare and Medicaid Services (CMS) longstanding user fee authority. Collections from the Risk Corridor program are not available to fund other CMS Program Management activities.

Current budget projections, including those by the Congressional Budget Office, anticipate that money collected from the risk corridor program will be sufficient for payments, allowing the program to be administered in a budget neutral manner during the three years for which it is authorized. In the unlikely event of a shortfall for the 2015 program year, HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers. In that event, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

4. Earlier this year, the Administration put out regulations that would fundamentally change the Medicare Part D program, including eliminating the six protected classes. These proposed changes were met with widespread and significant concern, such that the Administration indicated they would not move forward with finalizing these proposals at this time. If confirmed, would you ensure that the principles that have made the Part D program successful would continue to be advanced? Would you ensure that any proposed changes to the Part D program would be considered through a formal rulemaking process, including issuing a new proposed rule in the event any of the proposals put forward earlier this year are revisited?

Answer: It is my understanding that CMS has indicated they do not plan to finalize the following provisions of the proposed rule that you referenced:

- Lifting the designation of antipsychotics, antidepressants and immunosuppressants for treatment of transplant rejection as drug classes of clinical concern;
- Requiring Part D sponsors to accept any willing pharmacy in their preferred pharmacy networks;
- Setting new limits reducing the number of Part D plans a sponsor may offer; and
- Clarifying the statutory non-interference provision in regulation.

In the event that CMS make these or similar proposals again, the agency would only do so as part of a new rulemaking process, during which it would solicit public comment once more before deciding whether to publish final regulations. If confirmed, I will ensure CMS continues to use the notice and comment rulemaking process before making changes to Part D regulations.

5. **The Patient Protection and Affordable Care Act included a provision (section 3141) that essentially resulted in increased Medicare payments to hospitals in just several states to the detriment of hospitals and beneficiaries in every other state. My constituents have expressed concern to me that under the most recent Centers for Medicare and Medicaid Services' (CMS) proposed rule implementing this provision, 441 hospitals would benefit while 2,947 hospitals would potentially see reduced payments in Fiscal Year 2015. It is my understanding that CMS staff have previously referred to this provision as a "manipulation" of the payment system. Do you agree that this provision should be repealed to provide for a more fair distribution of Medicare payments to hospitals?**

Answer: While I have not been engaged on this issue during my tenure as OMB Director, if confirmed I look forward to learning about this issue and working with you to address any inequalities that currently exist.

Senator Roberts:

Questions for the Witness:

1. **One of the many taxes imposed by the Affordable Care Act that is of concern to me is the health insurance tax. This is a tax levied on all health insurers, but as the Congressional Budget Office has pointed out, it will largely be passed through to consumers in the form of higher premiums. Do you support eliminating this tax, which the Joint Committee on Taxation has estimated could decrease the average family premium in 2015 by \$350 to \$400?**

Answer: It is my understanding that the annual fee assessed on health insurance providers under section 9010 of the Affordable Care Act is administered by the Department of Treasury and Internal Revenue Service. I therefore respectfully refer to those agencies for further information regarding this issue.

2. **This tax will also be levied on Medicaid managed care plans. Because of this, the cost for these beneficiaries will increase by approximately \$1,500 per enrolled over the next 10 years and states relying on Medicaid managed care plans will bear up to \$14.9 billion in additional costs. Does it make sense to create a tax that will in turn be paid by the government through increased reimbursement rates? Or was the intent to create a new mechanism where states have to transfer money back to the federal government because part of the increased plan rates will be paid by the states?**

Answer: If confirmed, I look forward to understanding how the implementation of this provision specifically impacts Medicaid managed care plans and states and what additional guidance, if any, is required to ensure these entities have the information they need. For questions regarding the implementation of the tax, I would respectfully refer you to the Department of Treasury.

3. **In recent months, the former Secretary of Health and Human Services was questioned by Congress about transparency issues on the exchanges, specifically whether or not an individual can determine if a plan covers abortion. On many of the exchanges, the summary of benefits does not indicate whether or not the plan covers abortion. Do you agree that plan benefits should be transparent? If you were confirmed as secretary would you use your authority to enforce the law and insure this information is disclosed?**

Answer: I understand that CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. Additionally, each plan in the Marketplace must include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. If confirmed, I will continue the work of the CMS to assure that consumers have access to information regarding the coverage they are purchasing in the Marketplaces.

4. **When Secretary Sebelius testified during a subcommittee hearing of the House Energy and Commerce Committee last October, she promised to provide Congress with a list of federal insurers on the exchange that do and do not include abortion coverage in their plans. To date, Congress has not received that information. If you were confirmed as the next HHS Secretary, would you be willing to provide Congress with that information?**

Answer: As OMB Director, I was not directly engaged on this topic. I understand that CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. Additionally, each plan in the Marketplace must include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. If confirmed, I will continue the work of the CMS to assure that consumers have access to information regarding the coverage they are purchasing in the Marketplaces.

5. **In March, CMS Administrator Marilyn Tavenner notified Congress that certain provisions of the January 2014 Medicare Part D proposed rule would not be**

finalized. One of those proposals was to remove protected status for three of the six Medicare Part D protected classes- antidepressants and immunosuppressants in 2015, and antipsychotics in 2016. While the protection of the six classes will remain part of the program through the 2015 plan year, there was an indication that CMS might revisit the six protected classes policy in the future. Do I have your assurance that the existing protections for the current six protected classes will remain intact during your tenure as Secretary?

Answer: The proposed rule included many important provisions designed to strengthen the Medicare Part D program and reduce costs to beneficiaries and taxpayers. Congress and other stakeholders raised important concerns about some of the proposals, in particular the proposal to list the protected class definition from three drug classes. Given the complexities of these issues and stakeholder input, I understand CMS' final rule will not finalize these proposals.

Given the importance of access to medication, if confirmed, I will be supportive of CMS' efforts to continue to strengthen their review processes and appeals protections to ensure that beneficiaries have access to medically necessary prescription drugs at a reasonable cost.

- 6. The United States Preventive Services Task Force (USPSTF) recently gave a grade of "B" to annual Low Dose CT Screening Tests (LDCT) for patients at high risk of developing lung cancer, those between the ages of 55 and 80 who have a long history of tobacco use. As a result of this grade, private payers selling plans on the health insurance exchanges will be mandated to cover this screening test at no cost to the patient. HHS initiated a National Coverage Determination process and on April 30th convened a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) hearing to review the USPSTF's recommendation. This small group of outside analysts chosen by CMS staff recommended against LDCT coverage for the Medicare population. Which HHS advisory committee will you support concerning Medicare coverage for LDCT lung cancer screening – USPSTF or MEDCAC? Would you be comfortable allowing private insurance coverage of lung cancer screening for younger, high risk patients while not allowing the same preventative benefit for our seniors who may be even more vulnerable to this disease due to their age and co-morbidities?**

Answer: Although I have not had direct involvement with this subject as OMB Director, I understand that the Medicare statute gives the Secretary authority to add coverage of new Medicare preventive benefits if the service is given an A or B recommendation by the U.S. Preventive Services Task Force (USPSTF), and is found through the national coverage determination process to be "reasonable and necessary" for the prevention or early detection of an illness or disability, and to be appropriate for Medicare beneficiaries. Thus a USPSTF recommendation is a necessary prerequisite for consideration of Medicare coverage but does not, by itself, meet all the statutory criteria for such coverage.

I further understand that Medicare's national coverage determinations are based on a comprehensive, evidence-based, transparent process with multiple opportunities for public input. In some cases involving new or complex services, CMS may request an outside assessment

and/or review by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). Each of these elements is just one part of a larger process aimed at assessing the best available evidence, and provides an opportunity for independent experts to supplement input from other sources. I appreciate your concerns about the MEDCAC's conclusions in this particular case, and invite you and your constituents to make those concerns known to CMS during the public comment period that will follow release of a proposed coverage decision later this year.

- 7. As implementation of the Affordable Care Act (ACA) continues, one of the key issues that my constituents have raised is continued access to their current physicians. In particular, the networks established by many of the Exchange plans seem to be limited in their coverage of specialty physicians. What steps would you take as HHS Secretary to ensure that there is continued access to key providers, including specialty physicians?**

Answer: I understand that all qualified health plans (QHPs) must maintain a provider network that ensures that all covered services are available without an unreasonable delay. Ensuring that individuals have access to an adequate network of providers is a very high priority for this Administration and would be for me if confirmed. It is my understanding that CMS intends to closely monitor the market for any complaints involving enrollee access to covered services. I also understand that CMS has strived to implement Marketplace and QHP regulations creating a strong federal floor, but allowing states and issuers flexibility to innovate. Thus, while issuers must adhere to new network sufficiency and essential community provider standards, they still have room to make business decisions that work for them.

It is my understanding that in Federally-facilitated Marketplace states, CMS will now assess provider networks using a "reasonable access" standard, and will identify networks that fail to provide access without unreasonable delay, as required by federal regulations. In order to determine whether an issuer meets the "reasonable access" standard, CMS will focus most closely on those areas which have historically raised network adequacy concerns (e.g., hospital systems, oncology providers, primary care providers and mental health providers).

- 8. I have concerns that the Center for Medicare and Medicaid Innovation (CMMI) could enable CMS to circumvent existing patient protections and use "cost" such as cost-effectiveness standards or the "least costly alternative" to determine coverage policies. What steps have you taken to ensure that, as CMS tests payment models under CMMI, it preserves beneficiary access to treatment options, supports informed beneficiary decision-making, and does not limit beneficiary choices based on cost-effectiveness standards?**

Answer: CMS' first and most important responsibility is to ensure that its beneficiaries receive appropriate, high-quality care. CMS tests innovative models that preserve or enhance the delivery of care. It is my understanding that the Innovation Center models encourage providers to work together to provide more coordinated care to their patients. The statute requires that all Innovation Center models must be expected to preserve or enhance the quality of care and that models may not be expanded unless the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits.

The Innovation Center models promote beneficiary engagement without limiting choice. If confirmed, I will ensure that beneficiaries continue to have access to benefits to which they are entitled.

9. A February 2012 Congressional Research Service report confirms that “there are no references in statute to any external reviews or checks on the CMS administrator’s definition of “improving care” when it tests new payment models in the CMMI. I’m concerned that, without full transparency in this process, CMMI demonstrations could result in hidden harms to patients including the possibility of rationing. Can you describe the type of activities underway to protect patients? For example, how will CMS ensure that cost savings maintain or improve care access and quality? And, how is CMS soliciting broad stakeholder input to ensure the demonstrations do not undermine care quality or reduce beneficiary access?”

Answer: I understand from HHS that since its formation, the Innovation Center has held numerous regional meetings and listening sessions, engaging thousands of innovators from around the country. In addition, the Innovation Center has used Requests for Information to solicit ideas for payment and delivery models from stakeholders around the country. Hundreds of ideas for improving health care have been shared through the Innovation Center web site. The Innovation Center has also sought input from experts and stakeholders in the design of individual models. The details of each Innovation Center model, including consideration of how the model will preserve or enhance quality of care for beneficiaries is located on the Innovation Center web site to allow for transparency. If confirmed, I will work to ensure that the Innovation Center continues to solicit broad stakeholder input to ensure that models maintain or improve quality.

10. Recently, the OIG report found that uninsured patients served by the 340B program are not receiving the 340B price. I’m concerned that the program is failing to serve the most vulnerable patients. The OIG Report stated: “Eight of thirty covered entities reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements...All but one administrator reported being able to allow covered entities to offer the discounted 340B price to uninsured patients at contract pharmacies; however, some covered entities choose not to do so. Seven of the eight covered entities are DSHs.” The Health Resources and Services Administration (HRSA) is currently working to formalize program guidance through a regulation on the 340B Program. Will you make it a priority to ensure the HRSA rule establishes clear guidance and appropriate guardrails to help maintain the integrity of the 340B program?”

Answer: HHS recently submitted a rule on the 340B program for OMB review. It is OMB’s longstanding policy not to comment on rules under review. That said, we would welcome you or your staff to come in and share your views on the rulemaking with us, and updated information on the status of any review can be monitored at: www.reginfo.gov.

11. On March 10, 2014, CMS issued a memo outlining clarifications, final guidance and directives regarding the processing of Part D payment for drugs for patients enrolled in

hospice. I have heard from hospice caregivers in my state that the rollout of this final guidance has been very rocky, at best. Part of the instructions included "Hospice-Provider-Initiated Prior Authorizations (PAs)." Providers of hospice should be held accountable for paying for all drugs that are related to the terminal illness and related conditions, and all drugs unrelated to the terminal illness and related conditions should be paid for by Part D. What is disputed, however, is CMS' new broad, sweeping clarification of "relatedness." Will you commit to working collaboratively with Part D plans and hospice communities on this issue, including stakeholder meetings with all affected parties present such as hospice providers and Part D plans, to determine how best to achieve the stated policy goals without further disruption and confusion for stakeholders and beneficiaries?

Answer: Yes, if confirmed I look forward to working collaboratively with all stakeholders on this issue. It is my understanding that CMS has requested comments on changes the agency considering to the hospice regulations, including definitions for the terms "terminal illness" and "related conditions" and requirements for hospices to coordinate with Part D sponsors and is encouraging both Part D sponsors and hospice providers to provide input to inform the agency's decision making process.

12. Under the Affordable Care Act, the Stars program for rating Medicare Advantage boasts the ability to terminate plans and force beneficiaries from plans they like and enjoy this Fall despite some questions regarding the inherent methodology. Nearly 1 million seniors across the country will again not be able to keep their plan as they were promised if this happens. As Secretary, will you pause these terminations until the measures are appropriately updated?

Answer: The Medicare Advantage program is strong. Since the Affordable Care Act was passed in 2010, Medicare Advantage premiums have fallen by nearly 10 percent and enrollment has increased by 38 percent to an all-time high of more than 15 million beneficiaries. Today, nearly 30 percent of Medicare beneficiaries are enrolled in a Medicare Advantage plan. Furthermore, enrollees are benefiting from greater quality as over half of enrollees are now in plans with 4 or more stars, a significant increase from 37 percent of enrollees in such plans in 2013. If confirmed, I will ensure that the Medicare Advantage program remains strong, beneficiary protections are maintained, and we take stakeholder concerns into consideration as we continue to improve and refine the Medicare Advantage quality rating system.

13. Last year, the Administration issued a regulation to cut home health care that derived directly from the Affordable Care Act. Specifically, this regulation cuts Medicare funding for home health services by 3.5% per year in 2014 through 2017, totaling an extraordinary 14% cut. Avalere Health projects that 42% of the home health agencies in my state alone will suffer net losses by 2017 as a result of this regulation. Do you believe you would have the statutory authority under Section 1871 of the Social Security Act to fix this regulation retroactively? If confirmed, will you commit to taking a closer look at this rule and seeing whether additional analysis can be done and whether the requirements of the Affordable Care Act have to be met using the drastic cuts under the final rule or whether there is some other way to get those savings?

Answer: This is not issue on which I have been engaged as OMB Director, and if confirmed, I look forward to learning more about it. It is my understanding from HHS that the rebasing policy is required by the Social Security Act. In the CY 2014 Home Health PPS Final Rule, CMS estimated that of the approximately 40 percent of home health providers predicted to have negative Medicare margins in CY 2017, 83 percent reported negative Medicare margins in 2011. Therefore, many home health agencies that were operating with positive Medicare margins are expected to continue doing so based on the analysis in the Final Rule.

I further understand that in its March 2013 Report to Congress,^[1] MedPAC stated that during the interim payment system, when payments dropped by about 50 percent in two years, many agencies exited the program. However, new agencies entered the program (about 200 new agencies a year) and existing agencies expanded their service areas to enter markets left by exiting agencies. MedPAC reviews found that access to care remained adequate during this period. In addition, since their 2011 Report to Congress, MedPAC has consistently recommended accelerating the rebasing of home health payments by phasing-in these adjustments over 2 years instead of 4 years.

In the economic impact assessment section of the CY 2014 Home Health PPS Final Rule, CMS estimated that HHAs will experience an overall 1.05 percent decrease in payments in CY 2014. While CMS does not anticipate significant negative impacts of this rule, I understand that MedPAC will conduct a study on the rebasing implementation, which will include impact analysis on access to care and quality outcomes, and will submit a Report to Congress. If confirmed, I will ensure CMS closely monitors the effects of these payment adjustments on beneficiaries' access and quality of care.

Senator Grassley:

Questions for the Witness:

Sunshine Act Implementation

The Physician Payment Sunshine Act is intended to bring greater transparency to physician payments. It requires CMS to create a website that will list all of the payments physicians receive from the medical industry. Disclosure is very important, but it requires context. There are concerns that CMS will not include enough information to describe what kind of payments physicians received. Secretary Sebelius has said that context is critical, but it is still unclear how exactly CMS will address this issue. Also, while providers have the opportunity to dispute the reported information, it is unclear what will happen if disputes cannot be resolved or the timeline for resolution.

Additionally, there are concerns about whether the payment website will allow all covered entities to submit their data, or whether large volumes of data could cause problems with the system. According to the lead contractors developing the Open Payment

^[1] http://www.medpac.gov/documents/Mar13_EntireReport.pdf

website, reporting entities will have to upload their data by June 30th. Then providers will review the data and any disputes must be refilled.

- 1) How do you think the issue of context should be addressed for physician payments?
- 2) Do you know what kind of context will be provided?
- 3) Will there be an opportunity for the public to comment on CMS's rules on context? If not, why?
- 4) Is CMS doing anything to alleviate potential chokepoints in the data uploading process by requiring staggered reporting for covered entities?
- 5) When the reported data becomes available for providers to review, is CMS doing anything to prepare for the volume and avoid any system problems or overloading?
- 6) What is CMS's role in resolving disputes between reporting entities and providers?
- 7) Is CMS going to do any oversight of the dispute resolution process? In particular, will CMS compare the originally submitted information to the final information?

Answer 1-7: Although I have not had direct involvement with the implementation of the Physician Payment Sunshine Act ("Open Payments") as Director of OMB, I understand from HHS that implementation is underway. This program is one of many Affordable Care Act initiatives designed to create greater transparency in the health care market. The program's goal is to increase public awareness of financial relationships between drug and device manufacturers and certain health care providers.

CMS is leading the effort to implement the Open Payments program and will maintain the publicly accessible website where all the information regarding the financial relationships between drug and device manufacturers and certain health care providers will be available.

If confirmed, I will work to ensure that the implementation of the Open Payments program proceeds in a manner that is expeditious while also allowing time for sufficient stakeholder input.

Audit Contractors

There have been numerous complaints about contractors auditing Medicare claims, including the recovery audit contractors (RACs), Medicare audit contractors (MACs), qualified independent contractors (QICs) and zone program integrity contractors (ZPICs). Providers have raised concerns about inconsistencies between contractors, lengthy appeals, and lack of information and transparency from both the auditors and CMS. In January 2014, the Office of Medicare Hearings and Appeals (OMHA) decided to suspend administrative law judge review of audit appeals for at least two years due to a backlog of nearly half a million appeals.

In addition to the appeals delay, the current RAC contracts are supposed to be rebid this year. In anticipation of the rebidding, in February 2014 CMS began to "transition down" the current RAC contracts by instructing RACs to finish their outstanding work but not open any new reviews. However, the timeline for awarding contracts has been delayed several times and it is now unclear how long the RAC program will be suspended.

- 1) If you are confirmed as Secretary of HHS, do you expect to make changes to any of the audit contract programs? If yes, please explain what changes you would like to implement. If no, please explain why not.
- 2) What changes can you make to the audit contract programs using existing authority, and what changes would require new law?
- 3) What is the time frame for rebidding the RAC contracts?
- 4) If you are confirmed, would you allow the existing RACs to open new reviews while the rebidding process takes place?
- 5) If you are confirmed, will you take steps to reform the audit appeals process? If yes, please explain what changes you would make. If no, please explain why not.
- 6) If you are confirmed, will you take steps to increase the transparency of auditors and CMS to give providers more consistency and information about the process? If yes, please explain what changes you would make. If no, please explain why not.

Answer 1-6: The Medicare Fee-for-Service Recovery Audit program (or “RAC” program) has returned billions in improper payments to the Medicare Trust Fund. It is my understanding that CMS has and continues to take steps to improve the program. As OMB Director, I have not been involved in this or any other procurement process at HHS. However, I have been told by HHS staff that CMS is currently in the procurement process for the next round of Recovery Audit Program contracts and plans to award these contracts this year.

It is also my understanding that the Department has formed an intra-agency workgroup tasked with developing recommendations to improve the audits and appeals process. The Department is working diligently to identify short and long-term solutions that can be implemented expeditiously. And if confirmed, I will certainly support this effort.

Qualified Health Plans

The Social Security Act defines a “federal health care program” as any plan that is funded in whole or in part by the federal government. However, the Administration has decided that qualified health plans are not federal plans, even though they are paid for in part by federal subsidies. This decision exempts the qualified health plans from important anti-kickback provisions in the law.

- 1) Would a hospital or other third party be allowed to pay insurance premiums for individuals without the payment being considered a kickback?
- 2) Would a hospital or other third party be allowed to pay insurance co-pays and deductibles without the payments being considered a kickback?
- 3) What is the reasoning behind the Administration’s decision on the qualified health plans?

Answer 1-3: If confirmed, I look forward to better understanding and engaging in this important issue. It is my understanding that HHS has carefully considered this question and has concluded that qualified health plans (QHPs) are not federal health care programs. This conclusion was based on careful review of the definition of “federal health care program” in consultation with the Department of Justice.

The Administration is taking steps to protect consumers and ensure robust oversight of Affordable Care Act programs. It is my understanding that the HHS Office of Inspector General has jurisdiction to audit, investigate, and evaluate HHS-administered programs in Title I of the Affordable Care Act, as well as investigate the affairs of a Marketplace. The Affordable Care Act also expressly provides for the False Claims Act to apply to any payment made by through, or in connection with a Marketplace if the payment includes federal funds. All of these protections are in addition to federal and state criminal and civil authorities that apply regardless of whether a program meets the definition of “federal health care program”.

With respect to your questions about hospitals paying premiums or cost sharing for enrollees qualified health plans, I understand that, in November 2013, CMS released guidance regarding third party payments of premiums and cost-sharing obligations for QHPs in the Marketplaces. I believe that guidance articulates CMS’ concern about the possibility of hospitals, other health care providers, and other commercial entities supporting premium payments and cost-sharing obligations because it could skew the insurance risk pool and create an uneven competitive field in the Marketplaces. This guidance also clarifies that the CMS intends to monitor this practice and, if necessary, will take appropriate action.

Decrease in CMS Oversight Funds

In May 2014, the OIG deputy inspector general for audit testified before Congress that its Medicare and Medicaid oversight activities will be cut by 20 percent in FY 2014. This would severely impact the agency’s ability to combat waste, fraud, and abuse in these programs. It would also make it more difficult to identify improper payments. In FY 2013, Medicare and Medicaid issued \$64.3 billion in improper payments, accounting for over 60 percent of *all* federal improper payments made that year.

- 1) If confirmed, would you approve the 20 percent in cuts to oversight activities for Medicare and Medicaid in FY 2014? Why or why not?**

Answer: The Office of the Inspector General (OIG) is a key component of CMS’s efforts to protect the integrity of Medicare and Medicaid, as well as the health and welfare of the public. Shortfalls in appropriations compared to the President’s Budget requests in recent years, coupled with the effects of sequestration, has limited the scope of OIG’s activities. I support the President’s FY 2015 Budget Request to increase funding for OIG by \$105 million over the FY 2014 enacted levels to provide OIG with the resources it needs to target oversight efforts of HHS public health and human services programs.

- 2) Do you have any proposals to increase efficiency at HHS in order to do more with fewer resources? If so, please describe them.**

Answer: I believe that all government agencies should constantly seek better ways to ensure that they are spending taxpayer dollars as efficiently as possible. If confirmed, I look forward to evaluating strategies to better coordinate program integrity efforts across the Department.

3) What actions would you take as Secretary to increase the efficiency of the Medicare and Medicaid programs?

Answer: I welcome the opportunity to continue the work of the Department in developing methods by which Medicare and Medicaid can best serve the beneficiaries that receive care through these important programs, while also protecting their long-term fiscal sustainability. One of the core principles of the President's FY 2015 Budget Request is promoting government management that delivers improved services that are more effective, efficient, and supportive of economic growth. The Budget proposes additional targeted reforms to Medicare, Medicaid and other federal health programs that are projected to save \$402 billion over the next decade. These reforms will improve the long-term sustainability of Medicare and Medicaid by increasing the efficiency of health care delivery without compromising the quality of care for the elderly, children, low-income families and people with disabilities. If confirmed, I look forward to working with the Congress to meet these goals.

4) What actions would you take as Secretary to reduce improper payments within the Medicare and Medicaid programs?

Answer: I share your commitment to protecting Medicare and Medicaid beneficiaries and ensuring oversight and prudent use of federal funds in these programs. As with other programs, CMS must follow a number of statutory requirements including risk assessments and, when applicable, reporting an improper payment rate and implementing corrective actions. In addition, I understand that CMS is responsible for establishing internal controls to provide assurance for effective program operations, reliable financial reporting, and compliance with laws and regulations. If confirmed, I will look for ways to improve and expand current efforts aimed at reducing improper payments in these programs.

In service of this effort, I would encourage Congress to provide sufficient funding for key operational activities – and in particular, program integrity efforts. These efforts will help ensure accurate and timely payments, and remediate erroneous payments should they occur.

Research Integrity at HHS

I have been investigating a case of research misconduct that happened at Iowa State University, where a researcher committed fraud to make it seem as though his team created a vaccine that fought HIV. This case was reviewed by HHS's Office of Research Integrity (ORI). My investigation raised questions about ORI's role and authority within HHS. It appears that bureaucratic red tape is keeping ORI from being more effective at its mission. In February 2014, ORI Director Dr. David Wright resigned. In his resignation letter, he stated that up to 65 percent of his time was spent "navigating the remarkably dysfunctional HHS bureaucracy to secure resources and...get permission for ORI to serve the research community."

- 1. If confirmed as Secretary of HHS, would you investigate former Director Wright's comments about bureaucracy at HHS preventing ORI from doing its job?**

Answer: My goal, if confirmed, will be to ensure that all of the components of HHS are best positioned to deliver results and achieve the mission that Congress has established for their programs. I understand that under statutory direction from Congress and the regulatory framework, grant recipients have the primary obligation to conduct investigations of their own researchers, and must comply with regulatory policies and procedures that ensure due process; protection of all evidence relating to the misconduct; protection of public health, federal funds and equipment; the integrity of the Public Health Service (PHS) supported research process; and cooperation with the Office of Research Integrity's (ORI) oversight of the institution's response. ORI provides training and technical assistance to help institutions assess research misconduct allegations. ORI also has the responsibility to review the adequacy of the grantee institution's investigation, conduct additional analyses and develop evidence further, and the authority to recommend that HHS perform the investigation in the event that the grantee lacks the capacity to undertake an appropriate investigation or it is impracticable (for instance, where the grantee is too small an organization). If I confirmed, I will work with ORI to accomplish the vital role it plays in ensuring responsible conduct of PHS research activities and preserving public confidence in the integrity of biomedical and behavior research.

Medicare Part D

In March, CMS Administrator Tavenner notified Congress that certain provisions of the January 2014 Medicare Part D proposed rule would not be finalized. One of those proposals was to remove protected status for three of the six Medicare Part D protected classes- antidepressants and immunosuppressants in 2015, and antipsychotics in 2016. Thankfully, protection of the six classes will remain part of the program and patients will be well-served through the 2015 plan year. This was a good first step; however, I remain concerned about the ongoing protection of these six classes of medications. Included in CMS' March announcement, was an indication that CMS might revisit the six protected classes policy in the future. I would like your assurance that the existing protects for the current six protected classes will remain intact during your tenure as Secretary.

1. Can you assure me that CMS will not pursue changes to the six protected classes?

In 2003 when Congress created the Medicare Part D drug benefit, there was a great deal of discussion both privately, in the Finance Committee and on the Senate floor about the importance of protecting patients with certain illness, namely mental illness, HIV, Cancer, epilepsy and organ transplant. The result of those discussions was a decision by CMS to create the protected classes policy. This policy ensures patients with those conditions access to all medications in the classes and categories. Then, in 2008, Congress put this policy into statute. And again, in 2010, the ACA reasserted that the current six protected classes enjoyed additional protections. Yet, the Department of Health and Human Services in January of this year attempted to institute a new policy that would have reversed this long-standing and well-regarded policy and placed patient care in jeopardy.

Answer: I understand that the proposed rule included many important provisions related to the Medicare Part C and D prescription drug program. During the rule's comment period, CMS received numerous concerns about some elements of the proposal from members of Congress and stakeholders. In particular, there were concerns raised about the proposals to lift the protected class definition on three drug classes, to set standards on Medicare Part D plans' requirements to participate in preferred pharmacy networks, to reduce the number of Part D plans a sponsor may offer, and clarifications to the non-interference provisions. Given the complexities of these issues and stakeholder input, I understand CMS' final rule will not finalize these proposals.

In 2003 when Congress created the Medicare Part D drug benefit, there was a great deal of discussion both privately, in the Finance Committee and on the Senate floor about the importance of protecting patients with certain illness, namely mental illness, HIV, Cancer, epilepsy and organ transplant. The result of those discussions was a decision by CMS to create the protected classes policy. This policy ensures patients with those conditions access to all medications in the classes and categories. Then, in 2008, Congress put this policy into statute. And again, in 2010, the ACA reasserted that the current six protected classes enjoyed additional protections. Yet, the Department of Health and Human Services in January of this year attempted to institute a new policy that would have reversed this long-standing and well-regarded policy and placed patient care in jeopardy.

- 2. Can you explain what consultation you undertook with medical guides who treat individuals with these conditions, whether you consulted the FDA to understand the protocols related to each medication and whether there were any discussions with NIH, and particularly NIMH to understand the basic science of these conditions and how certain medications impact individuals differently?**

Answer: While I have not been engaged on this issue as OMB Director, I look forward to learning more about it if confirmed. It is my understanding that CMS has previously stated its intention not to finalize its proposed Part D regulation that would lift designation of antipsychotics, antidepressants and immunosuppressants for treatment of transplant rejection as drug classes of clinical concern and that, before pursuing a similar proposal again, would only do so as part of a new rulemaking process in which the agency would solicit public comment once more before deciding whether to publish final regulations.

In developing its proposal regarding the classes of clinical concern, it is my understanding that CMS convened a consensus panel of CMS pharmacists and the Chief Medical Officer for CMS, Center for Medicare to determine which categories or classes of drugs met the proposed criteria to qualify as a protected class. The panel was supported by contractors that performed background research and provided specific information on Part D utilization and analyses of widely-accepted treatment guidelines for each drug category or class, when available.

- 3. Can you provide me with communications between CMS and the National Institutes of Health, the CDC, and the Substance Abuse and Mental Health Services Administration on this subject?**

Answer: The Substance Abuse and Mental Health Services Administration and other components of HHS reviewed and provided comments on the proposal before it was published in the Notice of Proposed Rulemaking on January 10, 2014. I take the issue of transparency very seriously and, if confirmed, would work to ensure ongoing access to information.

A great deal of effort has been spent researching and documenting the financial benefit that is achieved through adherence to medications needed to treat complicated and expensive health conditions. Yet, in January, through a Department of Health and Human Services' regulation, a proposal was offered to limit access to certain medications covered under Medicare Part D. This policy was widely criticized and opposed by major medical guilds, patient organizations and Members of Congress. One of the reasons cited in those concerns was the harm limiting access to antidepressants, immunosuppressants and antipsychotics would have on adherence and ultimately would cost the Medicare program more money. Additionally, the policy advanced by CMS runs counter to a Congressional Budget Office (CBO) report issued in November of 2012 entitled, "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medicare Services," which states that access to prescription drugs under Medicare Part D actually saves money for Medicare due to patient adherence and better disease management. In your role as head of the OMB, you had to have considered the impact of the policy change on federal spending.

4. Did OMB believe that the potential savings in limiting access outweighed the cost to the Medicare program?

Answer: The proposed rule included many important provisions designed to strengthen the Medicare Part D program and reduce costs to beneficiaries and taxpayers. Congress and other stakeholders raised important concerns about some of the proposals, in particular the proposal to list the protected class definition from three drug classes. Given the importance of access to medication, I am supportive of CMS' efforts to continue to strengthen their review processes and appeals protections to ensure that beneficiaries have access to medically necessary prescription drugs at a reasonable cost.

3D Mammography

CMS still has not set a payment code for 3D mammography. While the FAQ last fall clarified that CMS would pay for 3D mammography using only the 2D mammography code, the absence of a payment differential remains a large problem. My offices has heard from several breast centers that they are less inclined to use 3D mammography with Medicare-eligible women because there is not a payment differential. Further, because there is not a separate 3D mammography code, there is no way for Medicare to collect quality/outcome measurements between 2D mammography and 3D mammography. I believe CMS needs to set a 3D mammography payment code and to make sure there is a differential between 2D mammography and 3D mammography that recognizes the increased time and cost of technology. Without a payment differential there is no payment incentive to give patients the screening technology that will better serve them by reducing call backs and improving early detection.

1. If confirmed, will you please see to it that this issue is given due consideration?

Answer: I agree that early and accurate detection of breast cancer is of extraordinary importance to women's health. While I do not have direct knowledge of the subject in the context of my role as OMB Director, I understand that CMS posted an FAQ that clarifies that Medicare covers all screening mammography -- including breast tomosynthesis that produces direct 3D Digital images -- and that providers can bill Medicare using available digital coding. I also understand that the AMA Current Procedural Terminology Editorial Panel is considering appropriate coding for breast tomosynthesis. If confirmed, I will work with the CMS on their valuation of new codes for breast tomosynthesis, when available.

HCQIS

I remain concerned that CMS may issue a Request For Proposals as early as this week that would limit competition for the Healthcare Quality Information System (HCQIS) IT contract. Congress continues to work toward health care policies that emphasize the quality of care delivered by our nation's health care providers. As we expand quality reporting requirements and tie more of a health care provider's Medicare reimbursement to quality of care, the importance of the HCQIS program will only grow. It seems imprudent to limit competition when such important work will be carried out via HCQIS. I am especially concerned that by using a preferential contracting method CMS could be setting up a repetitive cycle which would require a new contractor for every new contract.

1) Can you confirm that, by restricting the bidders to 8(a) contractors, any award winner will be excluded from a future contract renewal opportunity due to the size and scope of the contract?

Answer: As OMB Director, I have not been involved in this or any other procurement process at HHS. However, it is my understanding that the current contract for this work was awarded as a competitive 8(a) set-aside. If there is a reasonable expectation that offers can be obtained from at least two responsible small business concerns the procurement must be conducted as a set aside. In addition, in accordance with SBA guidelines when a procurement is awarded as an 8(a) contract, its follow-on or renewable acquisition must remain in the 8(a) Program. If confirmed, I look forward to learning more about this contract and working with you to ensure HHS funds are being used effectively.

2) Are you concerned that this could place unnecessary risk on CMS's quality programs by constantly shifting the HCQIS IT contract to new contractors?

Answer: As OMB Director, I was not involved in these type of procurement decisions, but I understand from HHS that the market research has been completed and the results support a reasonable expectation that the services required to support the HCQIS Infrastructure should remain in the 8(a) Program. It is also my understanding that CMS actively tries to meet the government-wide goal that 23% of the Agency's funds obligated via contracts go to small

business, where practicable. If confirmed, I look forward to learning more about this contract and working with you to ensure HHS funds are being used effectively.

Medicare Advantage Rate Release

On June 4, 2013, I sent a letter to you seeking information regarding the decision making on Medicare Advantage rates for 2014. The letter contained two questions and one document request. The July 3, 2013 response from OMB legislative affairs was totally inadequate and completely inconsistent with your commitments made to the Finance Committee in the hearing May 14. It completely ignored the two questions and the document request contained in my letter.

1. Before you are considered by the Senate, will you provide a substantive reply that is responsive to the individual questions and requests in my letter June 4, 2013 letter—consistent with the high standards you set for yourself and an agency you head?
2. Through information provided to me through the Department of Health and Human Services, I was able to document that at least 436 people in the Department were in possession of information regarding the final Medicare Advantage rates for 2014 before they were made public. Given the incredibly sensitive nature of the information and its material impact on a select few publicly traded companies, I question the appropriateness of delaying the release of such information for weeks while sharing it with a large number of government insiders. Such information should be released to the entire public in a fair and equitable manner as soon as it is available.
How many people at HHS and OMB were in possession of the information regarding 2015 Medicare Advantage rates prior to them being released to the public on April 7, 2014?

Answer: It is my understanding that the issue you raise is being investigated by federal authorities, including the HHS Office of the Inspector General. If confirmed, I look forward to learning more about the status and results of these investigations and will be committed to ensuring that HHS safeguards confidential and non-public information.

OMB and Market-Moving Information

On May 14, 2014, Senator Reed and I sent a letter to OMB seeking information about how OMB standardizes the release of market-moving data. The letter highlighted a recent audit conducted by the Department of Labor OIG, which noted that there is no specific statute that controls the release of market-moving information. As such, OMB's Statistical Policy Directive No. 4, which provides guidance on this issue, is the only controlling document in the federal government that outlines conduct for federal employees. While the Medicare Advantage rates referenced in my previous questions are arguably not statistical information, such market-moving information should also be released to the public in a fair and consistent process as soon as it becomes available. Senator Reed and I asked three questions about OMB's efforts to oversee compliance with Statistical Policy Director No. 4.

1. **Do you believe that a similar directive for market-moving information of a non-statistical nature should be considered to ensure public confidence in the fairness and integrity of government and the markets? Before you are considered by the Senate, will you provide a substantive response to our May 14, 2014 letter?**

Answer: As your question suggests, OMB has authority under the Budget and Accounting Procedures Act of 1950 and the Paperwork Reduction Act of 1995 to issue directives, standards, and guidance with regard to statistical policy. Statistical Policy Directive No. 3, *Compilation, Release, and Evaluation of Principal Federal Economic Indicators* designates 38 specific statistical series that provide timely measures of economic activity as Principal Federal Economic Indicators and requires prompt release of these indicators according to an established, publicly available schedule. The goals of the directive are to preserve the time value of such information, strike a balance between timeliness and accuracy, prevent early access to information that may affect financial and commodity markets, and preserve the distinction between the policy-neutral release of data by statistical agencies and their interpretation by policy officials. Statistical Policy Directive No. 4, *Release and Dissemination of Statistical Products Produced by Federal Statistical Agencies*, complements Statistical Policy Directive No. 3 by extending some of its provisions to non-market moving statistical products. The procedures in the directive are intended to ensure that statistical data releases adhere to data quality standards through equitable, policy-neutral, and timely release of information to the general public.

In terms of your specific question on non-statistical information, I do not yet have an opinion on whether a directive is necessary or helpful. In general, I believe that how the federal government handles potentially market-moving information is an important issue. We are reviewing your more detailed letter on these Directives, which we received a few days ago, and look forward to responding with all due speed.

Coverage Transparency

Many members of Congress believe that taxpayers deserve to know exactly what a healthcare plan will or will not cover. We need to be transparent with American consumers about the plans they are enrolling in, and that transparency should be extended to abortion coverage.

- 1) **If confirmed, will you make information available to consumers about healthcare plans that do or do not include abortion coverage on the healthcare exchanges?**
- 2) **Will you commit to ensuring that consumers are aware of abortion coverage before they purchase a healthcare plan?**
- 3) **Secretary Sebelius told Congress that she would provide a list of federal insurers on the exchange that do or do not have abortion coverage in their plans. Will you also commit to providing this information to Congress?**

Answer to 1-3: I understand that CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. Additionally, each plan in the Marketplace must include a Summary of

Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. If confirmed, I will continue the work of the CMS to assure that consumers have access to information regarding the coverage they are purchasing in the Marketplaces.

The Role of the States in Medicaid

Last Spring, the State of Iowa passed bipartisan, state-based health care reform, but it took the U.S. HHS until the last week of December to approve the State's associated waiver. This delay seemed to contradict the Administration's commitment to providing flexibilities to the states. Your approach to the role of the state creativity in Medicaid will be critical as Secretary.

- 1) In your opinion, what is the role of the states in the Medicaid partnership?**
- 2) How will you change the culture at HHS so states who want to put forward innovative state-based approaches do not run into unnecessary bureaucratic hurdles at the Federal level?**
- 3) If confirmed, what steps would you take to improve this process and remove barriers for states that come to CMS with innovative proposals to lower costs and improve care for Medicaid beneficiaries?**
- 4) How will you incorporate state by state best practices in HHS policy?**

Answer 1-4: States are at the core of the administration of the Medicaid program. In recent years, states have been granted waivers to test a variety of innovative models to deliver care to their Medicaid populations.

I understand that HHS has taken steps to streamline the application process for section 1115 demonstrations and enhance transparency in the review process through rulemaking and other administrative actions. At the federal level, HHS and OMB are working to improve and streamline collaboration in the review of section 1115 demonstrations. If confirmed, I will work to ensure that review of demonstration applications will proceed in a timely and responsive manner. I also look forward to evaluating the results of each of these models, and ensuring that we share these results with other states seeking to adapt their own Medicaid programs to better serve beneficiaries.

- 5) Do you believe there is a need for CMS to develop a pathway to permanency for successful state innovations?**

Answer: It is my understanding that section 1115 demonstration authority provides states flexibility to design and test policies that promote the objectives of the Medicaid program. These demonstrations can introduce new approaches to Medicaid service delivery and financing, which can lead to positive changes that can be shared with other States. As a state-based program, successful innovations in one state may not wholly transfer to another, but, if confirmed, I would work to ensure CMS continues to support learning amongst states, work directly with states that are interested in pursuing innovations that are working in other states, and consider how results of state-based demonstrations can influence broader Medicaid policy.

6) What do you see as the barriers to developing such a mechanism and, if confirmed, how would you address those obstacles?

Answer: As I indicated in response to the prior question, not all innovations that are successful in one state are wholly transferable to another. I also understand from HHS that there is no statutory authority to make 1115 demonstration permanent. That said, innovations can inform the creation and revision of Medicaid policy. If confirmed, I will work with CMS to better promote innovation amongst the states while protecting the integrity of the Medicaid program and its beneficiaries.

7) Do you believe that states should be allowed to share in federal savings directly attributable to their initiatives?

Answer: While I have not been directly engaged in this issue as OMB Director, I understand that CMS has been actively engaging states through guidance letters in ways to advance care delivery and payment models that improve health, improve care, and reduce costs within state Medicaid programs. As part of this guidance, CMS has had discussions with states on moving forward with shared savings programs that reward high performing providers that improve quality and lower cost. I understand that CMS is interested in individual state experiences and is committed to sharing these experiences amongst states so that all parties can understand how shared savings methodologies can be used to improve care and lower costs. If confirmed, I am interested in learning more about CMS' effort in the area of shared savings and how that work can be supported, expanded, or broadened, if appropriate.

8) If confirmed, how would you work with OMB to develop a shared savings methodology for statewide transformation efforts?

Answer: I understand from HHS that a number of states have embarked on exciting new initiatives to reward Medicaid providers for improved health outcomes, increased quality of care and lower program costs. CMS supports states in these efforts and has issued guidance to describe technical considerations for shared savings payment methodologies. In addition, CMS, through the State Innovation Models Initiative in the Center for Medicare and Medicaid Innovation, has engaged states that are interested in testing models for multi-payer payment and statewide health care delivery system transformation. CMS is working to both test and develop these initiatives directly with states and I am interested in seeing the results of this work. I also understand that the Financial Alignment Demonstrations offer states an opportunity to share in savings generated by state initiatives to improve care and reduce costs for individuals dually eligible for Medicare and Medicaid. If confirmed, I will evaluate the types of initiatives already underway at CMS and determine where those efforts are satisfactory and I also look forward to continuing HHS' work with its federal partners as we learn more about these initiatives.

Speech Generating Devices

On April 1, 2014 the Centers for Medicare and Medicaid Services (CMS) changed the manner in which it pays for Speech Generating Devices (SGDs) and certain power

wheelchair accessories. Under the change, called “capped rental,” people with ALS who need these technologies are required to rent them over a 13-month period, after which time they will own the device. Under the previous policy, people had the option to purchase the devices up front. While this switch may seem to be a minor change in policy, it will have significant impacts on patients.

Under capped rental, if people have an extended hospital stay or enter hospice or a nursing facility while they are in the 13-month rental period, Medicare payment will cease. The device must be returned to the vendor, forcing patients to either obtain a new one from the hospital, hospice or nursing facility, or pay the entire costs out-of-pocket. This will result in patients losing access to their personally programmed SGDs while they are institutionalized, during a time when their health is at the highest risk and when the devices are most needed to communicate with medical staff. These institutions generally do not currently provide SGDs and do not have staff experienced in providing SGDs. In addition, because SGDs are highly customized devices, designed and adjusted to meet the specific medical needs of each individual patient, they cannot readily be substituted with “off-the-shelf” technology. In short, the regulation will leave many patients with no way to communicate.

CMS has acknowledged that disruptions in service are likely to occur when patients are admitted to a hospital, SNF or hospice, and has indicated that the agency intends to develop a system to monitor these cases; however, the agency has not developed a plan to ensure continued access to SGDs for those patients who lose access to their device while institutionalized. Instead, CMS instructs patients to call 1-800-Medicare, something they are unable to do without an SGD.

1. Does CMS possess any regulatory flexibility to address this issue for people with ALS?

Answer: As I have mentioned, I am personally aware of the issues involved with caring for people with ALS. I do understand that patients may use long term durable medical equipment (DME) such as SGDs because of chronic conditions or permanent disabilities. While I have not been engaged in the discussion of Medicare policy in this area as Director of OMB, if confirmed I will work with CMS to ensure that they continue to carefully monitor beneficiary access such that beneficiaries are receiving medically necessary items and services.

Coverage of Obesity Treatment

On March 20, 2014, the Office of Personnel Management (OPM) issued guidance to Federal Employee Health Benefit program carriers informing plans that excluding coverage for obesity treatment services (citing FDA drugs specifically) based on lifestyle or cosmetic criteria is no longer permissible. In February, OPM issued guidance to Multi-State Health Plans stating that plans excluding coverage for obesity treatment services must provide OPM with a good rationale for not covering these services.

1. Will HHS issue guidance to state health exchange Qualified Health Plans along the same lines of OPM?

Answer: As OMB Director, I have not been personally engaged in the OPM guidance you reference, so I cannot speak to it specifically and would respectfully refer you to OPM for further information. However, as you may know, the Affordable Care Act requires qualified health plans to cover preventive services receiving a grade of A or B from the United States Preventive Services Task Force (USPSTF), without imposing cost sharing. I understand from HHS that the USPSTF currently recommends screening all adults and children aged 6 years and older for obesity. Specifically, they note that clinicians should offer or refer children and adolescents to comprehensive, intensive behavioral interventions to promote improvement in weight status. For adults, USPSTF recommends that clinicians should offer or refer patients with a body mass index above a certain threshold to intensive, multicomponent behavioral interventions. Because these recommendations received a “B” grade from the USPSTF, many health plans must cover them without imposing cost sharing.

Senator Crapo:

Questions for the Witness:

Part D

Given the proven success of Medicare Part D, concerns were raised when CMS proposed a rule in January that would have fundamentally changed the program. Following a letter my colleagues and I sent to Marilyn Tavenner, CMS agreed to withdraw the most problematic sections of the rule, including the elimination of three of the six Part D protected classes of drugs.

However, Administrator Tavenner implied the agency could revisit this proposal, which would be detrimental to seniors and to the program itself.

1. Can you identify specific benefits CMS believes will result from eliminating the Part D protected classes?
2. How will you consult with Congress prior to finalizing any rule that would dramatically change Medicare Part D?

Answer to 1 and 2: The proposed rule included many important provisions designed to strengthen the Medicare Part D program and reduce costs to beneficiaries and taxpayers. Congress and other stakeholders raised important concerns about some of the proposals, in particular the proposal to list the protected class definition from three drug classes. Given the complexities of these issues and stakeholder input, I understand CMS’ final rule will not finalize these proposals.

Given the importance of access to medication, if confirmed, I will be supportive of CMS’ efforts to continue to strengthen their review processes and appeals protections to ensure that beneficiaries have access to medically necessary prescription drugs at a reasonable cost.

The protected classes originate from the Part D non-discrimination language designed to ensure patients with certain serious diseases are not discouraged from enrolling in Part D plans. The same statutory language is found in the Patient Protection and

Affordable Care Act (PPACA), but there is no comparable PPACA policy yet for these "protected classes" of concern.

3. Will you encourage CMS to develop such a policy for PPACA's qualified health plans?

Answer: If confirmed, I would be happy to discuss concerns you may have regarding access to prescription drugs in qualified health plans. I understand from HHS that qualified health plans (QHPs) are subject to standards to ensure adequate coverage of prescription drugs. I also understand that plans are required to have an exceptions process to allow enrollees to request and gain access to clinically appropriate drugs not on a plan's formulary.

Similar in effect to the elimination of the protected classes, I have concerns about the Administration's Fiscal Year 2015 budget proposal to increase brand name co-pays for low-income subsidy (LIS) beneficiaries. As you know, the LIS population includes some of the most vulnerable Medicare beneficiaries. For these individuals, efficacy issues often present when switching between brand name and generic medication. Ultimately, we must ensure this population has access to necessary medication, be that brand name or generic.

4. What steps have you taken to ensure that, should this proposal be finalized, this population retains access to necessary medication?

Answer: Under this legislative proposal, low income beneficiaries could use the Part D exceptions and appeals process to pay a lower copayment if their doctor determined the brand name drug now assessed at a higher copay was medically necessary. If confirmed I look forward to working to ensure that all Medicare beneficiaries have access to necessary medication.

Preventative Health Care

In order to begin to address the projected insolvency of the Medicare program, reforms to the method of scoring preventative health care must be considered.

5. Do you have any objection to CBO implementing dynamic scoring for health care legislation?

Answer: The Administration believes current scoring methods provide the best estimates. While we think dynamic analysis can be a valuable supplementary tool for thinking through the effects of policy, similar to other types of supplementary analysis such as cost-benefit analysis or distributional analysis, our view is that is that depending on dynamic scoring to determine cost estimates of bills is far too uncertain.

6. In your opinion, would decreasing the prevalence of chronic conditions or ensuring the treatment of these conditions create savings in Medicare?

Answer: I appreciate the importance of ensuring that those with chronic conditions receive appropriate health care and if confirmed will work with CMS to continue to evaluate what more

we can do to ensure this is happening. Through the Center for Medicare and Medicaid Innovation, CMS tests innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for those individuals who receive Medicare, Medicaid, or CHIP benefits.

I understand from HHS that the Innovation Center's Independence at Home Demonstration is specifically focused on individuals with multiple chronic conditions. Under the Independence at Home Demonstration, selected primary care practices provide home-based primary care to targeted chronically ill beneficiaries for a three-year period. Home-based primary care may allow health care providers to spend more time with their patients, perform assessments in a patient's home environment, and assume greater accountability for all aspects of the patient's care. This Demonstration is designed to test if this focus on timely and appropriate care can improve overall quality of care and quality of life for patients served, while lowering health care costs by forestalling the need for care in institutional settings.

Obesity is often co-morbid with a variety of costly diseases, such as diabetes and ESRD. The Office of Personnel Management (OPM) recently announced coverage of weight loss medication cannot be excluded from Federal Employee Health Benefit plans. As Director of OMB, you were involved in that decision.

- 7. Legislation has been proposed to include Medicare coverage of weight loss medication. What considerations were made during the OPM decision that may be helpful when evaluating similar changes to Medicare?**

Answer: My understanding is that weight loss drugs are statutorily prohibited from Medicare Part D coverage. If confirmed as Secretary, I look forward to continuing to learn more about this issue, including the approach taken by OPM with respect coverage of such drugs under the Federal Employee Health Benefits Program.

Rural Health Care

The Administration has proposed various cuts to Critical Access Hospital (CAH) reimbursements and participation, including repealing CAH designation for facilities within 10 miles of another hospital. This would affect four hospitals in Idaho, two of which (Bingham Memorial in Blackfoot and Gritman in Moscow) are the largest and second largest employers in the communities they serve. These cuts have been proposed despite the fact that 40 percent of these small, rural facilities already operate with a negative profit margin.

- 8. What steps will you take to ensure rural residents continue to have access to health care services should CMS adopt this proposal?**

Answer: The issue of Critical Access Hospitals (CAHs) and care in rural communities is something I consider very important because of my background growing up in rural West Virginia. The proposals in the President's Budget are aimed at preserving beneficiary access while promoting payment efficiency. These proposals are aimed at reductions in cost-based

reimbursement only to those CAHs that are not the sole providers in their communities. If confirmed, I look forward to working with you to ensure that residents in rural areas have access to high quality health care and understanding what is happening on the ground more fully.

In rural and underserved communities, physician assistants (PAs) and nurse practitioners (NPs) frequently serve as primary care providers. Current CMS regulations that limit reimbursements for non-physician providers often create barriers to health care for these communities.

9. What can be done to guarantee regulatory burdens do not prevent access to care in rural areas?

Answer: I agree that physician assistants, advance practice nursing professionals, and other health professionals are an important part of our health care delivery system, and help to ensure access to care for many rural Americans. I believe that we should continue to ensure that providers are able to care for their patients without excessively burdensome and unnecessary regulations.

I understand that CMS recently announced a rule that included reforms to Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other health care providers will save nearly \$660 million annually, and \$3.2 billion over five years. For example, a key provision reduces the burden on very small critical access hospitals, as well as rural health clinics and federally qualified health centers, by eliminating the requirement that a physician be held to a prescriptive schedule for being onsite. This provision seeks to address the geographic barriers and remoteness of many rural facilities, and recognizes telemedicine improvements and expansions that allow physicians to provide many types of care at lower costs, while maintaining high-quality care.

By eliminating excessively burdensome regulation we can assure that the health care is more timely, the right treatment for the right patient, and more efficient in improving patient care across the board.

Patient Protection and Affordable Health Care

There are concerns that the health care marketplaces are hindering consumers' ability to compare prices and services. Small businesses are similarly affected. This is particularly true in dental health coverage since the marketplace combines all benefits into one single policy and premium.

10. If confirmed, what steps would you take to provide consumers with easily comparable insurance options based on price, benefit, services and quality?

Answer: This is an important point that I look forward to learning about in detail. Insurers must now compete on benefits, price, and quality in the Marketplaces, and consumers can now compare more easily across plans. That said, I believe it is critical that consumers have a clear understanding of the insurance plans from which they are able to choose, including their

financial obligations under those plans. If confirmed, I would continue to improve the user experience for consumers accessing the Marketplace through HealthCare.gov. This includes working to ensure that consumers can easily understand and compare the benefits and costs presented by each plan.

I am committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the plans available to them. The Affordable Care Act requires that each plan in the Marketplace include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. If confirmed, I look forward to working with you to find ways to expand consumer access to information in an affordable manner.

Senator Thune:

Questions for the Witness:

- 1. On January 6, 2014, CMS released proposed regulations that would make significant changes to the Medicare Part D program. After the overwhelming stakeholder response, CMS said, "Given the complexities of these issues and stakeholder input, we do not plan to finalize these proposals at this time." Should the agency pursue any of the proposals that will be omitted from this final regulation, will you commit to only doing so via the formal ruling making process?**

Answer: It is my understanding that CMS has indicated they do not plan to finalize the following provisions of the proposed rule:

- Lifting the designation of antipsychotics, antidepressants and immunosuppressants for treatment of transplant rejection as drug classes of clinical concern;
- Requiring Part D sponsors to accept any willing pharmacy in their preferred pharmacy networks;
- Setting new limits reducing the number of Part D plans a sponsor may offer; and
- Clarifying the statutory non-interference provision in regulation.

In the event that CMS makes these or similar proposals again, the agency would only do so as part of a new rulemaking process, during which it would solicit public comment once more before deciding whether to publish final regulations. If confirmed, I will ensure CMS continues to use the notice and comment rulemaking process before making changes to Part D regulations.

- 2. In the final 2015 notice of benefit and payment parameters and the proposed rule on future exchange standards starting in 2015, HHS indicated that the risk corridor program would be financed only by insurance companies and not taxpayers. Do you support an effort to codify that proposal?**

Answer: The temporary risk corridor provision in the Affordable Care Act is an important safety valve for consumers and insurers as millions of Americans transition to a new coverage in a brand new

Marketplace. For consumers, the program will play an important role in mitigating premium increases in the early years as issuers gain more experience in setting their rates for this new program.

Current budget projections, including those by the Congressional Budget Office, reflect money collected from the risk corridor program will be sufficient for payments, allowing the program to be administered in a budget neutral manner during the three years for which it is authorized. In the unlikely event of a shortfall for the 2015 program year, HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers. In that event, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

If confirmed, I look forward to working with Congress on ideas to strengthen this and other important Affordable Care Act programs.

3. **The world of telehealth and digital medicine has grown by leaps and bounds in the last few years. Unfortunately, it seems the regulatory environment related to payment and use of telehealth and digital medicine has not kept pace. What can HHS do to evaluate the current regulatory environment and make changes to catch up and keep up?**

Answer: While I have not worked directly on issues related to telemedicine in the capacity of OMB Director, I understand that telemedicine offers the promise of increased access to care and enhanced care coordination, particularly for many individuals living in rural or isolated areas of the country. I also understand that it is for this reason that the Department is testing approaches to providing clinical services through networks of local providers funded by HRSA's Telehealth Network Grant program. At the same time HHS provides telehealth information and technical assistance to communities and providers interested in establishing or enhancing their telehealth activities. The Department also works with licensing bodies to research the cross-state legal issues that may affect more wide-spread adoption of telehealth. If confirmed, I will ensure the Department continues its efforts regarding the use of telehealth to the benefit of patients.

4. **As new models of care are developed and used, particularly capitated payment models, the role and use of telemedicine are at the forefront of conversation. Telehealth has the ability to improve care coordination and care delivery at a lower cost.**

- a. **Do you believe that statutory restrictions on telehealth reimbursement for Medicare fee-for-service found at 1834(m) of the Social Security Act should be waived as it applies to Medicare Advantage?**

Answer: I have not been involved with this issue as OMB Director and I look forward to learning about it if confirmed. I understand that CMS recognizes the potential for telehealth technologies to support coordinated health care and allows Medicare Advantage plans to provide these technologies as mandatory supplemental benefits rather than as basic benefits, consistent with CMS' interpretation of statutory provisions.

- b. In the Affordable Care Act (ACA), Congress gave the HHS Secretary the authority to waive telehealth reimbursement restrictions for ACOs. Do you agree that all ACOs should be able to deliver care using telehealth technologies?**

Answer: I have not been involved with this issue as OMB Director and I look forward to learning about it if confirmed. It is my understanding that the Affordable Care Act requires accountable care organizations (ACOs) participating in the Medicare Shared Savings program to coordinate care for beneficiaries, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

- 5. I appreciate the comments you have made about transparency and responsiveness. Earlier this year, HHS decided to move the start of the 2015 exchange open enrollment period to November 15, and the federally facilitated exchange qualified health plan approval date to November 3 – which is conveniently a day before the election. The previous deadline was October 17. In an effort to be transparent, will you commit to make public 2015 rate filing information as soon as insurers submit it, even if that is well in advance of November 3?**

Answer: As OMB Director, I have not been directly engaged on this topic. However, I understand that this past March, the Department shifted open enrollment for the 2015 plan year by approximately one month. Open enrollment will now begin on November 15, 2014 and will end on February 15, 2015. This shift is beneficial for both consumers and insurers. It gives consumers more time to learn about plans and select a plan. It also gives insurers the benefit of more time to evaluate their experiences and collect additional rating data during the 2014 plan year, potentially reducing 2015 rates for consumers. It is my understanding that the Department consulted with stakeholders in making this change.

I am committed to transparency and accuracy. From what I understand, rate filing data submitted to HHS is proprietary in nature, and there may be some market sensitivities related to its public release. I look forward to getting a deeper understanding of this issue if I am confirmed.

- 6. It is no secret that Medicare Hospital Insurance Trust Fund will become insolvent by 2026.**
- a. Yes or No: Do you believe that beneficiary-side structural reforms are a necessary component to ensuring Medicare is available for future generations?**
 - b. If so, what beneficiary-side reforms do you think should be considered?**

Answer a-b: Proposals seeking structural reforms should be considered within the context of an overall package seeking to control Medicare costs that includes changes to provider reimbursement. The President's FY 2015 Budget includes a package of Medicare legislative proposals that will save more than \$400 billion over 10 years by more closely aligning payments with costs of care, strengthening provider payment incentives to promote high-quality efficient

care and making structural changes that will reduce federal subsidies to high-income beneficiaries and create incentives for beneficiaries to seek high-value services. Together, these measures will extend the Hospital Insurance Trust Fund solvency by approximately five years.

- 7. We both grew up in small towns and can appreciate the importance of ensuring continued access to health insurance in towns like your hometown of Hinton, West Virginia, and my hometown of Murdo, South Dakota. Recently, providers have been particularly concerned about the immense number of regulatory burdens like the critical access hospital 96-hour rule, the two-midnights rule, and the RAC audit process. I appreciate that HHS recently announced they were lifting some of the regulatory burdens in rural health care, but they seemed to miss the mark a bit on what constitutes the biggest regulatory challenges. What do you think can be done to evaluate the regulatory burdens on rural health care providers?**

Answer: As part of a regulatory lookback effort driven that OMB helps lead, CMS recently announced a rule that included reforms to Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other health care providers will save nearly \$660 million annually, and \$3.2 billion over five years. This rule specifically outlined ways to reduce burdens on rural health care providers.

For example, a key provision reduces the burden on very small critical access hospitals, as well as rural health clinics and federally qualified health centers, by eliminating the requirement that a physician be held to a prescriptive schedule for being onsite. This provision seeks to address the geographic barriers and remoteness of many rural facilities, and recognizes telemedicine improvements and expansions that allow physicians to provide many types of care at lower costs, while maintaining high-quality care.

With regard to Recovery Auditors, I understand CMS has taken, and continues to take, steps to improve the program. CMS' goal is to strike the right balance between their responsibility to ensure all beneficiaries maintain access to their providers, Medicare claims are paid appropriately, and improper payments continue to be identified without providers facing undue burdens that may keep them from providing care to beneficiaries. If confirmed, this is a place I know I need to engage.

If confirmed, I look forward to working with you and your colleagues to ensure that the burdens faced by rural providers are limited, by eliminating stumbling blocks and red tape we can assure that the health care that reaches patients is more timely, that it's the right treatment for the right patient, and greater efficiency improves patient care across the board.

- 8. Last year in the Home Health Service Prospective Payment Service final rule, home health agencies payments were significantly reduced for this year and going forward. Many seniors in my state rely on home health care, and I worry about the impact of these cuts on the seniors and on the home health agencies who provide these services. The Regulatory Flexibility Act (5 U.S.C. s. 601) requires federal agencies to carefully analyze the impact of any proposed**

regulation that would significantly impact a substantial number of small businesses, and in the home health prospective payment system final rule, CMS noted that over 90% of home health agencies meet the U.S. Small Business Administration definition of small home health businesses. Yet CMS failed to comply with the law and did not conduct a such analysis, claiming that home health agencies would not feel such impact. Elsewhere in the rule, however, CMS projected that “approximately 40 percent” of all home health agencies will operate at a net loss as a result of this rule.” In fact, the Small Business Administration filed a formal comment letter with CMS asking the agency to conduct the necessary analysis on the impact of small businesses. If confirmed, will you direct CMS to conduct this analysis on this particular rule?

Answer: It is my understanding that the Calendar Year (CY) 2014 Home Health Prospective Payment System Rate Update final rule includes an assessment of the impact of the rule on small businesses. HHS’s practice in interpreting the Regulatory Flexibility Act is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. Based on analysis of Medicare claims, CMS concluded that the policies finalized in CY 2014 rule will not result in an economically significant impact on Medicare payments to home health agencies. If confirmed, I will work to ensure that CMS continues to conduct robust analyses regarding the impact of regulations and other applicable guidance.

**STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER
U.S. SENATE COMMITTEE ON FINANCE HEARING OF MAY 14, 2014
NOMINATION OF SYLVIA MATHEWS BURWELL TO BE SECRETARY OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, today delivered the following opening statement at a committee hearing on the nomination of Sylvia Mathews Burwell to be Secretary of the Department of Health and Human Services (HHS):

I want to thank Chairman Wyden for convening this hearing to consider the nomination of Sylvia Mathews Burwell to serve as Secretary of the Department of Health and Human Services.

And, I want to thank Director Burwell for her willingness to serve in this capacity.

Director Burwell, let me start by saying something that I think you already know: If you are confirmed to this position, you will have your work cut out for you.

The size and scope of the Department of Health and Human Services surpasses that of any other federal cabinet-level Department. The HHS fiscal year 2014 budget totals almost a trillion dollars, which makes it larger than that of even the Department of Defense.

More importantly, HHS touches the lives of hundreds of millions of Americans.

From cradle to grave, HHS oversees many programs, from finding and approving new treatments for diseases, to providing a safety net for those who have run out of other options. The agencies under the HHS umbrella include the National Institutes for Health, the Food and Drug Administration, the Centers for Disease Control and the Centers for Medicare & Medicaid Services, or CMS.

CMS alone is the world's largest health insurer, with an annual budget of roughly \$860 billion.

While I believe you have the qualifications to do the job, there is still much that you will need to do in order to assure members of this committee that HHS is heading in the right direction and that your leadership will help steer the agency through the very turbulent times that lie ahead.

One of the greatest challenges facing HHS is shoring up the federal and state-based health insurance exchanges. Ensuring that the exchanges are operating efficiently and effectively will be one of your biggest challenges. Recent reports of the numerous issues being faced by the state exchanges attempting to implement the law have been cause for great concern among many members of Congress, including some on this committee.

As part of the Affordable Care Act, states are required to have an online healthcare exchange where citizens can go and shop for health insurance. States have the option of either building their own exchange, using the exchange provided by the federal government, or a hybrid.

Every state was given a \$1 million grant for the purpose of determining what type of exchange they would implement. Additional grants were given in two stages for those states who were building all or part of their own healthcare exchange.

HHS also awarded seven early innovator grants to states who quickly decided to build their own exchange in order to help support the development and implementation of necessary IT systems. In total, HHS gave \$4.7 billion to help states build their exchanges.

What is troubling is that at least seven states and the District of Columbia have failed to build a successful website and exchange.

These seven failing states received more than \$1.25 billion dollars from HHS to build their exchanges. That is a huge amount of taxpayer dollars that has apparently been spent with little or no accountability. Now, many of these states are looking to rebuild their systems and are seeking additional funds from the federal government.

That is why today I am joining Senator Barrasso in introducing The State Exchange Accountability Act. This bill requires that states who operated a state-based exchange in 2014 and then decided to abandon that exchange to repay all of the establishment and early innovator grants they received from HHS.

In addition to overseeing this massive new expansion of benefits the exchanges have created, you will also be charged with helping to ensure the longevity and solvency of the existing Medicare trust fund, which is projected to go bankrupt in 2024.

All told, between now and 2030, 76 million baby boomers will become eligible for Medicare.

Even factoring in deaths over that period, the program will grow from approximately 47 million beneficiaries today to roughly 80 million in 2030.

Maintaining the solvency of the Medicare program while continuing to provide care for an ever increasing beneficiary base is going to require creative solutions and a skillful Secretary at the helm working with CMS.

Finally, one of the most important responsibilities that you have to this committee is to be responsive.

I have heard several commitments made by nominees in these confirmation hearings about providing timely and substantive responses.

More often than not, I have been deeply disappointed. So I hope today, that your commitment will stand the test of time beyond your confirmation, because words and promises matter to me.

I hope that you will be up to the challenge.

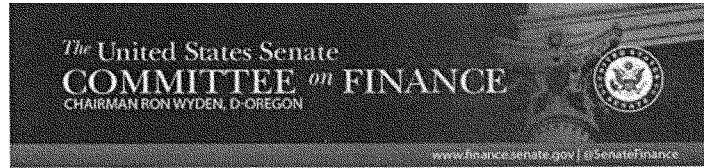
Like I said, overseeing the complex infrastructure of a Department like HHS is not a job for the faint of heart.

I wish you the best of luck as you work to address these challenges and as you continue going through the confirmation process.

You will need it.

Thank you, Mr. Chairman.

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Wyden Statement in Support of Sylvia Mathews Burwell for HHS Secretary

As Prepared for Delivery

The Finance Committee meets today to discuss the nomination of Sylvia Mathews Burwell to be the Secretary of the Department of Health and Human Services.

If one thing has become clear in the month since the President announced Ms. Burwell's nomination, it's that she is tremendously well-respected – not only by people she's led and worked with in the administration, but by Democrats and Republicans in Congress, too.

That should come as no surprise. Last year, the Senate confirmed her nomination to be the Director of the Office of Management and Budget by a vote of 96 to zero. That was a big – and well deserved – bipartisan endorsement, and Ms. Burwell's accomplished background and long record of results shows why she's earned it. She's a graduate of Harvard and Oxford, where she was a Rhodes Scholar. She served in the Clinton administration as a top economic advisor to the President and Treasury Secretary. And she has years of experience in the nonprofit sector.

First as COO and then President of Global Development at the Gates Foundation, she led efforts to address some of the most pressing global health challenges of this era. As the head of the Walmart Foundation, she was a tireless advocate for veterans hiring programs, and she was a leader in the fight against hunger in our communities. Ms. Burwell has also been a steady hand and an effective, communicative leader at OMB. She helped navigate the difficulties of the government shut down last fall. And in the year that she's served as director, the federal deficit has continued to plummet.

There is also one other important fact to keep in mind as we consider Ms. Burwell's nomination. You can't lead this generation's OMB without being steeped in health care. It's the biggest structural challenge in the budget and an essential part of the job.

Everyone knows the biggest task ahead of Ms. Burwell, should she be confirmed as HHS Secretary. The Affordable Care Act will be her central focus every day she serves as secretary. There are plenty of ways both parties can work together to improve the law and ensure America doesn't go back to the days when health care was just for the healthy and the wealthy.

There is also lots of promising news about Medicare for Ms. Burwell to build on as secretary. For example, Medicare's rate of spending growth is slowing. According to HHS data, spending went up by only 1.9 percent over a two-year period. That's slower than the overall economy, and it's far behind the

historic pace. The cause of lower premiums and a stronger, more secure future for Medicare is significantly boosted by this news.

With the bipartisan support of members of this committee, there have been big improvements in Medicare transparency. As the country's largest single purchaser of health care, Medicare has got to lead the way in making sure that all consumers and taxpayers have the information they need to get the best value for their dollar. I look forward to working with you, once you're confirmed, to continue the effort.

Next, Congress has never been closer to repealing the flawed Medicare physician payment system and replacing it with bipartisan reforms that reward the quality of care, rather than the quantity. I'm looking forward to working with you, once you're confirmed, to fix the Medicare physician payment system this year. After that is accomplished, the committee looks forward to working with you on the single biggest challenge in Medicare's future – managing chronic care.

Outside of the health care arena, this committee will need to maintain its close relationship with the HHS secretary on issues like foster care, child welfare and family support services.

Ms. Burwell, congratulations on your nomination and thank you for joining the committee today. The Senate's 96 to zero confirmation vote for your current role was clear evidence that people respect you and your work. And following a thorough review, I hope to have your nomination approved by the committee and the Senate as quickly as possible, and with equally strong bipartisan support.

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