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 $1billlion 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 Statue 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 recentdraft 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 us 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 refiled.

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 increases 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.

<u>Preventative Health Care</u>

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.

<u>Patient Protection and Affordable Health Care</u>

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 though 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 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.