

**Questions for Ms. Sylvia Mathews Burwell
Secretary of Health and Human Services-Designate
Committee on Health, Education, Labor, and Pensions
Hearing on May 8, 2014**

Senator Casey

Questions for the Witness:

Administration on Aging

Pennsylvania is home to two million adults over the age of 65, many of whom are supported by local programs. These programs, such as congregate and home delivered meals, health promotion and disease prevention activities, and various supportive services, receive federal funding from the Administration on Aging to assist a large number of older adults who are not quite poor enough to be Medicaid eligible.

1. Question: With the number of older adults expected to double by 2050, we are at a critical point in addressing the needs of America's older population. As Secretary, what steps will you take to ensure that the needs of our vulnerable older adults are met in a manner that recognizes the strengths of the local aging network while also maximizing efficiencies at the federal level?

Answer: If confirmed, I will continue to strengthen the robust collaboration with the National Aging Services Network—state and area agencies on aging, local service providers and the hundreds of thousands of volunteers—who dedicate their time and resources each day to assist older Americans live healthy and independent lives with dignity under the Older Americans Act. This Act and its network has provided 50 years of successful service as a complement to Medicare and Medicaid as a home and community-based person-centered program that lends a hand to the those most in need and provides information and services to those who seek assistance in the community. Given the demographic shift noted in your question, the importance of these partnerships and of strong coordination across a range of HHS agencies will be a priority.

BPCIA Implementation

2. Question: In the four years since the Biologic Price Competition and Innovation Act (BPCIA) was enacted, FDA has held only two public meetings and issued only three draft guidance documents on substantive BPCIA topics. I am concerned about the apparent lack of transparency about the agency's plans for implementation and how it intends to resolve key outstanding issues. Would you provide a brief outline of the FDA's plans for implementation of BPCIA?

Answer: I take the issue of transparency very seriously and, if confirmed, would work to ensure ongoing access to information about FDA's approach to the Biologic Price Competition and Innovation Act (BPCIA) and other programs. While I have not been engaged on this issue in my

role as OMB Director, my understanding from HHS is that to date, FDA has held two public hearings and issued four draft guidances on implementation of the BPCIA. The November 2010 public hearing provided a forum for interested stakeholders to provide input regarding the agency's implementation of the BPCI Act. FDA held 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 will take into consideration all received comments as we move forward in finalizing the four draft guidance documents and developing future policies regarding biosimilar products and interchangeable products. In the Center for Drug Evaluation and Research (CDER) and CDER's Guidance Agenda for 2014, FDA listed a number of draft guidances related to biosimilars that are under development. The public will be provided with an opportunity to comment on these new guidances. HHS 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. FDA has seen a high level of interest in the biosimilars program and it is an area of focus for the agency.

Project BioShield Funding

Last year, this Committee reauthorized the Pandemic and All-Hazards Preparedness Act (PAHPRA), including the Project BioShield Special Reserve Fund (SRF) at \$2.8 billion over five years. The availability of dedicated Special Reserve Fund (SRF) procurement funding over the last 10 years has allowed the US government to attract the pharmaceutical and biotechnology companies that are now delivering essential medical countermeasures to our national stockpile. I am concerned that the President's FY 2015 budget proposes less than one-fifth of the \$2.8 billion, five-year authorization.

3. Question: Do you believe that the \$415 million proposed in the FY 2015 budget is sufficient to ensure that the SRF is able to remain on track with its procurement goals over the remainder of the authorization? What was the rationale for proposing this amount of funding for FY 2015?

Answer: The tight discretionary budget caps currently in place require tough choices and close examination of the appropriate funding levels for key priorities such as biodefense. The Administration is committed to providing the funds needed in the second phase of Project BioShield to develop and procure an additional 12 medical countermeasures (MCM) on top of the 12 MCMs procured since 2004. The FY 2015 request, like last year's request, is tailored to reflect the MCMs that are mature enough for HHS/Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority to procure under Project BioShield in 2015 on the way toward meeting the five-year goal.

Critical to the continued success of Project BioShield is sustained funding for BARDA Advanced Research and Development (ARD). The FY 2015 request of \$415 million will allow BARDA to maintain the robust portfolio of candidate MCMs and allow for new starts if current programs are down-selected due to the sponsors' inability to show safety or efficacy.

As you know, Congress directed the Centers for Medicare and Medicaid Services to address improper payments under Medicare through the use of recovery auditors. The current contracts are set to expire on June 1, and new contracts have not yet been awarded.

4. Question: When does CMS expect to award the new contracts?

Answer: 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.

Senator Hagan

Questions for the Witness:

Director Burwell, I understand that the FDA has proposed a rule that would eliminate the use of paper package inserts for prescription drugs and require the exclusive use of electronic labels instead. The rule has been under review by the Office of Information and Regulatory Affairs (OIRA) since August of last year. I commend OMB for giving this issue the due diligence it deserves. This labeling includes all of the important information that healthcare professionals and patients need to safely take their prescription drugs.

Last July, GAO released a report finding that there was “no consensus among stakeholders on the advantages and disadvantages of eliminating paper labeling.” The disadvantages GAO noted include: (1) adversely impacting public health by limiting the availability of drug labeling for some providers, and (2) a lack of reliable, unbiased sources of information to support an electronic label.

1. Do you agree that this important information should be available at all times?

Do you agree that there is a risk that such information may not be available to all users electronically in technology-limited situations such as in rural areas or following a natural disaster?

Answer: As you note in your question, this proposed rule is currently under OMB review under Executive Order 12866. 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. As a general matter, I think it is very important that the benefits of rules justify their costs, and that public input plays an important role in that determination.

Senator Franken

Questions for the Witness:

1. In your written testimony, you refer to the work of the experts at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to find cures for the most serious diseases and to prevent them from spreading. One important example of this work is the National Diabetes Prevention Program (NDPP). This lifestyle intervention program for those with a high risk of developing type 2 diabetes began as a successful NIH clinical trial, and was pilot tested by the CDC in St. Paul, Minnesota and Indianapolis, IN. Based on this successful research, I developed legislation with Senator Lugar from Indiana to establish a grant program at the CDC to help community-based organizations offer this evidence-based program across the country. Our legislation, the Diabetes Prevention Act, passed as part of the Affordable Care Act and has received \$10 million in appropriations every year since then.

This program can and should be further expanded. While private insurers including UnitedHealthcare are beginning to cover this program for their beneficiaries, the Medicare program does not provide the program for pre-diabetic seniors. I heard from the CEO that UnitedHealthcare saves four dollars for every dollar it spends on this program. That's because the Diabetes Prevention Program keeps beneficiaries healthy and prevents them from needing expensive treatments. This is exactly the kind of cost-effective preventive health care we want all insurers to cover—including Medicare. I introduced legislation, the Medicare Diabetes Prevention Act, along with Senators Susan Collins and Jay Rockefeller, to do just that. If passed, the Medicare Diabetes Prevention Act would provide the NDPP as a covered benefit to clinically eligible Medicare beneficiaries.

Providing the NDPP through Medicare would help seniors stay healthy while making the Medicare program more efficient and saving taxpayers money. If you are confirmed as HHS Secretary, what specific steps will you take to give seniors access to the National Diabetes Program?

Answer: Diabetes is a serious chronic illness that has and will continue to be a priority for HHS. My understanding is that HHS is working to address diabetes and other chronic conditions in a number of ways, including through Medicare's annual wellness visit, which provides beneficiaries with personalized prevention plan services at no cost. Such visits are crucial to the early detection and successful management of chronic conditions like diabetes.

Through the Health Care Innovation Awards, the Center for Medicare and Medicaid Innovation is already testing on a large scale an intervention for diabetes prevention approaches in pre-diabetic Medicare beneficiaries. The goal is to prevent the progression of pre-diabetes to diabetes, which will improve health and decrease costs associated with complications of diabetes. If the project is successful at reducing Medicare expenditures while enhancing or maintaining quality, it could help inform future Medicare payment policy.

2. Under current law, the Secretary of HHS is prohibited from negotiating drug prices with pharmaceutical manufacturers on behalf of seniors in Medicare. This prohibition wastes billions of taxpayer dollars every year and raises prescription drug costs for seniors for the sole purpose of increasing profits for drug companies. I have legislation, the Prescription Drug and Health Improvement Act, to remove this ban and allow the

Secretary of HHS to negotiate directly with drug companies to get the best price on prescription drugs for seniors. This is a commonsense way to reduce spending in Medicare and improve access to treatments for seniors.

While I understand that the Obama administration does not have an official position on my legislation, the administration has strongly supported other measures to increase efficiency for the Medicare program and reduce costs for seniors. For example, a provision in the Affordable Care Act to close the so-called “donut hole” or coverage gap in the Medicare Part D program has saved seniors billions of dollars on their prescription drugs, and has been touted as a significant success.

How does reducing drug costs for seniors and improving the efficiency of the Medicare program help Medicare beneficiaries and American taxpayers?

If the Secretary were permitted to negotiate drug prices with pharmaceutical companies, how do you think this would benefit seniors in the Medicare program?

Answer: Lower drug prices can help save money for both Medicare beneficiaries and taxpayers, which is why the Administration has supported initiatives to this end. The Affordable Care Act took a number of steps to lower drug prices. It strengthened the Medicaid rebate and 340B programs. Additionally, beneficiaries in the Medicare Part D coverage gap currently receive a 50 percent discount from pharmaceutical manufacturers on their brand drugs. The Affordable Care Act closes this gap by 2020 through a combination of manufacturer discounts and federal subsidies. The President’s FY 2015 Budget proposes to increase manufacturer discounts to 75 percent beginning in plan year 2016, effectively closing the coverage gap for brand drugs in 2016. The phase-out for generic drugs would continue through 2020. This proposal would reduce prescription drug costs for beneficiaries and save \$7.9 billion over ten years.

To help improve the efficiency of the Medicare prescription drug benefits, the President’s FY 2015 Budget contains proposals to reduce costs on prescription drugs for both the Medicare program and beneficiaries, by aligning Medicare drug payment policies with Medicaid policies for low-income beneficiaries and accelerating manufacturer drug discounts to more rapidly close the Part D coverage gap.

Currently, drug manufacturers are required to pay specified rebates for drugs dispensed to Medicaid beneficiaries. In contrast, Medicare Part D plan sponsors negotiate with manufacturers to obtain plan-specific rebates at unspecified levels. Analysis has found substantial differences in rebate amounts and prices paid for brand name drugs under the two programs, with Medicare receiving significantly lower rebates and paying higher prices than Medicaid. Prior to the establishment of Medicare Part D, manufacturers paid Medicaid rebates for drugs provided to the dual eligible population. The President’s FY 15 Budget proposes to align these policies to allow Medicare to benefit from the same rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy, beginning in 2016. The proposal would require manufacturers to pay the difference between rebate levels they already provide Part D plans and the Medicaid rebate levels. Manufacturers would also be required to provide an additional rebate for brand name and generic drugs whose prices grow

faster than inflation. This proposal would save \$117.3 billion for the Part D program over ten years.

3. As you noted in your testimony, the rollout of healthcare.gov was unacceptable. There was a real failure in leadership around the launch of the website and a lack of accountability for it.

What do you think are the most important lessons learned from this rollout, and how do they affect your views about how information technology projects are managed and developed within the federal government and, specifically, the Department of Health and Human Services?

Answer: The Administration has been clear that the rollout of HealthCare.gov was unacceptable. There are several important lessons learned from this experience that can be used, where appropriate, to improve Information Technology (IT) development and procurement in the Department and across the federal government. Ownership and accountability are critically important in the IT procurement and delivery process; it is important to have a single entity serve as an integrator for both the business and IT sides of a project -- ensuring that the business owner and IT developer are connected throughout the process. Finally, the federal government may need to adopt more iterative approaches to procurement, like IT itself, that would allow projects to be tested and developed in stages. If confirmed, I would work to translate these lessons into better outcomes and impact at HHS.

What are you doing to support state-based marketplaces, including Minnesota's marketplace, MNsure, that have faced technical challenges when interacting with the federally facilitated marketplace?

Answer: I understand that CMS has given states flexibility in setting up their Marketplaces and is working closely with them. CMS communicates frequently with State-based Marketplaces and is providing both oversight as well as technical assistance. I will ensure that this proactive approach is continued if I am confirmed.

4. One of my top priorities as a senator has been to expand access to mental health care for everyone who needs it, particularly children. I hold Paul Wellstone's seat in the Senate, and among my first actions as a senator was to urge the Obama administration to fully implement the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. Finally, in the fall of last year, five years after the bill was passed, the administration released final rules to implement the law. However, those rules do not apply to Medicaid managed care or alternative benefit plans, or to plans under the State Children's Health Insurance (CHIP) program. Instead, the rules indicate that HHS will provide further guidance to states on how to apply parity to these important plans. To date, HHS has not yet released any further guidance.

If you are confirmed as Secretary of HHS, will you commit to issuing this guidance, which will clarify the application of the final rules to Medicaid and CHIP plans, before the end of this year?

Answer: Mental Health Parity is a priority for the Administration. However, I have not been engaged in the specific issue that you raise in my capacity as OMB Director and look forward to learning more if confirmed. My understanding from HHS is that in January 2013, the Centers for Medicare & Medicaid Services (CMS) issued a State Health Official (SHO) letter to provide guidance to states regarding the application of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) in Medicaid and to expand upon the guidance for CHIP. In this guidance, CMS detailed that all Medicaid Alternative Benefit Plans (ABPs) (including benchmark equivalent and Secretary–approved benchmark plans) are required to meet the provisions within MHPAEA, regardless of whether services are delivered in managed care or non-managed care arrangements. If confirmed, I will ensure that CMS continues to consider additional regulatory changes that may be necessary to properly implement MHPAEA.

Additional guidance regarding MHPAEA’s application to Medicaid is a priority and if confirmed, I will ensure that CMS assists states in implementing these requirements.

5. My home state of Minnesota provides among the best health care in the country. The Agency for Healthcare Research and Quality within HHS rated Minnesota as having the highest quality health care in the nation, and the nonpartisan Commonwealth Fund found that Minnesota’s health systems have the best performance in the country.

Unfortunately, because of the way that providers are reimbursed through Medicare, Minnesota’s providers and health systems are penalized rather than rewarded for our high-quality, low-cost health care.

If confirmed, what specific steps would you take to reward providers and health systems for providing high-value care?

Answer: The Affordable Care Act includes tools to improve the quality of health care that can also lower costs for taxpayers and patients. This means avoiding costly mistakes and readmissions, keeping patients healthy, rewarding quality instead of quantity, and building on the health information technology infrastructure that enables new payment and delivery models to work efficiently and effectively. These reforms and investments will build a health care system that will ensure quality care for generations to come.

Accountable Care Organizations (ACOs) are an example of an initiative showing signs of success in delivering high value care. On January 30, 2014 CMS released the interim financial results for the Medicare Shared Savings Program ACOs, which showed that in their first 12 months, nearly half (54 out of 114) of the ACOs that started program operations in 2012 already had lower expenditures than projected. An independent preliminary evaluation of the Pioneer ACO Model - the ACO model designed for more experienced organizations prepared to take on greater financial risk - shows that of the 23 Pioneer ACOs, nine had significantly lower spending growth relative to Medicare fee for service. These findings demonstrate that ACOs of various sizes and structures across the country are working to better coordinate care while reducing expenditure growth.

Through the Hospital Value-Based Purchasing Program, CMS is changing the way it pays hospitals, rewarding hospitals for the quality of care they provide to Medicare patients, not just the quantity of procedures they perform. Hospitals are rewarded based on how closely they follow best clinical practices, how well they enhance patients' experiences of care, and on the outcomes they achieve. When hospitals follow proven best practices, patients receive higher quality care and see better outcomes.

These are just a few examples of the initiatives underway. If confirmed, I look forward to overseeing continued efforts at CMS to actively transform Medicare from a passive payer of services into an active purchaser of high-quality, affordable care that enhances the value of services that Medicare beneficiaries receive.

6. This past week, the Department of Health and Human Services reported that the number of adverse events, including medication errors, fell by 9 percent between 2010 and 2012, and the 30-day hospital readmissions among Medicare Fee-for-Service patients fell 8 percent. Over the past few years, Minnesota has seen even more dramatic declines in the number of medication errors resulting from the implementation of innovative reforms, including programs that require pharmacists to reconcile medications upon hospital discharge. For example, Hennepin County Medical Center implemented a program through its electronic health record system to assign pharmacists to review medication orders at the time of discharge. As a result of this program, the medication error rate plummeted nearly to zero and the 30-day readmission rate was reduced by half.

This program has proven successful in Minnesota and similar efforts are showing results nationwide. These innovative delivery system reforms improve care for patients, save money, and most importantly, save lives. That's why I wrote a comment requesting that electronic health records certification criteria for Stage 3 Meaningful Use enable the collection of data to support this intervention that can save lives.

If confirmed as Secretary, how will you use your authority to push forward sensible delivery system reforms and what goals will you focus on in pursuing that reform?

Answer: To address the rising costs of health care, we must improve the way that health care is delivered, including the coordination and safety of care. The Affordable Care Act includes tools to improve the quality of health care that can also lower costs for taxpayers and patients. The Center for Medicare and Medicaid Innovation (Innovation Center), created by the Affordable Care Act, is an important part of these efforts.

This month, HHS released preliminary data that shows an overall nine percent decrease in hospital acquired conditions nationally during 2011 and 2012. National reductions in adverse drug events, falls, infections, and other forms of hospital-induced harm are estimated to have prevented nearly 15,000 deaths in hospitals, avoided 560,000 patient injuries, and avoided approximately \$4 billion in health spending over the same period. These improvements reflect policies and an unprecedented public-private collaboration made possible by the Affordable Care Act. The data demonstrates that hospitals and providers across the country are achieving

reductions in hospital-induced harm experienced by patients. These major strides in patient safety are a result of strong, diverse public-private partnerships and active engagement by patients and families.

HHS is working collaboratively – along with health care providers and other private sector stakeholders – to identify and scale best practices and solutions to reducing hospital acquired conditions and readmissions. If confirmed, I looked forward to continuing to work with the Committee to achieve these important goals.

Senator Warren

Questions for the Witness:

- 1. Last year, the FDA released the unique device identifier (UDI) final rule last year. UDIs are essential to transforming our understanding of the safety and effectiveness of medical devices. The FDA has stated in the past that in order to achieve the benefits of the UDI system, the UDI information must be captured in electronic health information. As you know, FDA does not have jurisdiction over health IT, electronic medical records incentives, or medical claims data.**
 - a) How do you plan to coordinate the FDA, Centers for Medicare and Medicaid Services, the Office of the National Health Coordinator for Health Information Technology, and the medical device industry to facilitate the integration collection of UDIs into electronic health information?**
 - b) What steps should each of these agencies take in order to achieve the maximum benefits of this system as soon as possible?**

Answer: In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. I understand from HHS that the FDA and the Office of the National Coordinator for Health IT (ONC) work closely on the shared goal of incorporating Unique Device Identification (UDI) into electronic health record technology. FDA's Center for Device and Radiological Health (CDRH) has collaborated with the ONC policy staff toward the development of a UDI requirement in ONC's Notice of Proposed Rulemaking (NPRM) for Electronic Health Records (EHR) Certification Criteria.

Recording the UDI is also part of the recommendations issued by the Health IT Policy Committee to the ONC and CMS related to meaningful use. ONC and CMS work closely to ensure alignment of the EHR certification criteria with meaningful use. These efforts represent the first steps towards enabling EHR technology to facilitate the widespread capture and use of UDI data to prevent device-related medical errors, improve the ability of hospitals and clinicians to respond to device recalls, and achieve other important patient safety and public health benefits consistent with the fundamental aims of FDA's National Medical Device Post-market Surveillance Plan.

- c) **Do you intend to facilitate collaboration between the FDA, CMS, and other payers to incorporate medical device information into the Sentinel Initiative – if not, why not, and if so, what steps will you take?**

Answer: In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. I understand from HHS that the current Sentinel Initiative data model focuses on querying privacy-protected administrative and claims data complemented, in part, by information in EHRs (such as lab results) and maintained by partner organizations. Unfortunately, most records accessible to the Sentinel Initiative lack manufacturer or brand-specific device identifiers and, therefore, cannot currently be leveraged to perform meaningful medical device post-market surveillance. However, as UDIs are implemented and adopted throughout the health care system, current efforts can be expanded to include this essential information for the purpose of medical device post-market surveillance.

Incorporating UDIs into claims will be a multi-year effort that will require ongoing engagement with stakeholders. Over the past two years, FDA has collaborated with the Brookings Institution (Engelberg Center for Health Care Reform) to create a “roadmap” for incorporation of UDIs into electronic health information. Input was garnered through a series of workgroup sessions with relevant stakeholders, most importantly CMS and other payer organizations.

The Sentinel Initiative will ultimately benefit from these efforts by incorporating UDIs into its claims data sources.

2. Currently, men who have sex with men (MSM) are deferred for life from donating blood. Current blood screening technology can detect HIV, meaning that our current policy turns away healthy, willing donors. A change in the current policy is supported by the 2010, the Advisory Committee on Blood Safety and Availability (ACBSA), the American Medical Association, the American Red Cross, and AABB (formerly the American Association of Blood Banks). In addition, other countries have reversed their lifetime bans. Further, the existing lifetime ban continues to perpetuate inaccurate stereotypes against gay and bisexual men.

HHS has already initiated several studies to assess the risks of a policy change and will all be complete this year. Last year, I led a letter with to Secretary Sebelius with Senators Baldwin and Enzi, Representatives Quigley and Lee, and 81 other members of the House and Senate asking for an update on the research studies and how HHS is using data collected in other counties that already changed their lifetime deferral policies for MSM.

- a) **Will you commit to making a policy change to a risk based deferral for MSM this year?**

Answer: In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. I understand from HHS that in June 2010, the HHS Advisory Committee on Blood Safety and Availability (ACBSA) heard presentations of available scientific data regarding the current policy of deferring men who have had sex with other men (MSM), even once since 1977, from blood donation. The ACBSA recommended to

the HHS Secretary that, while suboptimal, the policy should be retained pending the completion of targeted research studies that might support a safe alternative policy. Additionally, in September 2013, HHS Secretary Sebelius informed members of Congress that “Absent any unexpected delays in the completion or analyses of the studies, HHS anticipates finishing deliberations on a policy recommendation by late 2014.” It appears that the ongoing studies remain on track and HHS reports being on track to complete deliberations on a policy recommendation by late 2014. I look forward to following up on this issue if confirmed.

In December 2013, the HHS Advisory Committee on Blood and Tissue Safety and Availability recommended that before any change to the current lifetime ban on blood donation from men who have sex with men (MSM), a U.S. Donor Transfusion - Transmissible Infection Monitoring System must be established. Secretary Sebelius has not accepted or rejected that recommendation. The CDC estimates that 16,500 new cases of Hepatitis C, 18,800 new cases of Hepatitis B, 2,700 new cases of Hepatitis A, and over 20,000 new cases of HIV not in MSM, emerged in 2011. People at high risk for these diseases are removed from the donor pool by risk-based screening. According to the Red Cross, current blood screening techniques are not effective at detecting a newly infected individual with Hepatitis C for one week, a newly infected individual with Hepatitis A or B for 3 to 4 weeks, or a newly infected individual with HIV for 7-10 days. The agency has not found either these infection rates, or periods that screening is not effective at detecting the viruses, to be reasons to implement a screening system.

- b) Given the above data, why has the Committee not recommended a U.S. Donor Transfusion – Transmissible Infection Monitoring System in the past to address Hepatitis A, B, and C donations?**
- c) Given the faster turnaround time associated with the HIV test compared with the tests for Hepatitis A and B, why isn’t risk-based screening for HIV infections in MSM a sufficient replacement for the lifetime ban on MSM donation, even without a monitoring system in place?**

Answer: The United States blood supply is among the world’s safest due to multiple, overlapping safeguards against Transfusion Transmitted Infections (TTI). As correctly noted above, blood screening tests are limited by their inability to detect recent infections during a window period of viral replication. The donor screening questionnaire that is administered to all potential donors is used to help compensate for such limitations of the HIV, Hepatitis B, and Hepatitis C tests during the window period, and there is evidence that this questionnaire is responsible for a portion of the risk reduction achieved. Testing for Hepatitis A is not required, because transfusion transmission of this virus is extremely rare.

In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. I understand from HHS that, in response to Question b), the need for a blood safety surveillance system to assess the risk of transfusion-transmitted diseases has been addressed intermittently in the past through government-funded and private-sector studies.

In terms of implementation of such studies, I understand from HHS that the National Heart, Lung, and Blood Institute (NHLBI) funded studies of marker rates and risk factors in donors at various times between 1980 to the 1990's, then again in 2011-2012. Annual surveys for HIV in blood donors were carried out by CDC in 1988-1998. Similar studies were carried out by the Red Cross in 2010 and 2012.

In response to Question c), I understand from HHS that the risk of infection from transfusion depends on two factors: the time after infection during which there can be a false negative donor screening test (i.e., length of the "window period" when tests are negative in the face of infection) and the frequency of recent infections in donors ("incidence" of infections.) It is correct that the window period for failed detection of HIV using current test technology is very brief (average of 9-10 days). However, the incidence of HIV among MSM is higher than in the non-MSM population and a significant proportion of MSM are unaware of their risk.

If an individual, unaware of his risk, presents to donate during the window period, there is a chance for disease transmission. There is also evidence from look-back investigation of donated units that are found to be HIV positive that self-reporting of MSM behavior is not always accurate. Therefore, testing and donor screening questionnaires both contribute to blood safety.

If a you were to accept the Advisory Committee's recommendation regarding the establishment of the Infection Monitoring System – although a change in the discriminatory policy MSM policy that is already supported by science should happen this year and not be linked to an additional policy change that is not tied to the group in question – I have specific questions about how this system would be implemented.

- d) Which of the involved agencies (FDA, CDC, NIH) would be ultimately responsible for the implementation and maintenance of such a system?**
- e) What would be the timeline for implementation and cost associated with such a system?**
- f) How would this system be paid for?**
- g) Do you believe that HHS has the authority to implement this monitoring system without congressional direction?**

Answer: In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. HHS reports ongoing engagement of the PHS Agencies (NIH, FDA, and CDC) to consider a donor infectious disease surveillance system as recommended by the ACBTSA. As those considerations advance, HHS can address specific questions about possible implementation.

Senator Baldwin

Questions for the Witness:

- 1. The President's Budget proposes a new five-year collaborative Medicaid demonstration to encourage states to provide evidence-based psychosocial interventions to children and youth in the foster care system to reduce the over-prescription of**

psychotropic medications and to improve health outcomes. My bipartisan *Quality Foster Care Services Act* (S.1992) would improve access to the high-quality, evidence-based intervention therapeutic foster care (TFC) for children with special behavioral health needs and/or medical disabilities. My bill would improve access to these services by providing for a standard Medicaid definition for TFC. TFC works to keep particularly vulnerable youth out of costly and often ineffective institutional care. In addition, it provides needed clinical therapy options to youth in lieu of overmedication.

I am encouraged by the Department's existing efforts through CMS, SAMHSA, and ACF to evaluate TFC and I look forward to the report on these findings. As Secretary, how would you continue the critical work to improve access to TFC and other evidence-based interventions for vulnerable youth? And how would you collaborate with state partners to clarify the availability of Medicaid financing for TFC for children with serious mental and emotional disorders?

Answer: I share your commitment to ensuring that children in foster care who have special needs receive appropriate care. In particular, I share your goal of reducing over-medication of children covered by Medicaid. To that end, the FY 2015 President's Budget includes a \$750 million, five-year CMS and ACF collaborative demonstration project to encourage states to implement evidence-based psychosocial interventions targeting children in the foster care system as an alternative to the current over-prescription of psychotropic medications in this population. This transformational approach will include the development and scaling up of screening, assessment, and evidence-based treatment of trauma and mental health disorders among children in foster care in order to reduce the inappropriate reliance on psychotropic medications. We have been focusing on several evidence based practices that according to ACF, CMS, and SAMHSA are effective regardless of whether a child is living in a foster care family or in a therapeutic foster care family. HHS will continue to examine models of therapeutic foster care as well, and are interested in the evidence base regarding the impact various models have on effective treatment for children.

2. HIV/AIDS remains a public health crisis in our country. Every year, more than 50,000 Americans become infected with HIV, and there are almost 5,000 Wisconsinites currently living with the disease. The Affordable Care Act (ACA) makes significant advances in access to quality, affordable health coverage for Americans with HIV/AIDS. In addition, the Ryan White HIV/AIDS Program, which acts as a payer of last resort, provides medications, medical care, and coverage completion services to approximately 554,000 low-income, uninsured, and underinsured individuals living with HIV/AIDS.

Will you commit to continued support of all parts of the Ryan White Program through adequate funding, and ensure these critical services are adequately coordinated with the coverage gained under the Affordable Care Act?

Answer: The Administration strongly supports the Ryan White HIV/AIDS Program (RWHAP). Studies have shown that the successful treatment of individuals living with HIV can reduce the risk of transmission by over 90 percent. As such, efforts by the RWHAP providers to help individuals living with HIV adhere to treatment and remain in care – through the delivery of

health care services, the purchase of insurance coverage and prescription medication, as well as the provision of case management services – are critical to controlling the epidemic and achieving what all of us want, an AIDS-free generation. It also has helped create a public health approach to treatment by supporting systems of care that engage diverse populations in their community.

While the Affordable Care Act has enabled many RWHAP clients to enroll in Medicaid coverage or receive tax credits to help with the purchase of health insurance coverage through the new Marketplace, funding for the RWHAP will continue to be necessary in order to improve outcomes for people living with HIV, decrease HIV/AIDS morbidity and mortality rates and reduce disease transmission. If I am confirmed, HHS will continue to focus on meeting the goals of the National HIV/AIDS Strategy:

- Reducing the number of people with HIV;
- Increasing access to care and health outcomes for people with HIV; and
- Reducing HIV-related health disparities.

How do you plan to ensure that barriers to care and treatment are fully addressed for individuals living with chronic or life threatening conditions, such as HIV, as you move forward with ACA implementation? As part of these efforts, how would you address other deadly infections that disproportionately affect people living with HIV such as Viral Hepatitis?

Answer: The Administration has demonstrated a commitment to removing barriers to care and treatment for individuals living with chronic or life threatening conditions, such as HIV, throughout the implementation of the Affordable Care Act. For example, just recently, the Administration issued a regulation requiring Marketplace plans to accept the Ryan White HIV/AIDS Program payments for health insurance coverage for people living with HIV. HHS will continue to provide extensive technical assistance to Ryan White HIV/AIDS Program (RWHAP) grantees to maximize enrollment of people living with HIV into new available health insurance coverage and I look forward to advancing this work if I am confirmed.

Senator Michael Bennet

Questions for the Witness:

- 1. The HELP Committee has a long history of working in a bipartisan manner to pass numerous pieces of health care legislation into law. One of the Committee's strongest areas for bipartisan work is in the FDA space. We have done a lot of work with the FDA, our Colorado bioscience community, and patients, around reforming the laws to ensure patients have faster access to higher quality drugs and devices.**

This bipartisan work with Senators Hatch and Burr on Breakthrough Therapies will speed truly innovative and lifesaving drugs to market. We could potentially improve the law's implementation by helping CMS understand that the FDA's work is not just in

Breakthrough Therapies, but in many areas across the review process, including devices and biologics.

Would you be willing to work with us to improve the collaboration across CMS and FDA, in order to reduce obstacles to delivering these lifesaving products to patients in a timely manner?

Answer: Thank you for your leadership on the breakthrough therapies provision in the Food and Drug Administration Safety and Innovation Act (FDASIA). If confirmed, I look forward so supporting the Department's work with the Committee on patient access and ensuring collaboration across HHS on these issues.

Senator Christopher S. Murphy

Questions for the Witness:

1. An essential component of our plans to vaccinate the public in the event of a pandemic event is the availability of the needles and syringes that are required to inject these critical drugs. In numerous legislative vehicles, Congress has directed BARDA to prioritize ensuring that a sufficient supply of drug delivery devices are available to prepare for a public health emergency. However, I am concerned that we have not taken the necessary steps to secure the drug delivery devices that are required to ensure that we are appropriately prepared.

Can you provide details on the actions that the Department is taking to secure drug delivery devices, including projected timelines, for the following scenarios:

1) To distribute the vaccine that is currently in the Strategic National Stockpile and available for delivery today;

Answer: My understanding from HHS is that the CDC maintains vaccines for anthrax and smallpox at various Strategic National Stockpile (SNS) locations. In addition to these specific countermeasures, the CDC stockpiles ancillary supplies to support the administration of vaccines and other products. The Stockpile stores 28 million syringes that may be used to administer other vaccines, including pandemic influenza vaccines. The CDC/SNS does not procure or stockpile seasonal or pandemic influenza vaccine. These items are procured by BARDA. An annual review of the SNS inventory is performed and reported to Congress. The CDC/SNS plans and has carriers on contract to distribute these products in the event of a public health emergency.

2) To distribute the vaccine that BARDA is expecting to procure; and

Answer: I understand that the HHS pandemic influenza response plan designates CDC as the organization responsible for vaccine distribution during an influenza pandemic, such as the 2009 H1N1 pandemic. Likewise, BARDA can make use of existing contracts with influenza vaccine manufacturers and ancillary supplies to purchase these products for delivery to the CDC's

distribution. CDC will then instruct their distribution hubs to deliver these products to the designated sites.

3) To distribute the vaccine required in the event of a public health emergency.

Answer: It is my understanding from HHS that depending on the type of public health emergency, the CDC/SNS will distribute medical countermeasures including available vaccines and ancillary supplies from its stockpile hubs to the designated sites.

If the event is pandemic influenza, I understand that the HHS designates CDC as the organization responsible for vaccine distribution. Likewise, BARDA can make use of existing contracts with influenza vaccine manufacturers and ancillary supplies to purchase these products for delivery to the CDC's distribution. CDC will then instruct their distribution hubs to deliver these products to the designated sites. The CDC/SNS has operational plans to distribute the vaccines for anthrax and smallpox and select ancillary supplies to state and local partners in the event of a public health emergency. For pandemic influenza, vaccines are distributed by CDC/NCIRD/ISD. Vaccines for pandemic influenza, once developed and procured by BARDA, are distributed by CDC/NCIRD/ISD.

How many drug delivery devices has BARDA secured to address each of these scenarios? And could you please distinguish between contracts that have been awarded and contracts that have been in fact funded, specifying by how much relative to the awarded amount?

Answer: I am aware that the Strategic National Stockpile (SNS) program at CDC maintains stockpiles of vaccine against certain threats, as well as ancillary supplies to support administration of these products. In addition to ancillary supplies procured for specific vaccines, CDC/SNS also maintains ancillary supplies that could be distributed during a public health emergency (e.g. flu vaccines). The annual review of the CDC/SNS inventory that is performed and submitted to Congress addresses these needs using available annual funding to the CDC.

In the case of a pandemic, HHS pandemic influenza response plans designate CDC as the responsible organization for distribution of vaccines, as was done during the H1N1 2009 pandemic. During an influenza pandemic, I understand that BARDA would utilize its existing contracts with multiple manufacturers of influenza vaccines and ancillary to purchase these products for delivery to the CDC's distribution hubs. CDC, based on ordering from states and territories, would instruct the distribution hubs to deliver these products to the designated sites.

2. Director Burwell, current federal regulations define whether a health plan provides "essential health benefits" (EHB). Do you believe that the U.S. Department of Health and Human Services should consider whether plans that require cancer patients to pay far greater out-of-pocket costs for oral anti-cancer medication simply on the basis of the type of delivery mechanism used provide EHB? Can you commit to working with me and others on the Committee and other stakeholders on potential legislative and regulatory solutions to this urgent issue?

Answer: In my role as OMB Director, I was not engaged on this topic. That said, I understand from HHS that regulations implementing the Affordable Care Act provide detail on how health insurance plans in the individual and small group markets must provide the Essential Health Benefits (EHB). These regulations include cost-sharing protections that limit the amount of out-of-pocket expenses consumers and their families can be subject to, as well as anti-discrimination provisions that ensure that qualified health plans (QHPs) do not employ benefit designs that discriminate against individuals with significant health needs. If confirmed, I would be happy to look into your concerns.

Questions from Senator Alexander

Memberships and Positions Held Outside U.S. Government

1. On March 26, 2013, you submitted answers to the U.S. Senate Committee on Homeland Security and Governmental Affairs' Common Questions for Executive Nominees. Under memberships you listed yourself as a member of the Wasatch Group. Please explain the nature of this organization and your role therewith.

Answer: The Wasatch Group is an organization comprised of leaders from a variety of industries interested in working on youth issues. As a member, I attend the Group's annual gatherings in Wasatch, Utah.

2. In your April 2014 Executive Branch Personnel Public Financial Disclosure Report you list your participation in the Advisory Group for The Nike Foundation from March 2005 to April 2013. Please explain the full nature of your work for The Nike Foundation.

Answer: As a Member of the Nike Foundation Advisory Group, I provided advice to the CEO of the Nike Foundation on general issues of international development. The Nike Foundation is governed by a separate board of directors of which I was not a part.

3. Please explain the full nature of your work as a Director on the Board of Directors of MetLife.

Answer: The Board of Directors is responsible for managing the property, affairs and business of the Corporation. As a Director of the Corporation, and in accordance with the corporation's By-Laws, I also served on Board Committees, such as the Audit Committee and Governance and Corporate Responsibility Committee.

4. Please describe your work on "healthcare in the developing world" at the Gates Foundation that is referenced in your written testimony.

Answer: At the Gates Foundation, I worked on a range of issues in the health care space, from helping to create an office in India and supporting their work on HIV/AIDS, to working on creating a special purpose vehicle to increase private sector investments in vaccines for the developing world.

MetLife, Inc.

1. On February 28, 2013, the United States District Court for the Southern District of New York ruled that two of six claims related to allegations of an omission of material fact or untrue statement of material fact in an SEC filing could move forward against MetLife, Inc., MetLife executives, and 11 of 12 Directors from the MetLife Board of Directors. You were one of the Directors named as a defendant. Please explain your involvement in the defense of this ongoing litigation.

Answer: I am not directly involved in the defense of this litigation. It is being handled by MetLife and attorneys retained by MetLife.

2. When you appoint an agent for purposes of receiving service of process, and that agent receives notice of legal action taken against you, under the law you have received notice of the litigation. According to the court record in City of Westland Police and Fire Retirement System v. Metlife, Inc. et al, an attorney at Debevoise & Plimpton, LLP was designated as the attorney to receive service of process on your behalf, and a waiver of service was returned executed on May 5, 2012. On February 28, 2013, a United States District Court ruled that two claims in the suit could move forward against you and the other director defendants. However, your March 2013 Budget Committee and Homeland Security and Government Affairs Committee applications for your nomination as OMB Director did not disclose that you were a named party in this lawsuit, but stated in generic terms that you might be a defendant in litigation brought against MetLife. Why did you not disclose this specific, ongoing litigation to the U.S. Senate?

Answer: Like most corporations, MetLife is a defendant in a number of litigation matters and Board Members are sometimes named as defendants in those matters, as is the case in City of Westland Police and Fire Retirement System v. MetLife. Accordingly, in my response to the March 2013 questionnaires, I acknowledged the possibility that I might have been named in such matters. At that time, I did not recall any specific matters pertaining to my role as a MetLife Board Member in which I was a named defendant.

3. On February 26, 2013, you, along with your then-fellow MetLife Board Members, submitted an annual report to the SEC. In this report, the Board and MetLife executive officers stated the Patient Protection and Affordable Care Act (PPACA) and The Health Care and Education Reconciliation Act of 2010 “may lead to fundamental changes in the way that employers, including us, provide health care benefits, other benefits, and other forms of compensation to their employees and former employees.” MetLife also highlighted that both laws imposed particular requirements on the company as a provider of non-medical health insurance benefits and thus, “could adversely affect our ability to offer certain [types] of these products in the same manner as we do today. They could also result in increased or unpredictable costs to provide certain products, and could harm our competitive position [if either laws have] a disparate impact on our products compared to products offered by our competitors.”

Lastly, the report stated the following:

“In addition, we employ a substantial number of employees, including sales agents, in the United States to whom we offer employment-related benefits. We also currently provide benefits to certain retirees. These benefits are provided under complex plans that are subject to a variety of regulatory requirements. Either [law] could adversely affect our ability to attract, retain and motivate our associates. They could also result in increased or unpredictable costs to provide employee benefits, and could harm our competitive position if we are subject to fees, penalties, tax provisions or other limitations in the [laws] and our competitors are not.”

4. Did PPACA and/or any other related regulations and/or regulatory actions lead to fundamental changes in the way MetLife provided health care benefits, other benefits, and/or other forms of compensation to its employees and/or former employees? If yes, how? Did PPACA and/or any other related regulations and/or regulatory actions adversely affect MetLife’s ability to offer health care benefits, other benefits, and/or other forms of compensation to its employees and former employees? If yes, how?

Answer: The Annual Report contains forward-looking statements involving a number of risks and uncertainties affected by factors ranging from legislation to disruption in capital and credit markets. I resigned from the Board in April 2013 and do not have specific knowledge of the impact that subsequent factors, including the implementation of legislation or regulatory actions, may have on MetLife’s business operations.

5. Did PPACA and/or any other related regulations and/or regulatory actions adversely affect MetLife’s ability to offer non-medical health insurance benefits? If yes, how? Did PPACA and/or any other related regulations and/or regulatory actions result in increased and/or unpredictable costs for MetLife to provide certain products and/or harm MetLife’s competitive position because PPACA and/or any other related regulations and/or regulatory actions had a disparate impact on MetLife’s products compared to products offered by its competitors? If yes, how?

Answer: The Annual Report contains forward-looking statements involving a number of risks and uncertainties affected by factors ranging from legislation to disruption in capital and credit markets. I resigned from the Board in April 2013 and do not have specific knowledge of the impact that subsequent factors, including the implementation of legislation or regulatory actions, may have on MetLife’s business operations.

6. Did PPACA and/or any other related regulations and/or regulatory actions adversely affect MetLife’s ability to attract, retain and/or motivate its associates? If yes, how? Did the PPACA and/or any other related regulations and/or regulatory actions result in increased and/or unpredictable costs for MetLife to provide employee benefits? If yes, how? Did the PPACA and/or any other related regulations and/or regulatory actions harm MetLife’s competitive position because MetLife was subject to fees, penalties, tax provisions and/or other limitations and its competitors were not?

Answer: The Annual Report contains forward-looking statements involving a number of risks and uncertainties affected by factors ranging from legislation to disruption in capital and credit markets. I resigned from the Board in April 2013 and do not have specific knowledge of the impact that subsequent factors, including the implementation of legislation or regulatory actions, may have on MetLife's business operations.

Priorities as U.S. Department of Health and Human Services (HHS) Secretary

1. Health care costs and the cost of insurance continue to rise. What would you do as Secretary to address the key health cost drivers?

Answer: We need to move from a health care system that rewards quantity of care provided to quality of care provided. There are several key areas I hope to focus on in this space: 1) implementing delivery system reforms that build on the Center for Medicare and Medicaid Innovation's work to transform payment models to encourage better collaboration, efficiency, and improved outcomes; 2) carefully implementing cost savings measures in the Affordable Care Act and advocating for savings proposals in the President's budget; and 3) ensuring that we continue to focus on fighting fraud and abuse. I believe that it is also important to engage with the private sector so that all payers are aligned in this process.

2. On what specific policies will you work with Congress and the states to reduce the burdens of the new health care law that add to the cost of health insurance?

Answer: The new health care law provides grants to states to enhance their rate review processes. With this funding, states can review proposed premium increases to ensure that they are justified, and depending on state authorities, can potentially modify or deny premium increases that are not justified. Thus far, this program has led to a significant decrease in the number of requested premium increases that are above 10%, saving Americans \$1 billion in premiums since 2011. In addition, the premium stabilizations programs from the Affordable Care Act – risk adjustment, reinsurance, and risk corridors – will continue to help stabilize the insurance markets and keep quality coverage affordable.

3. With many recent resignations, there are very few individuals in leadership roles with experience in private insurance left at HHS, the Centers for Medicare and Medicaid Services (CMS), or the Center for Consumer Information and Insurance Oversight (CCIIO). How would you plan to address this lack of expertise at HHS?

Answer: Throughout the course of my career, including in several large and complex organizations, I have dedicated significant time and energy to recruiting and developing the best talent. You have to have the best people – and a range of experiences and viewpoints – around the table to solve the types of big challenges confronting OMB and HHS on a daily basis. I have worked to assemble a quality team at OMB and in all of my prior roles in the public and private sector. And, if confirmed, I will be committed to retaining and attracting the quality talent that the Department needs to deliver results for the American people.

- 4. According to the Galen Institute, the administration has executed at least 22 extra-legal “fixes” to PPACA, many of them after open enrollment began on October 1, 2013. What will you do as HHS Secretary to provide more stability to the public and private health insurance market so that last-minute, extra-legal changes are not necessary? What changes to existing law and regulation do you anticipate having to make before December 31, 2014?**

Answer: If confirmed, I will work with Congress, policy experts, and stakeholder groups to help facilitate stability in the health insurance market. I am committed to ensuring as smooth a transition as possible for consumers and issuers, and will want to listen to participants across the health care system as implementation of the law continues.

Priorities as Office of Management and Budget (OMB) Director

- 1. President Obama delivered his fiscal 2015 budget one month after its statutory deadline. How did this process, which you oversaw as OMB director, fall so far behind schedule? Please explain how you interpret a statutory deadline as having this level of flexibility. Do you believe that statutory requirements like this should routinely be ignored by the executive branch? Why or why not?**

Answer: I take statutory deadlines extremely seriously and work very hard to meet them. Where possible, the President’s Budget should incorporate final current year appropriations levels to provide Congress with an up-to-date fiscal picture. In this case, Congress did not file the near-final appropriations bills for Fiscal Year (FY) 2014 until January 13, 105 days after the start of the fiscal year. Given the delay in enactment of final FY 2014 appropriations, the Administration worked to release the President’s Budget as soon as possible after the FY 2014 appropriations levels became known.

- 2. As OMB Director you oversaw the Office of Information and Regulatory Affairs, which reviews the Regulatory Impact Analyses (RIAs) executive branch agencies produce when they issue major new regulations. Research from the Mercatus Center at George Mason University finds that RIAs produced by HHS are often seriously incomplete and less thorough than those produced by other executive branch agencies. The analyses accompanying the early regulations implementing PPACA were especially incomplete. What will you do as HHS secretary to ensure that Regulatory Impact Analyses provide thorough, evidence-based assessments of the factors Executive Order 12866 says they should assess, and that this analysis will be performed before HHS makes major regulatory decisions that the analysis is supposed to inform?**

Answer: I believe that thorough and robust regulatory impact analyses are very important. In general, it is important that the benefits of rules justify their costs and that rules accomplish their goals in the least burdensome way possible. It is also important that agencies use the most up-to-date economic information and the best available techniques for determining the estimated costs and benefits of a rule. Regulations should be tailored in such a way so as to impose the least burden on society while still accomplishing their goals.

OMB provides general guidance to agencies on how best to evaluate and present the economic impacts and benefits of rules. These factors and OMB guidance to agencies are set out in more detail in Executive Orders 12866 and 13563, and OMB Circular A-4, which is a guidance document to all agencies on how to conduct regulatory analysis. If confirmed, I would work to ensure that the analyses produced by HHS are consistent with these Executive Orders and the Circular.

Health Insurance Exchange

- 1. Will you commit to being more transparent about enrollment in the new health insurance exchanges by providing weekly updates to Congress and the American people? How many people have paid their first month's premium? How many people have paid their second and third month's premium? How many people were previously uninsured? How much money, and on behalf of how many people, has the Administration paid to each insurance carrier in cost-sharing and premium assistance subsidies? How many additional people enrolled in Medicaid, broken down by poverty level? How many new Medicaid enrollees were previously eligible?**

Answer: If confirmed, I will continue the Department's longstanding focus on transparency and accuracy. When CMS has accurate and reliable data regarding premium payments, I will see that this information is made available. I have included information below that is publicly available.

Premium Payment

Some issuers have made public statements indicating that 80 percent to 90 percent of the people who have selected a Marketplace plan have made premium payments. Issuers have the flexibility to determine when premium payments are due.

Prior Coverage Status

In addition to the more than 8 million people who have selected plans through the Marketplace during the initial open enrollment period, CBO recently estimated that an additional 5 million people have purchased coverage outside of the Marketplace in Affordable Care Act-compliant plans. Moreover, recent national surveys indicate that the number of Americans with health insurance coverage is growing, and the number of 18 to 64 year olds who are uninsured is declining. For example, Gallup has found a 5 percentage point decrease in the uninsured rate for adults (18 and over) from the third quarter of 2014 to April 2014 (18 percent versus 15 percent, respectively). Similarly, the Urban Institute estimates a 2.7 percentage point decrease in the uninsured rate for adults (18 to 64) from October 1, 2013 to March 31, 2014 (corresponding to a 5.4 million decline in the number of uninsured adults). Meanwhile, the RAND Corporation estimates a 4.7 percentage point decrease in the uninsured rate (corresponding to a net decrease of 9.3 million uninsured adults, ages of 18 to 64) from the last week of September 2013 through March 2014.

Premium and Cost-sharing Support

More than eight out of ten (85 percent) of the people who selected a Marketplace plan through the SBMs and FFM during the 2014 open enrollment period are eligible to receive federal financial assistance in paying their premiums.

Medicaid and CHIP Enrollment

Compared to enrollment before the Marketplace opened last October, 4.8 million additional Americans are enrolled in Medicaid and CHIP through the end of March. A detailed report on state agencies' eligibility determination activities and state data on total enrollment in Medicaid and CHIP programs is available on the CMS website.

- 2. The American people deserve to know the truth about their rising healthcare costs, and you promised in your confirmation hearing before the U.S. Senate HELP Committee that transparency would be a guiding principle in your work as Secretary. President Obama's administration has moved the start of the open enrollment season back to after this year's mid-term elections, meaning that voters will not know the full price of health insurance facing them next year when they head to the polls. Will you commit to fulfilling your promise of transparency and returning the open enrollment season to its original start date?**

Answer: I understand that this past March the Department shifted open enrollment for the 2015 plan year by approximately one month to give consumers more time to learn about plans and select a plan and health insurance companies additional time to collect additional rating experience. If confirmed, I look forward to working with you to address your concerns.

- 3. The ongoing problems with healthcare.gov require issuers to manually correct errors in many enrollment records they receive. These problems mean that for many consumers the exchange has "bad data" about them. What steps are being taken to correct this in preparation for the upcoming re-enrollment period in November? When will the full enrollment data reconciliation functionality be developed, tested and implemented? What is the specific timeline to fix these problems with the website and put these systems in place? How will you use your background as a manager of large, complex organizations to ensure the website gets fixed?**

Answer: It is my understanding that the Department has made specific fixes to correct information provided to insurers that allow applications to be processed and consumers to complete their payments. CMS has prioritized correctly transmitting consumer information to issuers. My understanding is that additional upgrades have been installed, focusing on direct enrollment and improving the consumer experience.

By the end of the first open enrollment period, HealthCare.gov was working well and helped millions of consumers sign up for quality, affordable health coverage. As HHS enters the next phase of this work, the technology team remains vigilant in continuing to make improvements that will enhance the consumer experience.

If I am confirmed, I will focus quickly on understanding what the team sees as the core remaining challenges and opportunities in this space and working with them to ensure that we continue to build on the progress to date to strengthen all aspects of the system.

- 4. The interim enrollment maintenance approach used by the exchange for special enrollment periods is error prone and has negatively impacted consumers because it is using cancellation and enrollment transactions in place of true maintenance transactions. When will the maintenance functionality to process “life events” be developed, tested and implemented?**

Answer: It is my understanding that after Open Enrollment, consumers may enroll in private coverage through the Marketplace if they have certain life events and other circumstances as provided in 45 C.F.R. § 155.420. Examples of such events and circumstances include a permanent move, loss of minimum essential coverage, certain changes in income, and changes in family size (for example, if you marry, divorce, or have a baby). Consumers are required to attest to their change in circumstance. In anticipation for a surge of user activity in March 2014, CMS enhanced Healthcare.gov at the end of February 2014 to include the ability for consumers to report relevant life events that could impact their eligibility and coverage.

- 5. Currently, issuers are following an interim payment process by which they are reporting on a monthly basis to CMS what subsidy payments should be made to them. When will these payments to issuers be reconciled and when will CMS, using their records, develop, test and implement the formal payment process using transactions that are compliant with industry standards?**

Answer: It is my understanding that CMS continues to make improvements to the functionality of HealthCare.gov for the 2015 open enrollment period, including improvements to the financial management processes, and has put in place an interim process to calculate and make payments to issuers on time. This process includes regular data validation with issuers. This interim process does not impact consumers’ access to advance payment of premium tax credits or cost-sharing reductions.

- 6. The current essential health benefits benchmark, as well as many exchange rules, only apply to 2014 and 2015. Both states and insurance carriers need to know as soon as possible if changes are likely for 2016. Do you believe these rules need to be changed for 2016 and beyond? What assurances can you give that states and carriers will be involved and notified in a timely manner?**

Answer: On January 1, 2014, millions of Americans gained access to critical consumer protections in a reformed health insurance market, including for the first time, a set of essential health benefits that individual and small group market plans must provide. In my role as OMB Director, I was not engaged on this topic. That said I understand that HHS has had close working relationships with states and the issuer community over the past several years. If confirmed, I assure you that I will continue to engage states, issuers and all stakeholders to ensure that future policy is developed with their input. Getting input to ensure that we continue to improve implementation is something I think is important.

- 7. At least five state-based exchanges, including Oregon, Massachusetts, Nevada, Maryland, and Hawaii accepted tens of millions of federal taxpayer dollars but struggled to enroll people into their plans. What would you do to recoup the money wasted and ensure that future exchange establishment dollars are better spent?**

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 the federal government and the taxpayer has had funds misused, I believe that we need to use the full extent of the law to get those funds back for the taxpayer. Finally, we need to make sure that we try to ensure that all those who need access to quality, affordable health care receive that access.

- 8. Will you attempt to recover any payments to contractors who may have acted negligently in building healthcare.gov and its related operations or may not have met contract standard of care terms? If no, why not?**

Answer: If confirmed, I look forward to learning more about this important issue and take the action necessary. It is my understanding that CMS continues to monitor and manage all of its contracts in accordance with the requirements of the Federal Acquisition Regulation. If confirmed, I will work with CMS to determine appropriate next steps for any contractors who may have acted negligently within the confines of federal acquisition regulations.

- 9. The President's 2015 budget indicated that the risk corridor program will be budget neutral. Please clarify whether this program will be budget neutral every year (versus neutral over a three-year time period) and detail the safeguards in place to protect taxpayers from bailing out insurance companies if their losses exceed money available for reimbursement in the risk corridor program? In addition, where is HHS's statutory authority to reduce the risk corridor program payments to insurers on a pro-rated basis?**

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.

- 10. A recent report by McKinsey and Co. found that 74 percent of those selecting a new 2014 plan were previously insured. In another McKinsey and Co. survey, only 83 percent of enrollees had paid their first month's premiums, bringing the effectuated enrollment rate for previous uninsured to 22 percent of this year's enrollees. What**

were the metrics for success for covering the uninsured, and do these figures meet that goal? If yes, how?

Answer: The Congressional Budget Office projected that 6 million people would obtain health insurance through the Marketplaces, and sign-ups indicate that we have surpassed that figure. There are a number of different surveys that indicate that the number of Americans with health insurance coverage is growing, and the number of 18 to 64 year olds who are uninsured is declining. Survey experts agree that data collection around prior insurance status leads to widely varying estimates depending on how the question is asked, and is prone to misinterpretation, so must be used cautiously.

11. At your confirmation hearing, you discussed the importance of metrics in establishing good health policy. An important metric for ascertaining the impact of the health reform law is an official count of the number of uninsured who have gained coverage under the law. What has HHS done and what will it do in the future to measure this number in a manner consistent with how these numbers were measured when the law was passed?

Answer: If confirmed, I will be sure that the Department continues to work with experts in the field and various survey instruments both within HHS and elsewhere to assess the number of uninsured and make those findings public.

12. A statement by CMS Administrator Marilyn Tavenner posted on the HHS website reads, "It is important to understand that the Hub is not a database; it does not retain or store information." However, Government Accountability Office (GAO) Report 13-601 says, "According to CMS, the agency is required to establish Data Use Agreements only with OPM and the Peace Corps because these two entities provide batch files of data for processing data hub queries, which CMS stores in the data hub environment." Please elaborate on what the Office of Personnel Management (OPM) and Peace Corps data is stored on the Data Hub, and on whether any other data is stored on the Hub.

Answer: It is my understanding that CMS has designed the Hub as a routing tool that helps Marketplaces provide accurate and timely eligibility determinations. The Hub verifies data against information contained in already existing, secure and trusted federal, state, and contractor databases. I understand from HHS that CMS has security and privacy agreements with all entities connecting to the Hub. The Hub is not a database; it does not retain or store information. The FFM and State-based Marketplace eligibility, redetermination, and appeals systems do store certain eligibility and enrollment records in order to fulfill specific functions, including helping a consumer with an application or eligibility problem. The FFM also stores the OPM and Peace Corps files needed to verify eligibility based on whether the individual has existing minimum essential coverage through these entities.

The privacy and security of consumer data is a top priority for HHS and CMS, and it will remain a top priority for me if confirmed. I understand that the Hub and its associated systems have been built with state-of-the art business processes based on federal and industry standards. CMS has developed an extremely strong enterprise information security program to protect consumer

information in a secure and efficient manner during open enrollment and beyond. I recognize that this is an area that will require ongoing vigilance, focus, and iterative improvement.

13. In a February 5, 2014, letter to CMS Administrator Marilyn Tavenner, I asked the following questions:

- a. Which division within CMS is responsible for managing exchange-related appeals and which divisions had the ultimate responsibility for overseeing the development and operational functionality of the exchange appeals process?**
- b. How many healthcare.gov appeals has CMS addressed and resolved to date?**
- c. What is the schedule for resolving the current backlog of appeals?**
- d. How long does CMS anticipate it will take to resolve the average appeal and how is CMS communicating to appellees about the length of time for resolution of their appeals?**
- e. What is the timeline for building the infrastructure necessary to route appeals to the proper channels so that CMS officials can address their needs and resolve them expeditiously?**
- f. When will consumers be able to file appeals by phone or electronically?**
- g. What is CMS' rationale for not including the appeals infrastructure in the initial phase of the Federal exchange functionality?**
- h. Why was a contingency plan for handling appeals not developed sooner given the lack of infrastructure to handle appeals that was present from the launch of the exchanges onward?**

Answer a-h: My understanding is that consumers applying for health coverage in the Marketplace receive an eligibility determination that informs them whether or not they are qualified to purchase coverage through the Marketplace or receive financial assistance. Consumers who disagree with the determination may request an appeal.

I further understand that CMS first attempts to resolve the appeal directly with the consumer through informal resolution, which involves contacting the consumer as expeditiously as possible to work through the consumer's concerns. This approach has worked particularly well for consumers who filed appeals early in the open enrollment period, before system errors were corrected. Many of these consumers have since been able to successfully enroll in a qualified health plan and have withdrawn their appeals. I also understand that CMS prioritizes medically urgent appeals, and as a result, is working to resolve those appeals as quickly as possible. CMS is now holding hearings for those cases that are not otherwise resolved through an informal process.

Premiums, Co-Pays and Deductibles

- 1. President Obama promised that premiums would decrease for American families by an average of \$2,500 per year. The opposite has come true, which outgoing Secretary Sebelius acknowledged when she said that "the increases are far less significant than what they were prior to the Affordable Care Act." How much has the average premium increased in the individual market?**

Answer: 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.

It is also important to remember advance premium tax credits will lower the actual cost of health insurance premiums for many consumers purchasing coverage through the Marketplace. More than eight out of ten (85 percent) of the people who selected a Marketplace plan through the SBMs and FFM during the 2014 open enrollment period are eligible to receive federal financial assistance in paying their premiums.

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.

2. It is important for individuals and families choosing insurance plans on healthcare.gov to understand their total financial obligation, including premiums, subsidies, deductibles, co-payments and co-insurance. What would you do to better educate consumers and help them understand the total cost of products they are buying through the federal marketplace? What changes would you make to healthcare.gov?

Answer: 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, such as premiums, subsidies, deductibles, co-payments and co-insurance, as well as the quality of the plans. If confirmed, I would work to ensure that consumers can easily understand and compare the benefits and costs presented by each plan. Continuing to refine the consumer shopping experience on HealthCare.gov is a top priority for CMS, and will be a top priority for me if I am confirmed as Secretary.

3. In comparing silver-level plans in the exchange to a typical employer-sponsored health plan, many individuals are finding more of their prescription drugs in higher cost-sharing tiers and fewer in-network doctors and hospitals. What steps, if any, would you take to ensure that consumers who are buying coverage through the

exchanges have accurate, easily accessible information about which drugs are covered, which doctors are covered, and how much they cost?

Answer: 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.

- 4. PPACA creates a 90-day [grace period](#) for individuals with subsidized coverage to pay their premiums before they are fully removed from their insurance. Patients are considered covered for this entire 90-day period, but insurers are only required to pay claims incurred in the first 30 days. That leaves a 60-day gap in which people are accessing health care services and incurring costs for which they may have no intention to pay. Who will pay the providers for the treatments that patients receive during this 60-day period?**

Answer: I understand that the Affordable Care Act provides individuals receiving a tax credit a three-month grace period to pay any unpaid premiums. This only applies to individuals who have already paid their first month's premium in full. The rules governing the grace period require plans to notify providers of the possibility for denied claims when an enrollee is in the second and third months of the grace period. If confirmed, I look forward to working with plans and providers to make sure the grace period is implemented in a way to reduce adverse effects to plans, providers, and consumers.

- 5. What has been the total cost of creating healthcare.gov to date? What has been the total cost of "fixing" healthcare.gov? Please include a detailed accounting of all costs associated with this website, including (but not limited to) salaries and expenditures, contractor costs, and training.**

Answer: It is my understanding that as of February 28, 2014, CMS has obligated a total of approximately \$834 million on Marketplace-related IT contracts and interagency agreements. These expenditures include the website and the systems that support enrollment through the Marketplace, such as the data services hub as well as other supporting IT infrastructure, including cloud computing, to support Marketplace IT development.

- 6. What financial outlays are expected for fixing the backend of healthcare.gov? Please include a detailed estimate of future costs for fixing and maintaining the website, including (but not limited to) salaries and expenditures, contractor costs, and training.**

Answer: The President's Budget reflects a need for approximately \$200 million for all Marketplace-related IT in FY 2015, some of which is funded through user fees. Much of this amount reflects ongoing operational and maintenance costs of HealthCare.gov, as well as continued development.

- 7. With the number of PPACA delays and exemptions approaching 40, there is a great deal of confusion as to what parts of the law are being enforced and which parts will be delayed indefinitely. Going forward, how will you approach enforcement of other unpopular provisions of the law that are necessary to holding down costs?**

Answer: I am committed to working with the President, Congress, states, and other federal agencies to continue the implementation of the Affordable Care Act in a common sense manner that is consistent with the law. If confirmed, I look forward to working with this Committee to help ensure that health care cost continue their downward trend toward affordability.

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.

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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 increases 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.

- 8. Americans between the ages of 18 and 34 are typically the healthiest individuals in the population and therefore cost insurance companies the least. Yet under PPACA young men and women are seeing their insurance premiums double and even triple. This, in combination with the new guaranteed issue rules, has created a situation in which for many young people remaining uninsured is less risky and more financially reasonable than ever before. This is evidenced by the enrollment numbers showing young people are enrolling at lower than expected rates. What actions should we expect to see from you that would address the economic disincentives for young people to purchase health insurance under PPACA, and instead create an environment where young people are being incentivized to obtain health insurance?**

Answer: First, the provision that allows young people to stay on their parents' plans until they are 26 gives young Americans more flexibility early in their careers.

Additionally, 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.

SHOP Exchange

- 1. Last year, CMS determined that eligible small business employees would not be able to select from any health plan on the SHOP exchange, but would only be able to enroll in a single health plan of the employer's choosing. Then, in November, CMS announced that small employers who applied for coverage through the federal SHOP had to start over and apply for coverage directly through participating health plans. This was very disruptive to small employers. What steps are being taken to ensure that HHS can implement what it had originally planned for 2014 that will allow employees to choose from among multiple health plans?**

Answer: It is my understanding that HHS is continuing to work toward implementing employee choice in all SHOPS, because in the long run employee choice will bring significant benefits to small business owners and their employees. As noted in the March 2014 proposed rule, *Exchange and Insurance Market Standards for 2015 and Beyond*, however, some issuers and state insurance commissioners have expressed concern that employee choice might significantly disrupt some small group markets, and might therefore have a negative effect on the ability of small business owners to access coverage. To address these concerns and smooth the transition, HHS has proposed, based on the recommendation of a state regulatory agency, to not implement employee choice in 2015 if doing so is not in the best interest of consumers. I understand that HHS issued a propose rule on this topic, and will issue a final rule in the near future.

- 2. Are CMS, its vendors, and business partners working under a coordinated federal timeline for SHOP Exchange implementation? If so, what are the deadlines and key milestones in the timeline? Please supply that timeline to the Committee.**

Answer: In my role as OMB Director, I was not engaged on specific deadlines and key milestones on SHOP. It is my understanding, however, that CMS continues to work with stakeholders on SHOP. The Federally-facilitated SHOP is open to otherwise-eligible employers with 50 or fewer full-time-equivalent employees (FTEs) and enrollment is open year-round. If confirmed, I will commit to working as expeditiously as possible on this important issue.

Employer Issues

- 1. The Congressional Budget Office projected in February of this year that there would be a decline in the number of full-time-equivalent workers of “about 2.5 million in 2024, compared with what would have occurred in the absence of the ACA.” However, Secretary Sebelius has denied that PPACA would have any such impact, saying, “There is absolutely no evidence -- and every economist will tell you this -- that there is any job loss related to the Affordable Care Act.” Do you agree with Secretary Sebelius, or do you accept the CBO’s findings that the ACA will result in a decrease in the number of full-time workers in this country?**

Answer: Prior to the Affordable Care Act, many people could not leave their jobs because they relied on their jobs for health insurance. This “job lock” created significant strain both economically and personally. Over the longer run, the Affordable Care Act will give people more choices and, by providing people with a new source of coverage through the Marketplaces, people are now able to make employment decisions based on what works best for them, be it retiring early, working part-time, or changing to a different job that may not offer health benefits. These are active decisions on the part of empowered Americans.

- 2. After the administration made two major delays to the employer mandate, former White House Press Secretary Robert Gibbs said that he does not believe the employer mandate will ever go into effect. Will the employer mandate go into effect? Will any more delays or changes to the employer mandate be made by the administration?**

Answer: For businesses with more than 100 employees, the employer mandate is scheduled to go into effect in January 2015. As you know, employer responsibility provisions are under the purview of the Department of Treasury, so I would respectfully refer you to the Department of Treasury for additional information regarding this question.

- 3. Employers have clearly been responding to the incentives created by the ACA’s definition of “full time employment” as 30 or more hours per week. Many [employers are cutting hours](#) or reducing the size of their workforce to avoid the employer mandate. Excepting the multitude of delays of the mandate, how should the negative effects of the ACA on the American workforce be addressed? If it became apparent that employers continued to be unwilling or unable to adhere to the mandate in December 2014, should we expect more delays?**

Answer: By providing quality, accessible health care coverage through the Health Insurance 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.

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.

Medicaid

In January, [Kaiser Health News](#) reported that problems with healthcare.gov were preventing the applications of almost 150,000 low income individuals from being transferred to the states for Medicaid and Children's Health Insurance Program enrollment. In response to this growing problem, Secretary Sebelius [said](#) during an April 10th Senate Finance Committee hearing that CMS may cut states' federal matching rate for Medicaid funds as an incentive for states to clear their transferred application backlogs.

1. Are states responsible for the delay in processing applications from healthcare.gov?

Answer: It is my understanding from HHS that CMS has been working collaboratively with the states in order to achieve a seamless eligibility system that provides consumers with a “no wrong door” approach to accessing affordable health coverage. CMS continues to work with these states to achieve this technical capability.

2. How would cutting state funding that is available for processing Medicaid applications improve the process?

Answer: One of the important impacts of the Affordable Care Act is a seamless eligibility system that allows consumers to access the offer of affordable health coverage through state Medicaid agencies or through the Federally-facilitated Marketplace (FFM). CMS has worked in partnership with states to achieve improvements to state eligibility systems so that seamless access to enrollment can be achieved. If confirmed, I look forward to working with you and with states to ensure consumers continue to have access to Medicaid

3. Are applicants who have been deemed eligible for Medicaid on healthcare.gov being counted as Medicaid enrollees by HHS? If yes, how many?

Answer: My understanding is that in the regular public reports on the Health Insurance Marketplaces, individuals determined or assessed as eligible for Medicaid or the Children's Health Insurance Program (CHIP) are not included in the FFM enrollment counts. Those determinations and assessments are listed elsewhere on the reports.

4. What is done to inform these individuals on the status of their applications?

Answer: It is my understanding from HHS that when an individual has applied at the Federally-facilitated Marketplace (FFM) and has been determined or assessed as eligible for Medicaid or CHIP, the individual receives a notice informing them of that decision and that their account is being transferred to the Medicaid agency for enrollment. In some cases the individual is contacted directly and encouraged to apply directly with the state Medicaid agency.

Medicare

1. PPACA cut funding for the popular Medicare Advantage (MA) program. To date, PPACA has reduced benefits for seniors enrolled in MA by roughly [\\$1,500 per](#)

beneficiary on average, and used the savings to fund new subsidies through the health care exchanges. However, only about 20 percent of the ACA mandated cuts to MA have been implemented so far. Would you support efforts to repeal these damaging cuts, which disproportionately impact low-income seniors who often cannot afford a Medigap plan? Or, do you believe it is appropriate to cut benefits to seniors to fund a new entitlement program?

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.

2. The Medicare Part D program is a resounding success, coming in more than 40% under budget with a customer satisfaction rating in the middle 90s. In March, CMS rescinded the ill-advised proposed Part D rule that garnered bipartisan, bicameral opposition because of the drastic effect it would have on seniors. As HHS Secretary, would you commit to not implementing any of these controversial provisions pertaining to Medicare Part D as included in CMS' January 10th proposed rule?

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 has previously indicated that the final rule will not finalize these proposals.

3. As HHS Secretary, would you commit to inviting a diverse group—including providers, beneficiary/patient advocacy groups, payer/plan sponsor groups and other related stakeholders in the Part D program—to advise and consult CMS on developing any future changes to the program so as to ensure greater transparency and collaboration in the rulemaking process?

Answer: If confirmed, I am committed to continuing to work with Congress and external stakeholders to ensure that the Part D program works best for Medicare beneficiaries while remaining affordable.

- 4. I was particularly concerned by CMS' re-interpretation of the "non-interference" clause in the January proposed Part D rule. Has the agency had the opportunity to review this re-interpretation in light of the agency's previous 9 years' experience, statements and rulemaking—as well as the HHS' OIG interpretation—of "non-interference"? Upon completing your review of all these materials, would you share your views of CMS' interpretation of the "non-interference rule" as put forward in the January Part D proposed rule?**

Answer: It is my understanding that, due to feedback on the proposal and the need for more time to consider the policy, CMS does not plan to finalize this proposal at this time.

- 5. My understanding is that several of the policy changes put forth in the proposed Part D rule were based upon incomplete and inconclusive data analyses (specifically on networks and mail order/retail pharmacy costs). None of these studies were reviewed outside of CMS. CMS did not release the underlying data behind these studies and has not done so to this day. Many commenters (including MedPAC and several actuarial firms) have questioned CMS' methodologies behind these studies. Would you commit to requiring that CMS either submit future internal analyses/studies based on its data to peer-review, open public comment, the Office of the Actuary, and/or the Assistant Secretary for Policy and Evaluation before permitting their use as a basis for future policy changes to the Part D program?**

Answer: It is my understanding that data analyses that were used as the basis for proposed regulations in the Notice of Proposed Rulemaking (NPRM) entitled "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" were cited in the NPRM and made available for public comment. This is consistent with longstanding CMS practice in rulemaking.

The CMS Office of the Actuary also prepares independent analysis in support of the Regulatory Impact Analysis for proposed and final rules. External engagement and input is obtained through the notice and comment rulemaking process as well as through the frequent engagement between CMS staff and external stakeholders and experts, including MedPAC. If confirmed, I look forward to working to ensure that this practice is continued and to address any additional concerns you have regarding this process.

- 6. Under the [Sustainable Growth Rate \(SGR\) rules](#), the Medicare physician fee schedule should see a 20.1 percent cut in 2014. What has become known as the "Doc Fix" has continuously delayed implementing these cuts. If Congress fails to find a solution to the rapidly rising cost of Medicare by 2015, PPACA gives members of the [Independent Payment Advisory Board](#)—or if the board is not yet confirmed, the Secretary of HHS—the power to force Medicare cuts that would place an increased burden on Medicare Advantage and Medicare Part D plans in the first five years. How would you, if given the power, attempt to find the savings required by PPACA and PAYGO, without sacrificing Medicare access and quality?**

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.

Employer Wellness Plans

- 1. During congressional consideration of the health care law, an amendment was adopted related to wellness incentives for employees. Wellness plans permit employers to offer incentives to employees who participate and achieve improved health outcomes through programs targeted at a few conditions that can be managed or improved to reduce long-term health effects. These programs help individuals lose weight, reduce high blood pressure, manage diabetes and quit smoking, for example. Unfortunately, the final rules hamper wellness efforts that incentivize employees to achieve a goal. Those employees who can't achieve a goal because of an underlying medical condition should certainly be exempt or given another alternative. But the final rules say that an employee, without a medical reason, must be given another option at any time during the plan year. At a time when the Administration is working to encourage all Americans, including employers, to design and participate in innovative approaches to achieving improved health outcomes, would you commit to urging the appropriate federal officials to give employers the regulatory flexibility they need, and currently do not have, to innovate and motivate employees to work to improve their own health and prevent diseases?**

Answer: Appropriately designed wellness programs have the potential to contribute importantly to promoting health and preventing disease. Figuring how to balance the laudable goals of wellness programs while ensuring that an employee does not face discrimination in eligibility, benefits or premiums based on a health factor, as required by the law, is key. I look forward to working with you on these issues if confirmed.

Health Insurance Tax

- 1. The health insurance tax is levied on all insurers, including many federal programs, Medicare Advantage plans, and Medicaid managed care organizations. By taxing these programs, the federal government has in fact taxed itself (through its subsidization of Medicare and – in part – Medicaid) and state governments (through**

Medicaid). How much of the health insurance tax will be borne by the federal and state governments?

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 you to those agencies for further information regarding this issue.

Expatriate Health Plans

- 1. When PPACA became law, it included dozens of new regulations on health insurers, but it did not distinguish between health insurance sold to consumers in the U.S. and expatriate health insurance sold to employees and families outside of the U.S. The House recently passed legislation with bipartisan support that would exempt expatriate plans from PPACA given the unique challenges of offering this coverage. HHS has already made several exemptions for expatriate plans through regulation. Would you support a permanent fix in legislation?**

Answer: The Administration remains willing to work with the Congress to address the special circumstances of expatriate plans and to maintain basic consumer protections for all workers. If confirmed, I look forward to working with you on this issue.

Regulatory Changes to PPACA

- 1. Please cite the legal authority for each of the following delays, waivers, or changes to the statutory requirements in PPACA:**

***Medicare Advantage patch:* The administration ordered an advance [draw](#) on funds from a Medicare bonus program in order to provide extra payments to Medicare Advantage plans, in an effort to temporarily forestall cuts in benefits and therefore delay an early exodus of MA plans from the program. (April 19, 2011)**

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

***Employee reporting:* The administration instituted a one-year [delay](#) of the requirement that employers must report to their employees on their W-2 forms the full cost of their employer-provided health insurance. (January 1, 2012)**

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.

Subsidies may flow through federal exchanges: The [IRS issued](#) a rule that allows premium assistance tax credits to be available in federal exchanges although the law only specified that they would be available “through an Exchange established by the State under Section 1311.” (May 23, 2012)

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.

Delaying a low-income plan: The administration [delayed](#) implementation of the Basic Health Program until 2015. This program would have provided more-affordable health coverage for certain low-income individuals who were ineligible for Medicaid. (February 7, 2013)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Closing the high-risk pool: The [administration decided](#) to halt enrollment in transitional federal high-risk pools created by the law, blocking coverage for an estimated 40,000 new applicants, citing a lack of funds. The administration had money from a fund under Secretary Sebelius’s control to extend the pools, but instead used the money to pay for advertising for Obamacare enrollment and other purposes. (February 15, 2013)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Doubling allowed deductibles: Because some group health plans use more than one benefits administrator, plans are [allowed](#) to apply separate patient cost-sharing limits for one year to different services, such as doctor/hospital and prescription drugs, allowing maximum out-of-pocket costs to be twice as high as the law intended. (February 20, 2013)

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 HHS along with other 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Small businesses on hold: The [administration has said](#) that the federal exchanges for small businesses will not be ready by the 2014 statutory deadline, and instead delayed until 2015 the provision of SHOP (Small-Employer Health Option Program) that requires the exchanges to offer a choice of qualified health plans. (March 11, 2013)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Employer-mandate delay: By an [administrative action](#) that's contrary to statutory language in the ACA, the reporting requirements for employers were delayed by one year. (July 2, 2013)

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.

Self-attestation: Because of the difficulty of verifying income after the employer-reporting requirement was delayed, [the administration](#) decided it would allow "self-attestation" of income by applicants for health insurance in the exchanges. This was later partially retracted after congressional and public outcry over the likelihood of fraud. (July 15, 2013)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

***Delaying the online SHOP exchange:* The administration first [delayed](#) for a month and later for a year until [November 2014](#) the launch of the online insurance marketplace for small businesses. The exchange was originally scheduled to launch on October 1, 2013. (September 26, 2013) (November 27, 2013)**

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

***Congressional opt-out:* The administration [decided to offer](#) employer contributions to members of Congress and their staffs when they purchase insurance on the exchanges created by the ACA, a subsidy for which the law does not provide. (September 30, 2013)**

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 Office of Personnel Management. The legal basis for such decisions may be described in rulemaking, guidance, or other relevant documents. I would respectfully refer you to the Office of Personnel Management for any information about the relevant legal determination not contained in those documents.

***Delaying the individual mandate:* The administration [changed](#) the deadline for the individual mandate, by declaring that customers who have purchased insurance by March 31, 2014 will avoid the tax penalty. Previously, they would have had to purchase a plan by mid-February. (October 23, 2013)**

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

***Insurance companies may offer canceled plans:* The administration announced that insurance companies may [reoffer](#) plans that previous regulations forced them to cancel. (November 14, 2013)**

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Exempting unions from reinsurance fee: The administration gave unions an [exemption](#) from the reinsurance fee (one of PPACA's many new taxes). To make up for this exemption, non-exempt plans will have to pay a higher fee, which will likely be passed onto consumers in the form of higher premiums and deductibles. (December 2, 2013)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Extending Preexisting Condition Insurance Plan: The administration [extended](#) the federal high risk pool until January 31, 2014 and again until [March 15, 2014](#), and again until [April 30, 2014](#) to prevent a coverage gap for the most vulnerable. The plans were scheduled to expire on December 31, but were extended because it has been impossible for some to sign up for new coverage on healthcare.gov. (December 12, 2013) (January 14, 2014) (March 14, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Expanding hardship waiver to those with canceled plans: The administration [expanded](#) the hardship waiver, which excludes people from the individual mandate and allows some to purchase catastrophic health insurance, to people who have had their plans canceled because of PPACA regulations. The administration later [extended](#) this waiver until October 1, 2016. (December 19, 2013) (March 5, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Equal employer coverage delayed: Tax officials will not be [enforcing](#) in 2014 the mandate requiring employers to offer equal coverage to all their employees. This provision of the law was supposed to go into effect in 2010, but IRS officials have “yet to issue regulations for employers to follow.” (January 18, 2014)

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.

Employer-mandate delayed again: The administration [delayed](#) for an additional year provisions of the employer mandate, postponing enforcement of the requirement for medium-size employers until 2016 and relaxing some requirements for larger employers. Businesses with 100 or more employees must offer coverage to 70% of their full-time employees in 2015 and 95% in 2016 and beyond. (February 10, 2014)

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.

Extending subsidies to non-exchange plans: The administration released a bulletin through CMS [extending](#) subsidies to individuals who purchased health insurance plans outside of the federal or state exchanges. The bulletin also requires retroactive coverage and subsidies for individuals from the date they applied on the marketplace rather than the date they actually enrolled in a plan. CRS issued a [memo](#) discussing the legality of these subsidies. (February 27, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Non-compliant health plans get two year extension: The administration [pushed back](#) the deadline by two years that requires health insurers to cancel plans that are not compliant with PPACA’s mandates. These “illegal” plans may now be offered until 2017. This extension will prevent a wave of cancellation notices from going out before the 2014 midterm elections. (March 5, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Delaying the sign-up deadline: The administration [delayed](#) until mid-April the March 31 deadline to sign up for insurance. Applicants simply need to check a box on their application to qualify for this extended sign-up period. (March 26, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Canceling Medicare Advantage cuts: The administration [canceled](#) scheduled cuts to Medicare Advantage. The ACA calls for \$200 billion in cuts to Medicare Advantage over 10 years. (April 7, 2014)

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 HHS. 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, if confirmed, I look forward to working with HHS counsel to address your remaining concerns.

Rights of Conscience

- 1. The HHS regulation that all organizations which provide health insurance to their employees must provide the full range of contraceptive services, with only a few exceptions, flies in the face of religious liberty in this country. Is it your intention to maintain this requirement even against organizations that claim such a requirement violates their deeply held religious beliefs?**

Answer: I believe that religious freedom and women's preventative health are both important. The Department outlined a clear path forward to address religious liberty concerns while ensuring that women have access to key preventive services, including contraception. The final rule includes an accommodation for non-profit religious organizations, such as non-profit religious hospitals and universities that object to contraceptive coverage. Non-profit religious organizations are not required to provide, fund, administer, or contract or refer for contraceptive coverage, but their employees will be automatically provided separate contraceptive coverage without cost-sharing. There is also an exemption for houses of worship. Houses of worship are not required to provide, fund, administer, or contract or refer for contraceptive coverage.

2. President Obama has said he supports current federal laws on protection of conscience rights, such as the Weldon amendment and the Church amendment. Do you support these protections? Do you intend to give them maximum effect in the way you administer programs at HHS?

Answer: I support the protection of conscience rights, and if confirmed, I would ensure that HHS programs are administered consistent with all federal laws protecting conscience rights, including the Weldon and Church amendments.

3. Secretary Sebelius has publicly committed to providing a list of exchange plans that do not provide abortion coverage, so that people can purchase insurance coverage that does not violate their conscience. I am unaware of that list having been made public. Please provide the list of plans in the state and federal exchanges that do not provide abortion coverage.

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.

Health IT

1. As the Meaningful Use Electronic Health Record Incentive program winds down in the next few years, do you plan to scale back the Office of National Coordinator's (ONC) role and allow market forces, patients, and providers, to determine the technologies, systems and practices best suited to increase efficiency and the quality of care in our health system? How will you ensure that the agency stays focused on its convening and coordination role and does not stray into over-regulating in ways that stifle Health IT innovation?

Answer: ONC was first established in 2004 by Executive Order during the Bush Administration and was established by legislation in 2009, with the enactment of the HITECH Act, part of the

Recovery Act. HITECH provided broad, permanent authorities for ONC to promote the widespread adoption of standardized and certified health information technology, facilitate the secure use and exchange of interoperable health information, and promote the delivery of safe, high-quality, best-practice care.

As the federal entity charged with achieving this vision, ONC focuses on high-level coordination across the Administration and with the private sector. The agency will continue to serve as convener on health IT advancement and innovation in the nation with the aim of enabling and informing health delivery and payment reform and improving the public's health. If confirmed, I will work to ensure that ONC continues to meet its goals and objectives.

- 2. Congress intended the Medicare and Medicaid electronic health record (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. Indeed, 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. Why hasn't the Administration taken steps to address provider concerns about the challenges 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?**

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 working with CMS and ONC on these ongoing efforts.

Patient Privacy

- 1. Since the passage of the Patient Safety and Quality Improvement Act of 2005, CMS has engaged in a practice of encouraging State Survey Agencies to believe that they are entitled to receive and make public patient safety work product (confidential information). In spite of the fact that dissemination of this protected information is a criminal offense, many hospital executives must make a difficult choice between complying with the survey agencies' request and facing other survey sanctions. Efforts to get CMS and the Agency for Healthcare Research and Quality (AHRQ) to clarify this issue and to avoid continued violations of the Patient Safety and Quality Act have failed. Will you commit to working with this committee to continue to protect patient safety work product and to ensure that CMS and AHRQ do not issue policies or guidance or otherwise engage in practices that violate this fundamental protection?**

Answer: Yes, if confirmed I believe that patient safety should be one of the highest priorities and will be happy to review this issue with the Department and work with Congress to eliminate the risk of future violations.

Food and Drug Administration

- 1. I have heard a lot lately about the cost and complexity of FDA regulations, and there seems to be a pattern that regulations from FDA officials have a well-intentioned goal, but do not provide evidence showing how the regulation will achieve the stated goal. As one example, the Animal Feed regulation claims reduced risk to humans and animals as a benefit, but has no empirical evidence that contamination would be less likely if the proposed rule is implemented. Would you ensure that cost and complexity of FDA regulations are justified to protect the public health, and include evidence to justify that conclusion?**

Answer: In its rulemaking activities, FDA has complied with the numerous federal requirements to analyze the regulatory impact of each proposed rule and to conduct cost/benefit analyses. FDA's goal in implementing the FDA Food Safety Modernization Act (FSMA) has been to improve public health protections while minimizing undue burdens on the affected industry. FSMA provides an opportunity to significantly strengthen our food safety system by focusing more on preventing food safety problems rather than reacting to problems after they occur. The benefits of this shift to a focus on prevention are significant.

The proposed rule entitled, "Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (preventive controls for animal food proposed rule) would require facilities that produce animal food to identify the hazards associated with the product and control these hazards. The reduction in contaminated food would reduce the risk of illness or injury to animals, to humans handling animal food, and to

humans consuming food products of animal origin, which in turn would generate social benefits in the form of potential improvements in public health.

FDA solicited comment on the Preliminary Regulatory Impact Analysis (PRIA) report that accompanied the proposed rule and will carefully consider the comments before finalizing the rule.

- 2. The FDA recently proposed a “tentative determination” to ban certain fats, a regulation which has reportedly driven some restaurants and food manufacturers to return to using regular liquid saturated fats with the same long standing oxidation problems (which were determined to lead to cirrhosis of the liver and early death). In addition to the increased health concerns with such a ban, this “determination” was issued by FDA without any OMB review even though the cost estimate is in the tens of billions of dollars. How did such a significant rule escape OMB review? Will you review this policy and proposal with an eye toward a true cost-benefit analysis?**

Answer: FDA has established procedures under 21 CFR 170.38(b)(1) for issuing notices in the Federal Register when proposing to determine that a substance is not “Generally Recognized as Safe” (GRAS) and is, therefore, a food additive subject to section 409 of the Act. In short, the procedures include a requirement that FDA place all of the data and information it used to make this determination in the public docket, and publish a Federal Register notice with the name of the substance, its known uses, and a summary of the basis for the determination, for public notice and comment. Finally, the procedures require an additional Federal Register notice of the final determination, whether or not the substance is ultimately found to be GRAS.

FDA followed these procedures when announcing its tentative determination that partially hydrogenated oils are no longer “GRAS.” In addition, FDA shared a draft of this action with OMB, and we reviewed it including evidence of its costs and benefits. The comment period for this action closed on January 7, 2014. FDA is in the process of considering public comments and determining appropriate next steps.

- 3. There was considerable interest in many of the decisions made by OMB related to implementation of the Sequester. One issue in particular that caused considerable consternation and required Congress to intervene was OMB’s decision to sequester FDA user fees. Were you personally involved in OMB’s decisions about how to implement the Sequester? Did you have a role in the decision to sequester FDA user fees? Do you believe that sequestration was the appropriate course of action for private industry-funded fees? Can you provide the specific statutory reference that mandates that privately paid user fees be sequestered by the government? What criteria did OMB use to deem a user fee “voluntary” versus “involuntary”? Would you commit to maintain the use of FDA user fees only for their intended and authorized purpose, and not for redirection to deficit reduction or other activities?**

Answer: Determinations regarding the application of sequestration to specific accounts are made by OMB’s Office of General Counsel, in consultation with the relevant agency general

counsel. The vast majority of such determinations were made before I became Director, including the determination regarding FDA user fees, and thus I was not personally involved in those determinations.

That said, the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA), as amended, provides the Administration with little flexibility with respect to the application of sequestration. As set forth in BBEDCA, sequestration reduces budgetary resources in all budget accounts, unless expressly exempted by the law.

Consistent with what OMB has stated in response to previous inquiries on this topic, the determination that FDA user fees are subject to sequestration is consistent with long-standing, government-wide application of the relevant provisions. Both BBEDCA and the Congressional Budget and Impoundment Control Act of 1974 provide that the authority to spend offsetting collections, such as FDA user fees, constitutes budgetary resources. As mentioned above, sequestration reduces budgetary resources in all budget accounts, unless expressly exempted by the law. No such exemption from sequestration applies to FDA's authority to spend offsetting collections.

Pursuant to BBEDCA, sequestered FDA user fees remain as an unavailable balance in FDA's Salaries and Expenses account and may not be used for other purposes. Congress can appropriate that funding in subsequent years, as it did in Fiscal Year 2014.

Early Childhood Development

1. In 2012, the Government Accountability Office cited over 45 programs that may provide services for early childhood development, 12 of which have an explicit program purpose of providing early learning or child care services. If confirmed as Secretary, how will you work to allow states to implement GAO's recommendation to improve coordination among these programs in order to reduce program fragmentation and streamline the numerous early childhood programs the federal government funds, including those housed at the Department of Health and Human Services?

Answer: Over the past several years, the Administration has been aggressively addressing alignment of early childhood programs by working toward aligning standards, streamlining monitoring, and coordinating technical assistance and professional development efforts, among other activities.

The Early Head Start-Child Care Partnerships (EHS-CCP) are an example of our strong commitment to alignment across programs. These grants are breaking down the barriers between two programs and in doing so enhancing their quality and reach. EHS-CCP grants align the Early Head Start and child care programs and provide more of our nation's children and families with high quality early learning experiences that will set them up for success in school and beyond.

The Administration plans to continue building on alignment efforts to develop and strengthen a seamless, high quality continuum of early education for children and families birth to school

entry. It's important to keep in mind however, that the most significant problem we face is access to high quality early education. Even Early Head Start, the largest federal early childhood program for infants and toddlers, only serves about 4% of all eligible children. We are not even close to filling the need, although the \$500 million Congress provided in the Omnibus is welcomed and will expand access to high-quality care for infants and toddlers through partnerships and Early Head Start expansion.

If confirmed, I will continue to work with states and our partners across the federal government to assure strong alignment, with the goal of giving every child the early experiences that set them up to achieve their full potential, which directly affects our country's competitive edge in a global economy.

2. If confirmed as Secretary, how will you create an environment to free up States to overcome the fragmentation that exists among early childhood programs so that they can serve a greater number of families while minimizing unwarranted overlap and reducing conflicting and inappropriate federal mandates on what states do with limited federal funds?

Answer: If confirmed, I will build on the work that has begun at the Department to reduce any potential overlap and fragmentation in these important programs. For example, the EHS-CCPs demonstrate the Administration's strong commitment to eliminating fragmentation and aligning programs at the federal level, while also expanding the reach and enhancing the quality of early education for children across the country. States and local communities across the country, as well as non-profit and for-profit agencies, are eligible to apply for these grants, creating an important opportunity for federal-state and within-state policy alignment across child care, Head Start, and other early learning programs.

HHS is working toward ensuring statewide coordination and collaboration among the wide range of early childhood programs and services in the state through state advisory councils. If confirmed, I will continue the work that has begun at the Department on this effort.

3. How can the Department of Health and Human Services help states have more control over Federal early childhood development programs so that states can determine the best methods of mixed delivery models that includes services provided by private providers, including child care centers that work for their populations?

Answer: States across the country are taking the lead in expanding early education programs around the country. States like West Virginia, Georgia, and Oklahoma are doing incredible work using mixed delivery models that work for their children and families.

If confirmed, I look forward to working with states to make existing programs work better for them and for the young children and families that are depending on us to level the playing field, and give them a real shot at success by identifying best practices in states and supporting the sharing of information.

Head Start Program

- 1. The implementation of the process required under the Head Start Act of 2007 under which underperforming Head Start grantees must re-compete in order to continue operating those centers was a dramatic improvement in the management of the Head Start program; now, Head Start grantees are more accountable for performance and maintaining the standards of the program. Will you commit to continuing this competitive process to re-designate Head Start grantees with questionable performance, and how might this process inform the way the Department of Health and Human Services manages other Federal programs and grants serving children and?**

Answer: If confirmed, I commit to continuing the Designation Renewal System (DRS) under which underperforming grantees must compete for funding. Additionally, I am committed to ensuring that the system promotes high quality services for children and families and continuous improvement for grantees. I will look at the results of the DRS evaluation once it is completed to assess its successes and challenges and to determine if it is applicable to other programs within the Department.

- 2. The Head Start Act of 2007 authorized the designation of some 200 Centers of Excellence as a means to support best practices in early childhood programs as well as improve the dissemination of those practices to other Head Start centers and service providers. In 2009, HHS designated 10 Head Start Centers of Excellence and provided funding to support such activities through 2014. If confirmed as Secretary, will you commit to support effective implementation of the Centers of Excellence concept as a means to develop and disseminate best practices in order to improve the outcomes for Head Start participants?**

Answer: Yes, I commit to continuing to learn from the Centers of Excellence specifically and from local innovation generally. It is essential that local programs inform our understanding of best practices. The Centers of Excellence designation and funding has allowed programs to sustain best practices and disseminate information to other Head Start programs. Funding was previously provided to support one cohort of Centers of Excellence grants, and their period of performance ends in 2014. However, during the next year I understand that HHS will review the effort to see what it can learn from the program and how that information can be used going forward.

Child Abuse Prevention and Treatment

A 2014 report by the Government Accountability Office found that federal agencies have provided limited support in the form of training, guidance and resources, federal funding, and data collection related to child sexual abuse. Furthermore, these efforts are not well coordinated or disseminated. Most states and local officials are not aware of the federal resources that are currently available and have been left to address sexual abuse and misconduct with minimal federal guidance.

- 1. As the principal federal agency that provides oversight, training, and education to states and local officials on implementation of federal child abuse and welfare requirements, how do you plan to strengthen the child abuse, neglect prevention, and treatment programs to raise awareness and reduce the incidents of child abuse and neglect nationwide?**

Answer: This is an important issue and a priority in terms of protecting some of our nation's most vulnerable children. The 2014 GAO report referenced, *Child Welfare: Federal Agencies Can Better Support State Efforts to Prevent and Respond to Sexual Abuse by School Personnel*, is specific to sexual assault by school personnel. It provides a review and assessment of efforts to address child sexual abuse by school personnel. As such, GAO's recommendations focus primarily on how the Department of Education should take action to prevent and respond to child sexual abuse by school personnel in collaboration with the Secretary of HHS and the Attorney General to leverage resources, expertise and capacities departments.

The purview of HHS through the Children's Bureau is the oversight of child welfare services, including the prevention of abuse and neglect of children by parents and caregivers as defined by state statute. In this capacity, efforts are underway to raise awareness and prevent the sexual abuse of children. Work includes the Children's Justice Act (CJA), the Community-Based Child Abuse Prevention Program (CBCAP), the Child Welfare Information Gateway and the annual Prevention Resource Guide.

If confirmed, I will continue to advance the current programmatic and awareness initiatives and partner with the Department of Education to assist with further efforts to address child abuse through leveraging resources, expertise and capacities across departments.

- 2. What steps will you take to work with the U.S. Departments of Education, Justice, and other federal agencies to strengthen the coordination of the child abuse and neglect programs to ensure greater efficiency and focus for direct services?**

Answer: If confirmed, I look forward to working with the Departments of Education, Justice, and other federal agencies to strengthen the coordination of child abuse and neglect programs. The Department has managed efforts to broadly share and disseminate information, promote awareness, and create, foster and implement opportunities for collaborative efforts to address child abuse and neglect, including through the Federal Interagency Workgroup on Child Abuse and Neglect (FEDIAWG), which provides a forum for staff from federal agencies to share and disseminate information, promote awareness, and create, foster and implement opportunities for collaborative efforts to address child abuse and neglect.

Child Care and Development Block Grant

- 1. The United States Senate recently passed the Child Care and Development Block Grant of 2014. If this reauthorization proposal becomes law, would the regulations proposed by the Department of Health and Human Services (45 CFR part 98) be withdrawn and new regulations proposed that fit within the framework authorized by Congress?**

Answer: Should Congress pass and the President sign legislation to reauthorize the Child Care and Development Block Grant program, the Administration would revisit the rule as part of its work to implement the new statute.

2. How will the Department of Health and Human Services work to support services like those under the Child Care and Development Block Grant that provide States with flexibility to implement programs in a manner that meets the need of the State and encourages parental choice in order to meet the individual needs of residents?

Answer: I understand that the Child Care and Development Block Grant provides state, territory, and tribal grantees with flexibility to meet the needs of low-income families and children within their jurisdiction, and I look forward to working with you to ensure that the program best meets the needs of those it serves. I understand that HHS has established national centers to provide technical assistance on topics such as child care quality improvement and subsidy innovation and accountability, as well as worked collaboratively with states, territories, and tribes through on-site visits and regional meetings. As implemented, the CCDF program ensures parental choice to a wide variety of child care providers—with over 460,000 providers participating across a range of settings, including centers and family child care homes.

Questions from Senator Enzi:

- 1. The enrollment period for 2015 health plans was originally scheduled to run from October 15 to December 7, but the Administration has pushed the opening date back passed the mid-term elections so that the enrollment period will run from November 15 through January 15. Secretary Sebelius told me last month that this change was done in collaboration with insurers looking at their calendar. Which insurers did HHS collaborate with to make this change?**
- a. Which insurers supported the move?**
 - b. Which insurers opposed the move?**
 - c. What costs will taxpayers incur because of this move?**
 - d. What costs will insurers incur because of this move?**
 - e. If this is not information available to you yet, and if you are confirmed, will you commit to providing full and complete answers to each of the above questions within one month of your**

Answer a-e: As OMB Director, I was not 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 because the unique, initial open enrollment period lasted through March. 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 and it also gives insurers the benefit of more time to monitor 2014 enrollments, prior to submitting their 2015 rates. If confirmed, I want to work with you to ensure that we continue the opportunity for the public to give input and comment on regulations to ensure continued access to quality, affordable health care coverage.

- 2. As Director of OMB, you are responsible for coordinating and reviewing all significant Federal regulations. Between the day you were confirmed as OMB Director and this week, there were 30 Affordable Care Act final or interim rules released, including the employer mandate delay. What legal analysis did you use to approve that rule since the Affordable Care Act expressly states the mandate should take effect in 2014?**
- a. What economic analysis did you use to justify this delay but not a delay of the individual mandate or the other burdensome provisions of this law?**
 - b. As OMB director, did you require an analysis on the impact of this change on the taxpayer?**
 - c. If not, why not?**
 - d. Were you surprised when CBO subsequently found that it would cost the taxpayers \$12 billion?**

Answer: OMB reviews regulations to determine whether, among other things, the benefits of rules justify their costs; the rules are consistent with, and non-duplicative of the regulations and activities of other federal agencies; the rules explore reasonable alternatives and examine flexibility for small businesses; the agency is using the most up-to-date scientific, technical, and other information; and the rule accomplishes its goals in the least burdensome way possible. These and other principles are spelled out in more detail in Executive Orders 12866 and 13563. OMB also runs an interagency review process on rules it reviews so that other relevant agencies in the federal government can provide their views.

In general, the Administration's approach to regulation is to maintain a common-sense balance between our obligation to protect the health and safety of Americans and our commitment to promoting economic growth, job creation, and innovation. The regulations that OMB reviewed over the Administration's first five years are expected to have an overall value to society worth about \$200 billion annually when implemented, even after considering potential costs. The Affordable Care Act and the rules that implement it have significant economic benefits. For example, in its most recent baseline estimate, CBO reaffirmed that the Affordable Care Act as a whole will decrease both short-term and longer-term federal deficits.

With respect to the IRS employer mandate rule, that rule was not reviewed by OMB. Because of a longstanding agreement between Treasury and OMB, dating back to the Reagan Administration, OMB does not typically review IRS rules and has not reviewed any IRS rules related to the Affordable Care Act while I have been Director.

- 3. During your tenure at OMB, we saw a massive failure of Healthcare.gov – a website the Administration had 3 years and \$600 billion to build. As Director of OMB, you are responsible for oversight of agency performance and information technology. While you said HHS and your CIO oversaw the role out, as the head of OMB, what oversight role did you play in approval of the website?**

Answer: As Director of OMB, I had no involvement in the technical development, operation, or approval of the website. OMB's oversight responsibilities were in two main areas: 1) facilitating interagency technical coordination through OMB's Office of E-Government & Information

Technology; and 2) regular Affordable Care Act budget and policy work through OMB's Health Resource Management Office (RMO). As Director of OMB, I was responsible for overseeing the efforts of these two offices.

a. What is being done to protect taxpayers from making erroneous payments?

Answer: OMB is working closely with the Departments of Treasury and Health and Human Services to ensure oversight and prudent use of federal funds in the programs established under the Affordable Care Act. As with other programs, agencies must follow a number of statutory requirements including risk assessments and, when applicable, reporting an improper payment rate and implementing corrective actions. In addition, agencies are responsible for establishing internal controls to provide assurance for effective program operations, reliable financial reporting, and compliance with laws and regulations.

In service of this effort, I would encourage Congress to provide sufficient funding for key operational activities – and in particular, program integrity efforts – at both HHS and the IRS. These efforts will help ensure accurate and timely payments, and remediate erroneous payments should they occur.

- 4. In February the New York Times reported that one in five people who complied with the individual mandate didn't pay their premiums in January. At that time a CMS spokesman said the Administration couldn't say how many people had paid their premiums. On April 30, the House Energy and Commerce Committee reported that only 67 percent of enrollees had paid their first premium by April 15.**
- a. While the Administration disputes this figure, you've yet to release your own official numbers. If confirmed, will you commit to determining who has paid their premiums and is actually "covered" as required by the individual mandate and providing that information to Congress within 60 days of your confirmation?**
 - b. If confirmed, how will you measure success of Obamacare – based on folks who sign-up for coverage or based on folks who pay their premiums and are actually covered?**
 - c. If confirmed, what will you do about people who thought they were covered, sought healthcare, and now have medical bills but no insurance?**

Answer a-c: It is my understanding from HHS that a group of insurers recently testified before the House Energy & Commerce Committee, and stated that 80 to 90 percent of enrollees have paid their premium.¹ If confirmed, I will continue the Department's longstanding practice of focusing on providing reliable, complete and accurate information. When HHS has accurate and reliable data regarding premium payments, I will ensure that it is made available to the public.

¹ <http://www.bloomberg.com/news/2014-05-06/insurers-say-most-obamacare-customers-paid-first-premiums.html>

From my perspective, the success of the Affordable Care Act is about access, affordability and quality. If I am confirmed, I will work to make sure that individuals have the best clarity possible on their coverage status.

5. **In March I asked you how the Administration would ensure that the Preschool for All initiative is not duplicative of Head Start, the Child Care Development Block Grant, or other programs authorized through No Child Left Behind, the Individuals with Disabilities Education Act, and numerous other laws. You acknowledged the need for such an effort and suggested some general tools the Administration could use to align the programs, but if confirmed, you would be specifically charged with coordinating these programs and eliminating duplication.**
 - a. **One way you could do that is by undertaking a review of the duplication and overlap in early childhood education programs and submitting a plan to Congress on ways to consolidate and streamline the various programs. In fact, the Senate adopted my amendment to the CCDBG reauthorization bill in March to do just that. The vote on my amendment was 98-0, so I think it's a common sense approach. And I don't think you have to wait for that language to be signed into law to start the review.**
 - b. **If confirmed, would you commit to conducting that review and submitting a plan to Congress on ways to reduce duplication and overlap of early childhood programs within one year?**

Answer: Yes, if confirmed I am committed to improving coordination and reducing duplication. I will continue the efforts the Department has already started to better coordinate early childhood programs including aligning technical assistance, standards, monitoring and professional development to use of federal resources to provide services to more children and families in an efficient and effective manner.

With respect to the GAO report, it is my understanding HHS is working with the Department of Education to align programs and ensure that they are working well for states, communities and children. One challenge is access to high quality early education. Even Early Head Start, the largest federal early childhood program for infants and toddlers, only serves about 4% of all eligible children. As HHS continues working with our Partners across the government to assure strong alignment, we must keep in mind that we are far from reaching our goal of giving every child the early experiences that set them up to achieve their full potential, which directly affects our country's competitive edge in a global economy.

Questions from Senator Isakson

1. **For many residents of rural areas, the "Affordable Care Act" is proving to be anything but affordable. For example, in southwest Georgia, the cheapest "bronze" plan has a premium of over \$12,000 per year – and that's for a plan with a \$12,600 deductible. A March 19 article in The Hill, titled "O-Care premiums to skyrocket," quoted insurance officials stating that rates are likely to double or even triple in some parts of the country. According to the article, "areas of the country with older, sicker, or smaller populations are likely to be hit hardest." Do you believe the rates**

facing southwest Georgians constitute “affordable care”? If confirmed, would you work with Congress to find ways to allow our constituents to have access to lower rates, such as by rolling back excessive regulations that drive up the cost of coverage?

Answer: If confirmed, I am committed to working with Congress to help all Americans access affordable health care. The Administration has promoted greater competition of insurance companies in rural American through the Multi-State Plan and CO-OP Programs. One out of every four issuers in the Marketplace in 2014 newly offered such coverage. The Affordable Care Act also offers all consumers, including those in rural Georgia, tools to make insurance more affordable - insurance affordability programs, including premium tax credits and cost-sharing reductions, will help many eligible individuals and families, significantly reducing the monthly premiums and cost-sharing paid by consumers. Premium tax credits may be paid in advance and applied to the purchase of a QHP through the Marketplace, enabling consumers to reduce the upfront cost of purchasing insurance. In addition, cost-sharing reductions will lower out-of-pocket payments for deductibles, coinsurance, and copayments for eligible individuals and families.

2. It has been widely reported that under prior leadership, the Office of Management and Budget (OMB) directed agencies to postpone the publication of economically significant regulations, including a number of regulations implementing the Patient Protection and Affordable Care Act (PPACA), until after the November 2012 presidential election. Additionally, the Department of Health and Human Services has postponed the start of 2015 open enrollment from October 1 to November 15, 2014 – a change that you approved in your capacity as OMB director. Do you believe that the date of federal elections is ever an appropriate factor to consider when HHS sets timelines for implementing PPACA and other legislation enacted by Congress?

Answer: 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. With regard to rulemakings in particular, I believe it is important that, among other things, the benefits of rules justify their costs and that regulations are tailored in such a way so as to impose the least burden on society while still accomplishing their goals. These factors and others are set out in more detail in Executive Orders 12866 and 13563, and OMB Circular A-4, which is a guidance document to all agencies on how to conduct regulatory analysis.

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 mandates and goals of the law in the most effective, efficient and common sense way possible.

3. In 2011, Georgia enacted legislation at the state level permitting insurers to offer policies that have been licensed in other states. Section 1333 of PPACA directs the Secretary of HHS, in consultation with the National Association of Insurance

Commissioners (NAIC), to issue regulations no later than July 1, 2013, providing for the establishment of “health care choice compacts” under which states could enter into reciprocal arrangements for the sale of health insurance across state lines. However, over 10 months later, no proposed regulations on this topic have been published in the Federal Register. What is the status of implementing Section 1333, and has HHS initiated consultations with NAIC on developing proposed regulations?

Answer: As OMB Director, I have not been directly engaged on this topic. That said, I understand that HHS continues to work in close partnership with the NAIC on many components of Affordable Care Act implementation, and I look forward to building on that work if confirmed.

- 4. PPACA’s medical loss ratio (MLR) rule requires insurance companies to spend at least 80% of premiums (85% for insurers in the large-group market) on paying medical claims. HHS has interpreted this rule to include commissions paid to independent insurance agents and brokers in the denominator of medical loss ratio, even though this compensation is not actual revenue to the insurer. As a result, commissions have been cut significantly reducing consumers’ access to independent agents and brokers. In November 2011, the National Association of Insurance Commissioners adopted a resolution urging that “Congress should expeditiously consider legislation amending the MLR provisions of PPACA in order to preserve consumer access to agents and brokers.” Do you agree that commissions to independent agents and brokers should not be included in the MLR calculation? If confirmed, would you work with Congress to enact legislation that excludes agent and broker commissions from the MLR?**

Answer: As OMB Director, I have not been directly engaged on this topic. I understand that agents and brokers act as trusted counselors, providing service at the time of plan selection and enrollment and customer service throughout the year and if confirmed, I am happy to continue to work with Congress to help agents and brokers continue to play this important role. I understand from HHS that the MLR regulation adopted the recommendations of the National Association of Insurance Commissioners (NAIC), including the NAIC recommendations on the treatment of agent and broker fees and commissions. Data collected by the NAIC Health Care Reform Actuarial Working Group in 2011 showed that prior to the Affordable Care Act, agent and broker commissions were first rising at the same rate as health care premiums, and then began to decline steadily. This data suggests that commissions began to decline prior to the passage of the Act and that issuers may have had business considerations that influenced their decision to reduce commission rates other than the MLR requirements.

- 5. In implementing the health insurance exchanges, the Administration has prioritized navigators and other “assisters” over state-licensed insurance agents and brokers. I have heard from agents and brokers who have expressed strong frustration with the lack of tools available to them to assist consumers in exploring coverage options through the healthcare.gov website. What role do you envision for licensed agents and brokers in future exchange enrollment periods?**

Answer: My understanding is that agents and brokers will continue to play a vital role in enrolling individuals and businesses in coverage, as they do today. Agents and brokers act as trusted counselors, providing service at the time of plan selection and enrollment and customer service throughout the year.

6. In February, National Review reported that the Illinois Department of Insurance revoked the certification of a PPACA navigator after being informed by the U.S. Attorney for the Eastern District of Michigan that she had been convicted in 1969 for participating in a series of terrorist attacks in Israel, including one bombing that killed two people. Georgia, along with several other states, has enacted legislation requiring navigators to undergo criminal background checks. Do you believe the federal government should require background checks for all navigators who receive taxpayer funding and have access to consumers' personal information?

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.

7. Insurance agents and brokers are generally required to purchase professional liability insurance. Given the risk of identity theft or data breaches whenever personally identifiable information is shared, do you believe entities that receive taxpayer funds to conduct navigator or other consumer outreach activities should be required to carry liability insurance?

Answer: While I have not been directly engaged on this issue as OMB Director, I understand from HHS that all Navigator grant awardees must meet any licensing, certification, or other applicable standards prescribed by the state or Marketplace so long as these state Navigator standards do not prevent the application of the provisions of Title I of the Affordable Care Act. If confirmed, I look forward to learning more regarding this issue and understanding any concerns you have regarding the insurance needs of these entities.

^[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.

- 8. Section 1342 of PPACA provides for the establishment of a temporary risk corridor program for health insurance companies in the individual and small group markets. The law specifies that the program is to operate for calendar years 2014, 2015 and 2016. In February, the Washington Examiner reported that the Administration is considering a plan to extend the risk corridor program beyond 2016. In your view, does the Secretary of HHS have statutory authority to implement an extension of the risk corridor program?**

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. To my knowledge, the Department has no plans to administratively extend the temporary risk corridors program beyond 2016.

- 9. Please describe your perspective on the role of the Centers for Disease Control (CDC) in monitoring, investigating, and responding to serious public health threats. If confirmed as Secretary, how would you ensure that the work of CDC and other public health initiatives is appropriately prioritized within a Department that has recently been more focused on administering health coverage programs?**

Answer: I believe CDC has an important role in monitoring, investigating, and responding to serious public health threats. Just this past week, CDC announced that the first two cases of Middle East Respiratory Syndrome (MERS) have arrived in the US. These cases are a reminder of the centrality of CDC to protecting the health of Americans, and are also a reflection of how our capabilities to detect and respond to such threats have improved since H1N1. The President's FY 2015 Budget includes new resources for CDC to address priority threats, and I am committed to working with Congress to ensure that critical CDC capabilities are supported.

- 10. It is imperative for CDC to have the resources necessary to carry out its core mission of protecting Americans from public health threats. In recent years, a significant portion of the CDC's budget has been backfilled from the Prevention and Public Health Fund created in PPACA. As a result, the amount of discretionary funding for CDC in the President's FY 2015 budget request is nearly 10 percent less than the agency received in FY 2010. How will you work to ensure that CDC continues to receive adequate resources once the Prevention and Public Health Fund has been exhausted?**

Answer: I agree that CDC needs to have the resources needed to carry out its core mission. The recent US cases of Middle East Respiratory Syndrome (MERS) remind us that new threats continually emerge to challenge our capabilities. The President's FY 2015 Budget includes new investments in Advanced Molecular Detection that were made through the FY 2014 appropriations process, along with the President's FY 2015 request for new investments in protecting against antimicrobial resistance are examples of how we can ensure such progress.

The Prevention and Public Health Fund (PPHF) together with annual appropriations have supported a broad range of CDC initiatives. Under provisions of the Affordable Care Act, the PPHF is newly appropriated and allocated each fiscal year, meaning it is renewed and expended annually; it is not a time-limited funding stream and will continue each year unless changed by law.

If confirmed, I will continue to work with the Administration and Congress to ensure that critical CDC capabilities are supported and that appropriate and sustainable funding sources are used to achieve this goal.

11. One of the Surgeon General’s statutory roles is to oversee the US Public Health Service Commissioned Corps, which provides medical response for national and local emergencies including natural disasters and terrorist attacks as well as carrying out a variety of other public health missions. Some have criticized the President’s current nominee to this position for lacking substantial on-the-ground public health experience. In your view, how do the Surgeon General’s office and the Commissioned Corps fit into the overall mission of the Department of Health and Human Services?

Answer: The Department is the principal federal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. As one of the seven uniformed services of the United States, the Commissioned Corps includes 6,800 officers stationed around the world furthering the HHS mission, with a particular focus on furthering the Department’s strategic initiatives including: eliminating health disparities through delivering health services to underserved and vulnerable populations; protecting American’s health and safety during emergencies and fostering resilience in response to emergencies; and a variety of other functions related to promoting the health of the Nation.

The Corps’ role in emergency and crisis response is unique in providing not only medical resources, but the broadest spectrum of public health resources. I am aware that within the past two years, its officers and multi-disciplinary response teams were deployed to Hurricane Sandy (14 response teams and over 500 officers), the Sandy Hook shootings, the Boston Marathon bombings, Saipan, the Crow Nation, and in support of numerous National Special Security Events.

In addition to overseeing the U.S. Public Health Service, the Surgeon General provides Americans with the best scientific information available on how to improve their health and reduce the risk of illness and injury through Surgeon General’s Reports and Publications. If confirmed, I look forward to working with this office to ensure that it continues to achieve its mission.

12. The Food and Drug Administration (FDA) has a difficult balance to strike between protecting consumers from unsafe or ineffective medical treatments and ensuring that they have access to innovative products that prevent disease or extend life. Recently, there have been many cases where Americans are unable to obtain

products years after they have been approved in other countries. For example, despite rapidly growing rates of melanoma with nearly 10,000 deaths in 2013, the FDA has not approved any new sunscreen ingredients since the 1990s, with eight pending applications awaiting approval since 2002. Many of these sunscreen ingredients are widely available in Europe and other countries. While I am encouraged that the FDA has committed to work with Congress to find a solution to the sunscreen issue, I am concerned that this is just one example of a broader problem of inertia at the agency. Do you believe the FDA is currently striking the right balance between safety and innovation?

Answer: I agree that FDA has an important role in both ensuring safety and effectiveness and in supporting innovation. The agency is committed to finding ways to ensure that safe and effective products can get to the people who need them as swiftly as possible.

I understand that FDA's accelerated approval pathway has helped bring innovative drugs to market for patients suffering from serious or life-threatening illness, who have limited or no treatment options, as soon as it can be concluded that the therapies' benefits justify their risks.

If confirmed, I look forward to working with you in ensuring the integrity of a review process that promotes effectiveness and safety while also encouraging innovation.

13. Development of new drugs and medical devices is a high-risk, high-cost endeavor for many reasons, not least of which is the lengthy FDA approval process. For businesses and entrepreneurs investing in research and development, it is important for the FDA's regulatory approach to have predictability and certainty. One tool for improving regulatory certainty is the Special Protocol Assessment process, under which the FDA and an applicant enter into an agreement on the design of a clinical trial and what results will need to be demonstrated for a drug or biologic to be approved. The FDA recently revoked a Special Protocol Assessment days before the deadline for the agency to make a final decision on approval of a product. In response to concerns expressed by several members of this Committee, the FDA stated that such a revocation is appropriate whenever there is a "paradigm shift" in how the agency thinks about a scientific question. Unfortunately, this is just one example of an agency culture that often seems ignorant of how its decisionmaking can affect the willingness of the private sector to make the investments necessary to bring innovative products to market. If confirmed as Secretary, what steps would you take to ensure that the FDA develops a predictable regulatory culture that is conducive to maintaining America's global leadership in medical innovation?

Answer: Having spent time in the private sector, I appreciate the importance of as much predictability as possible. I also appreciate the importance of safety and effectiveness. I understand that FDA is also developing performance metrics that align with program requirements to help drive outcomes. If confirmed I look forward to working you and with FDA to understand how we can better maximize innovation, effectiveness, and safety.

14. As scientists gain a greater understanding of the human genome, we are moving into an era of “personalized” or “precision” medicine in which it is increasingly possible to predict which treatments will be effective for individual patients. In the past, a clinical trial in which only 5 percent of patients demonstrated improvement might have been labeled a failure, but that is not the case if researchers can determine what genetic factors can be used to identify that 5 percent. What kinds of changes need to occur in federal regulatory and reimbursement policies to ensure that patients can receive the benefits of precision medicine?

Answer: Over the past few years, a number of products that signal a new era of medical product development have entered the market or come on the horizon. In just the last two years, for example, I understand that FDA approved new cancer drugs for use in patients whose tumors have specific genetic characteristics identified by a companion diagnostic test. FDA also approved a new therapy for use in certain cystic fibrosis patients with a specific genetic mutation. Each of these examples demonstrates the promise of “personalized medicine,” which tailors medical treatment to the individual characteristics, needs, and preferences of each patient. If confirmed, I look forward to working with Congress on how these new tools can best be deployed to efficiently and effectively serve patients.

15. Regenerative medicine therapies aim to augment, repair, replace or regenerate cells, tissues or organs in order to restore or establish function. Research on regenerative medicine, including ethical stem cell research that does not involve the destruction of a living embryo, holds great promise to develop cures for a broad range of debilitating diseases. A 2006 HHS report recommended a coordinated federal approach to supporting regenerative medicine, warning that U.S. leadership in this area is “in danger of being eclipsed” by foreign governments’ initiatives. What actions would you take as Secretary to improve coordination of HHS activities affecting regenerative medicine research and development?

Answer: If confirmed, I would continue to work to bolster the many activities underway at HHS in this area and encourage the continued coordination of regenerative medicine research across the federal government. Within HHS, NIH and the FDA have key roles in supporting the development of regenerative medicine and facilitating a coordinated federal approach.

NIH-funded research is exploring potential clinical applications in regenerative medicine, as well as studying the molecular pathways in biological development and human disease. In Fiscal Year 2013, NIH awarded \$831 million for regenerative medicine research. I understand from HHS that formal coordination in regenerative medicine research occurs in part through the Multi-Agency Tissue Engineering Science (MATES) Interagency Working Group, which is currently chaired by the FDA. MATES aims to maximize the benefits to society of the federal investment in tissue science and engineering.

Through cross-agency research and coordination activities, HHS plays a central role in supporting regenerative medicine research, and, if confirmed, I would seek to foster and strengthen those activities.

16. The National Cancer Institute at the National Institutes of Health (NIH) provides cancer center support grants to research institutions that have received a cancer center designation. The allocation of these grants appears to be based primarily on grant amounts from prior years, and I have also heard concerns that political factors have played a role in setting grant levels. Georgia currently has among the lowest per-capita funding levels of any state with an NCI-designated cancer center. If confirmed, would you commit to working to ensure that this and other funding streams at NIH are allocated in a merit-based manner?

Answer: It is my understanding from HHS that at the request of the NCI Director, the National Cancer Advisory Board (NCAB), the NCI's external advisory group, recently reviewed the NCI's policies for allocation of funds to NCI-designated Cancer Centers to determine whether historical funding patterns unduly influenced current Cancer Center Support Grant (CCSG or P30) awards and, if so, consider whether or not alternative approaches should be explored. The NCAB working group, which represented a diverse subset of NCI-designated cancer centers, concluded that significant disparities exist in the sizes of CCSG awards due to factors other than current merit, including longevity, size of the NCI budget in the application year, and historical performance. Further, these disparities have been perpetuated due to outdated cancer center grant funding policies. The working group offered recommendations designed to resolve these disparities by changing the way grant funding is calculated. The NCI is now working closely with the NCAB to refine the recommendations, and design an appropriate implementation strategy.

If confirmed, I would work with the NCI to ensure that the changes made in these policies are successfully executed.

17. According to a recent report by the University of California (Davis) Comprehensive Cancer Center, racial and ethnic minorities make up less than 5 percent of participants in NIH-funded cancer clinical trials. The lack of diverse participation in clinical trials is particularly troubling as medical research increasingly focuses on genetic biomarkers, and the reasons for this disparity are still poorly understood. If confirmed, will you make it a priority to support research aimed at increasing minority participation in federally funded clinical trials?

Answer: Inclusion by sex/gender, race, and ethnicity is important in clinical research. For example, the National Cancer Institute (NCI) is currently implementing the NCI Community Oncology Research Program (NCORP), which supports cancer research in the community setting, with access to larger and more diverse patient populations. If confirmed, I will continue to work to reduce disparities and improve outcomes for underserved populations.

18. Earlier this year, President Obama signed into law a bipartisan reauthorization of the Children's Hospital Graduate Medical Education (CHGME) program. The purpose of this program, which has consistently received overwhelming bipartisan support in Congress, is to ensure that children's hospitals receive the same support that other teaching hospitals receive through Medicare GME payments. In fact, the CHGME program supports training for half of our nation's pediatric workforce.

Although the CHGME program pays significantly less per resident than Medicare, the President's FY 2015 budget proposal calls for eliminating CHGME and directing most of its funding into a new pool of money for which residency programs that already receive Medicare GME payments would be eligible. If confirmed, will you work with Congress to support and strengthen the CHGME program?

Answer: Ensuring all individuals, including children, have access to health care is a priority for this Administration. As such, the President's Budget for FY 2015 includes a new workforce proposal, the Targeted Support for Graduate Medical Education program, which will train 13,000 new providers over the next 10 years – responding directly to the documented need for primary care providers, as well as other subspecialties experiencing an inadequate supply. It also aims to redesign residency training to produce the next generation of providers with skills aligned to provide care based new models of health care delivery.

This proposal sets aside \$100 million a year set for the first two years for CHGME. In addition to this \$100 million set aside, pediatric hospitals and providers would have an opportunity to compete in the broader pool for additional resources. The Administration is deeply committed to strengthening the health workforce and prioritizes the importance of making investments in the pediatric workforce as a component of that effort. While we outlined a high-level approach to making investments in GME in our budget, we are very open to working with Congress to make adjustments to this proposal in ways that are informed by the full range of considerations raised by stakeholders and members. If confirmed, I look forward to working with you and other members of Congress to ensure that the goals of this program are realized.

19. The 340B drug discount program administered by the Health Resources and Services Administration (HRSA) is a vitally important program that enables safety-net hospitals and clinics to purchase outpatient prescription drugs at discounts comparable to what the government receives through Medicaid. Because the criteria for determining a hospital's 340B eligibility are largely based on how many Medicaid patients the hospital treats, participation in the program has grown substantially over time and is poised to expand even further in states that have chosen to implement PPACA's Medicaid expansion. If confirmed, would you be willing to engage in a dialogue about how to better identify the true safety-net providers who bear most of the burden of indigent care and who should be the primary focus of programs such as 340B?

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.

20. Ensuring access to life-saving trauma care has long been one of my top health care priorities. Trauma is the leading cause of death for Americans under age 45. Although getting seriously injured patients to Level 1 trauma centers can reduce the chance of death by up to 25%, 45 million Americans currently lack timely access to high-level trauma care. Partly due to financial pressure, nearly one third of trauma

centers have closed since 1990. Congress has authorized funding through the Public Health Service Act to support trauma centers and improve trauma systems and access. However, the Administration has not requested funding for any of these programs. Hospitals often report that they have to use various Medicare payment streams to cross-subsidize their trauma care, meaning that the burden of financing trauma access is falling on taxpayers even in the absence of direct federal support. If confirmed, how will you seek to prioritize ensuring access to high-quality trauma care?

Answer: Health care coalitions (HCCs), supported through the ASPR Hospital Preparedness Program, help ensure the provision of medical care when certain emergencies exceed the limits of a community's medical capabilities. HCCs are collaborative networks that include local and state trauma centers, in addition to hospitals, health care organizations, emergency medical services, long-term care facilities, dialysis centers, behavioral health, public health departments, emergency management, law enforcement, and other public and private sector health care partners within defined regions. These networks help mitigate the overwhelming demands of casualties and other traumatic incidents by enhancing the movement of information, resources, and patients across a community during both routine and disaster responses. HCCs aim to develop a support system that is gradually less dependent of federal resources and provides increased opportunities for community-based response to emergencies. If confirmed, I will work with the ASPR to help ensure HCCs continue to address trauma care needs.

21. HRSA's Organ Procurement and Transplantation Network is in the process of considering possible revisions to regional organ allocation boundaries with the goal of reducing wait times. Although the principles developed by OPTN's liver committee call for maintaining geographically contiguous regions, hospitals in Georgia have expressed alarm that two proposed options reportedly under consideration by the committee would place Georgia in a region with Pennsylvania, New York, West Virginia, and western Ohio, potentially disadvantaging Georgia transplant patients. Will you commit to ensuring that any new map is developed in an open and transparent manner with full opportunity for public input?

Answer: In my capacity as OMB Director, I have not been engaged in the specific issue that you raise and look forward to learning more if confirmed. Reducing geographic disparity in liver allocation is critical to ensuring patient access to necessary transplantation. If confirmed I will ensure that any discussions on liver allocation policies are governed by clear regulatory requirements, including a strong emphasis on transparency and opportunity for public comment.

22. Obesity is a serious public health problem in our country. I believe there are basically two approaches we can take to confronting this challenge. One is to educate and empower people to make healthier diet and exercise choices for themselves and their families, which I believe is the better and more effective approach. The other alternative is to tax and regulate and try to use the power of the government to stop people from making choices that are viewed as unhealthy. What do you believe is an appropriate role for HHS in combating obesity?

Answer: I agree that we need to do a better job of educating and empowering people to make better choices regarding nutrition and physical activity. I also believe that everyone has a role to play in improving nutrition and physical activity choices and weight outcomes, including: individuals, families, caregivers, schools, local community leaders, businesses, the media, and all levels of government.

HHS plays a vital role in tracking trends in obesity by demographic group, conducting research to understand the causes of obesity, as well as developing and testing interventions at the individual and community level (including partnering with state and local jurisdictions and other organizations) to develop approaches to facilitating environmental changes so that the easy choice is the healthy choice.

The Department is starting to see some early indications that individual and environmental changes are having an impact. In some age groups and in some cities and states, rates of childhood obesity are declining. If confirmed, I look forward to continuing the work of the Department on this critically important issue.

23. Some proponents of “behavioral economics” suggest that government should adopt policies that attempt to “nudge” people in the direction of making choices that government officials view as better or healthier, without outright regulation or prohibition of alternatives. Do you believe this is an appropriate role for the federal government?

Answer: Many parts of the U.S. tax structure are set up to incentivize activity that will be of benefit to individuals and society as a whole, from mortgage interest deductions, to deductions for contributions to charitable organizations, to a number of provisions designed to encourage individuals to save for retirement. Policymakers have the option of considering a range of tools in developing and implementing policy. If confirmed, I would welcome understanding any specific ideas that you have in this area.

24. The last few years have seen a notable increase in consolidation among health care providers, particularly with respect to hospitals buying physician practices. Proponents of consolidation argue that it will allow for better integration and coordination of care, while skeptics have expressed concern that it will increase the market power of large health care systems, enabling them to charge higher prices. Which of these perspectives do you find more persuasive?

Answer: I am aware that hospital acquisitions of other health care entities, such as physician practices, by hospitals have been commonplace in the last few years. It is my understanding that one of the ways CMS is encouraging competition is through the operation of the Medicare accountable care organizations (ACOs). I believe that competition among ACOs will foster improvements in quality, innovation, and choice for Medicare beneficiaries. The antitrust agencies (Department of Justice and Federal Trade Commission) are monitoring the competitive effects of ACOs. These agencies issued guidance for providers seeking to become ACOs and

established a voluntary expedited review process to give feedback to providers on potential anti-competitive activities.

In addition, the testing of the Advance Payment ACO model has led to increased participation by smaller organizations in the Medicare Shared Savings Program, thus increasing competition.

25. As regulatory and reimbursement systems become more complex, they can create an advantage for large companies or organizations that have the resources to navigate bureaucratic hurdles. This is of particular concern as the federal government's influence over health care continues to expand. How will you ensure that HHS regulatory and reimbursement decisions do not become a tool for established players in the health care market to freeze out competition and block innovative new ideas?

Answer: It is my understanding that the Department shares your concerns and is working to ensure that providers are able to care for their patients without excessively burdensome and unnecessary regulations. 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. 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. If confirmed, I will continue to support the important work of CMS in this area.

26. Health-related activities carried out by different agencies, both within and outside HHS, create the potential for wasteful duplication of effort. For example, a recent GAO report found substantial duplication among autism research initiatives sponsored by seven different HHS agencies, as well as the Department of Defense, the Department of Education, and the National Science Foundation. What actions can the HHS Secretary take to improve coordination among different agencies working on similar projects?

Answer: Based on my understanding, NIH funded the majority of federally funded autism-related research from fiscal years 2008 through 2012. Therefore, coordination among the NIH Institutes and Centers (ICs) that fund autism research represents a large component of HHS' ongoing efforts to avoid unnecessary duplication in research. To achieve this coordination, NIH has an internal Autism Coordinating Committee (ACC), which include staff from the National Institute of Mental Health (NIMH), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), and the National Institute of Environmental Health Sciences (NIEHS). ACC members collaboratively plan and co-fund major autism-related research initiatives and scientific workshops. Moreover, they share information related to autism research activities at their respective Institutes, including information about activities in which the NIH ICs participate or coordinate with other federal agencies. They also share information they learn about nongovernment-funded autism research through participation in scientific meetings and other

activities sponsored by non-government organizations. Therefore, collaborations and information exchanges through the NIH ACC provide important opportunities for averting unnecessary duplication before it happens, both within and beyond the NIH.

27. According to the most recent projections by the Congressional Budget Office, mandatory spending on HHS programs – including Medicare, Medicaid, CHIP, health insurance subsidies, and family support and foster care – is projected to total over \$1.05 trillion in fiscal year 2015, while the total amount of all discretionary spending controlled by Congress will be \$1.11 trillion. The growing share of federal spending that is effectively on “autopilot” makes it increasingly difficult for Congress to produce a fiscally responsible balanced budget. However, the President’s FY 2015 budget for HHS proposes to shift a number of programs that have historically been funded through the discretionary budget to mandatory spending. Under what circumstances do you believe it is appropriate to take programs out of the normal budget and appropriations process and move them to mandatory status? If Congress were to adopt a two-year budget cycle, along the lines of bipartisan legislation I have proposed with Sen. Jeanne Shaheen, would it become feasible to shift more programs out of mandatory funding and back into the regular budget and appropriations process?

Answer: The President’s Budget renews our commitment to critical health care and workforce services now, before these essential programs expire, to continue the momentum built in the last five years. As we look to full implementation of the Affordable Care Act this year and beyond, there is still work to be done to ensure that essential health services, like primary care and mental health care, reach all Americans. These investments, which aim to improve access to health care and our health workforce, are challenging and take several years to realize results. It is important that we make a commitment to our communities, universities, and training partners that go beyond one year, and it is not uncommon to request mandatory funding for such investments.

One area where we have requested additional mandatory funding is for the Health Centers Program. The President’s Budget plans for a surge in newly-insured patients in FY 2015 through FY 2018. Those who are now eligible for insurance through the Marketplaces or Medicaid expansion are historically low-income Americans who have relied on health centers for discounted care. These patients are likely to continue seeking care at health centers because of the high patient satisfaction rate, availability of comprehensive services, and established relationships with doctors and staff. Further, health centers will continue to serve patients who are medically underserved, as well as provide services that are not typically covered by insurance.

In another case, the Administration has requested \$319 million in discretionary funding for the Health Care Fraud and Abuse Control Program (HCFAC) and \$378 million in proposed new mandatory funding for HCFAC. Starting in FY 2016 the Administration is requesting that all additional HCFAC funds be mandatory, instead of through the discretionary cap adjustment included in the Budget Control Act. This would provide a dedicated, dependable source of additional resources to perform program integrity activities, which often require a multi-year commitment, primarily in the Medicare and Medicaid programs.

The Administration has not taken a position on moving to a biennial budget cycle nor on the specific legislation you mention, but is always open to working with Congress on new ways to advance the goal of greater certainty in the budget process. With respect to biennial budgeting, this approach has both advantages and disadvantages. On one hand, in theory it could help facilitate greater budgetary certainty, better agency planning, and more time to focus on execution and effectiveness. On the other hand, there are good reasons to believe that biennial budgeting may not advance the goal of a regular budget process that functions smoothly and provides certainty, and could potentially lead to unintended consequences such as increased reliance on supplementals or a further drawn-out budget process that would not achieve the goals. If confirmed, I look forward to working with the Congress on HHS' FY 2015 Budget request.

Questions from Senator Kirk

- 1. CMS recently instituted a policy change for certain products used to treat rheumatoid arthritis (RA) to ensure patients who cannot self-administer have access to the physician administered form of the product. Don't you believe that CMS should apply this policy change consistently to all products within the class, including Humira, to ensure patients have equal access to all products as needed?**

Answer: I understand from HHS that CMS did not institute a policy change for drugs to treat rheumatoid arthritis (RA). Under the Social Security Act, drugs that are not usually self-administered are payable under Medicare Part B. CMS has defined "not usually self-administered" to be not administered by the patient 50 percent or more of the time. The decision about whether a drug is "not usually self-administered" is generally left to the Medicare Administrative Contractors. In the case of one RA drug, CMS made a decision last Fall that the drug meets the criteria to be paid under Medicare Part B because the data demonstrated that it is not usually self-administered. In the case of Humira, both Medicare's contractors and CMS reviewed the data and found that the drug is usually self-administered by the patient.

- 2. Ms. Burwell, HHS recently renewed an Action Plan for the Prevention, Care and Treatment of Viral Hepatitis which seeks to increase the number of individuals diagnosed and reduce transmission of these diseases. If confirmed, will you continue to focus cross agency attention on addressing the viral hepatitis epidemic and implementing the Action Plan? Hepatitis C could be eliminated in our lifetime if appropriate attention is paid to addressing this public health need. As you consider key issues to focus on as Secretary will you include viral hepatitis on that list?**

Answer: Yes, if confirmed I will focus on this issue and continue the CDC's critical work in this area. CDC estimates that between 3.5 and 5.3 million Americans are living with chronic viral hepatitis due to hepatitis B and/or hepatitis C, and don't know it. This places these Americans at risk for severe, even fatal complications from these infections and increases the likelihood that they might unknowingly transmit the infection to others. If confirmed, I will ensure that HHS continues to support the implementation of a national, coordinated strategy to prevent viral hepatitis and to improve health outcomes for those who are already infected.

- 3. A number of the most innovative and effective anti-cancer drugs that have been - and are - under development are oral drugs. In many cases, oral chemotherapy is the only treatment available. Unfortunately, while intravenous treatments are covered under a health plan's medical benefit, requiring only a small co-pay, oral chemotherapy drugs are often covered under the health plan's prescription benefit which results in patients being responsible for up to thousands of dollars in out-of-pocket costs per treatment cycle. Senator Franken and I introduced S.1879 to remedy this issue. Can you describe for this Committee your views on this important problem and commit to working with me and others on the Committee and other stakeholders on potential legislative and regulatory solutions to this urgent issue?**

Answer: As OMB Director, I was not directly engaged on this topic. I understand that regulations implementing the Affordable Care Act provide detail on how health insurance plans in the individual and small group markets must provide the Essential Health Benefits (EHB). These regulations include cost-sharing protections that limit the amount of out-of-pocket expenses consumers and their families can be subject to, as well as anti-discrimination provisions that ensure that qualified health plans (QHPs) do not employ benefit designs that discriminate against individuals with significant health needs.

Additionally, I understand that in March 2014, the Centers for Medicare & Medicaid Services (CMS) issued the 2015 Letter to Issuers in the Federally-facilitated Marketplace, to provide guidance for issuers on how CMS would review plans submitted for the 2015 plan year to ensure non-discrimination in QHP recent guidance from benefit design. Specifically, CMS will perform an outlier analysis on QHP cost sharing as part of the QHP certification application process. QHPs identified as outliers may be given the opportunity to modify cost sharing for certain benefits if CMS determines that the cost sharing structure of the plan submitted for certification could have the effect of discouraging the enrollment of individuals with significant health needs. CMS's outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits, including but not limited to prescription drugs.

I have not yet reviewed S. 1879, but am told that the provisions in the current regulations and guidance provide strong consumer protections. However, if confirmed, I look forward to working with you on any additional concerns you may have.

- 4. FDA has indicated that they would like to regulate in the area of advanced diagnostic lab tests. Accordingly, they have developed a draft guidance which I understand has been pending review at OMB for over two years. In a November 2013 commentary in the New England Journal of Medicine, FDA Commissioner Peggy Hamburg and NIH Director Francis Collins stated that "putting in place an appropriate risk-based regulatory framework is now critical to ensure the validation and quality of LDTs."**
 - a. When do you expect for the draft guidance to be cleared by OMB and issued by FDA?**

Answer: We are currently working with FDA on its draft guidance on laboratory developed tests (LDTs), and I cannot comment on the timing of when it will be issued. That said, we would welcome you or your staff to come in and share your views about the draft guidance.

- 5. NIH and NCI provide all kinds of grants to researchers to provide support for investigator-initiated projects. These grants are integral to researcher's ability to pursue academic careers. I have heard from several constituents that many young, promising MD/PhD investigators are leaving their training programs to go into private practice- abandoning their scientific scholarship because there isn't funding to support their labs. This is a general problem, but I'm particularly concerned about the field of radiation oncology. I understand that when the NCI did a review of its grants, it determined that about 5% of NCI's budget was going to fund radiation oncology grants/projects. I'm not sure what the right number would be, but 5% seems awful small given that radiation oncologists treat roughly two-thirds of all cancer patients. Does 5% seem small to you? And are you willing to review your internal processes to make sure that there aren't any problems in the way radiation oncology proposals are reviewed that is leading to such a low funding rate?**

Answer: The NCI's primary goals are to support and conduct a broad spectrum of cancer research. The research NCI oversees uses a wide variety of approaches and funding mechanisms, with several goals: improving our understanding of the causes and biological mechanisms of a large variety of cancers; preventing cancers; detecting and diagnosing all types of cancers; and treating cancers, as well as the symptoms and sequelae of cancers, more effectively. NCI's research projects and programs include studies of the basic aspects of cancer biology at the molecular and cellular levels: investigations of how cancer cells and processes affect and are affected by the cellular environment in which they exist, and applications of these discoveries toward successful detection, diagnosis, treatment, prevention, and control of cancers of all types.

In my role as OMB Director, I have not been personally involved in account level funding allocation decisions within individual NIH Institutes.

I understand that all research efforts supported by the NCI are subjected to rigorous review for quality and purpose by expert peer reviewers, program staff, and advisory groups.

Radiation therapy plays a critical role in NCI's portfolio of cancer clinical trials. It is incorporated as a standard part of the treatment plans for many cancer patients. Investigational questions related to new radiation therapy techniques as well as how to best combine radiation therapy with systemic therapies and surgery comprise a major part of the portfolio of studies carried out by the NCI's National Clinical Trials Network (NCTN). The NCI currently supports 50 national trials that incorporate radiation therapy as a component of the investigational program under examination. In addition to the substantive resources provided for radiation therapy-related clinical trials, NCI supports basic research into radiation therapy and radiobiology. If I am confirmed, I look forward to learning more about the concerns raised in your question.

6. As you know, Section 1341 of the Patient Protection and Affordable Care Act establishes a transitional reinsurance program intended to stabilize premiums for coverage in the individual market from 2014 to 2016. The Act requires \$20 billion to be collected from health insurance issuers and group health plans, including self-insured employers, over the three-year period. HHS has proposed a national per capita fee in 2014 of \$63 per covered life, including employees, dependents, early retirees, and COBRA eligible individuals. An additional \$5 billion will be collected by the U.S. Department of Treasury.
- a. I am concerned about impact of this program on employer-sponsored coverage, particularly given the recent regulations that would carve out some self-administered, self-insured entities. I recently introduced a bill to address this problem and it is widely supported by the business community as well as by labor. The bill would delay the collection of the fee for three years, keeping the program itself intact. Would you consider an administrative delay of the fee collection?

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.

Questions from Senator Murkowski

Head Start

The following questions were suggested by Mark Lackey, President of the Alaska Head Start Directors Association. If you are confirmed:

1. **What would your priorities be for the reauthorization of the Head Start Act?**

Answer: If confirmed, I will review all the changes made in the Head Start program since the last reauthorization in 2007. We will continue to learn from these experiences. I know that the Department is continuing to evaluate the Designation Renewal System (DRS) and its effects on quality in particular. If confirmed, I will study all of these efforts, including the DRS evaluation, and determine priorities for moving forward.

2. **How do you plan to deal with Head Start grantees' anxiety and uncertainty surrounding recompetition of Head Start grants, which is resulting in high turnover among Head Start directors?**

Answer: I understand that adoption of the DRS was a major policy shift and that competition has created anxiety for some grantees. However, DRS is an opportunity to improve program quality. The overall staff turnover rate for Head Start remains significantly lower than the national average for the early childhood field more broadly. If confirmed, I intend to continue the work of the Department on this issue.

3. What actions would you take to address the fact that the professional development requirements for Head Start employees make them eligible for higher-paying school districts jobs—salaries that Head Start grantees cannot match?

Answer: The Department is committed to attracting, training and retaining highly qualified staff in order to improve program quality. Local grantees set personnel policies such as salaries and make decisions to help retain qualified staff. The Head Start Program Information Report (PIR) collects data on teacher turnover and reasons that teachers report leaving their jobs. According to the latest PIR data, in 2013 the turnover rate for Head Start pre-school teaching staff was 15 percent and only 24 percent of those teachers (4% of all teachers) reported leaving for compensation reasons. Most teachers report leaving their Head Start positions for “other reasons” which include retirement, termination, personal/family reasons or health issues. If confirmed, I intend to continue the work of the Department on this issue and look forward to working with external stakeholders to devise effective recruitment and retention strategies.

4. Do you intend to make any changes to the current CLASS system of performance standard measurement?

Answer: The Department is undertaking an evaluation of the DRS, which includes CLASS. If I am confirmed, I will work with the Assistant Secretary of the Administration for Children and Families to examine the results of the DRS evaluation and determine any actions going forward.

Community Pharmacies

1. I have heard multiple concerns from Medicare patients and local pharmacies about the problems and confusion associated with Medicare Part D Preferred Pharmacy Networks. CMS proposed to alleviate these problems and confusion in a recent proposed rule, however on March 10th CMS released a statement that they would not move forward at this time with a solution. What will you do to ensure that patients don't have to travel large distances or are forced to use mail order to access special savings in Medicare and to ensure that patients can continue using the pharmacy of their choice?

Answer: It is my understanding that although CMS has announced that it does not plan to finalize certain proposals related to preferred cost sharing included in our proposed rule published in the Federal Register on January 10, 2014, it continues to focus on beneficiary access to and understanding of preferred cost sharing arrangements. In order to further analyze this issue, I understand that CMS has awarded a contract to study beneficiary access to preferred cost sharing. This study will analyze beneficiaries’ geographic access (i.e., time and distance) to pharmacies offering preferred cost sharing in plans’ networks. Based on the results of this study and comments received on the proposed rule, CMS will evaluate whether and how to set standards for network adequacy for pharmacies offering preferred cost sharing, similar to current standards for retail network adequacy.

Questions from Senator Burr

1. The Agency for Toxic Substances and Disease Registry (ATSDR), within the Centers for Disease Control and Prevention (CDC), in its ongoing statutory role investigating and conducting studies for a Public Health Assessment (PHA) of the water contamination that occurred at Marine Corps Base Camp Lejeune, North Carolina from 1953-1987, has had in its possession since March of 2013 several thousand documents that relate to vapor intrusion in buildings on Camp Lejeune that were located above the largest underground contamination plumes in the groundwater. It is clear from the dates on some of these documents that the ambient air quality in these buildings posed a potential health hazard to the occupants of certain buildings and that harmful human exposures may have occurred in those buildings for more than a decade and a half after the last of the contaminated water wells were shut down in 1985.

a. Since ATSDR received these thousands of documents in 2013 from the Department of Navy (DoN), what specific actions did the agency take in 2013 and to date in 2014 to conduct a Vapor Intrusion/Inhalation Exposure Pathway (VI/IEP) analysis to further inform ATSDR in its ongoing effort to revise and reissue the retracted 1997 PHA for Camp Lejeune?

Answer: I have not been directly engaged on this issue as OMB Director. However, I understand from HHS that ATSDR's work to date on soil vapor intrusion (SVI) at Camp Lejeune has involved identifying voluminous documents that contain information potentially relevant to determining whether vapors seeped from the shallow aquifer into buildings at Camp Lejeune, potentially exposing those in the buildings to dangerous chemicals and posing health risks. Information and data on a broad range of topics are potentially relevant to soil vapor analysis, including environmental, industrial hygiene, base safety, public works, GIS, and health. I further understand that ATSDR staff have met with base leadership at Camp Lejeune to identify relevant data, and is identifying relevant data sources from ATSDR's Camp Lejeune Data Mining Work Group effort. If confirmed, I will work with you to appropriately address and respond to the issues confronting Camp Lejeune.

b. Why did ATSDR delay informing Congress and the Camp Lejeune Community Assistance Panel (CAP) of the existence of these documents until April 4, 2014?

Answer: As OMB Director, I have not been made aware of any delay in the provision of information regarding this issue. However, I understand from HHS that there was some discussion of the documents during two Community Assistance Panel (CAP) meetings in 2013—on May 3 and September 6. ATSDR has since provided an index of the document titles of interest identified to date to the CAP has provided a briefing to both the CAP and interested Congressional staff on ATSDR's process for reviewing and identifying documents of interest. If confirmed, I will look into this issue and work to keep Congressional staff and the CAP informed as the process moves forward.

- c. **Has ATSDR cross referenced all the documents it obtained from the DoN in 2011 as a result of the ATSDR-DoN Data Mining Technical Working Group to determine which of the documents it received from DoN in 2013 on Soil Vapor Intrusion and thereafter are not part of that ATSDR's Data Mining Technical Working Group's past efforts and is ATSDR employing its resident subject matter experts who supported the Data Mining Technical Working Group in this effort on Soil Vapor Intrusion? If not, please explain why.**

Answer: I was not aware of the specifics of this issue as OMB Director, but understand from HHS that ATSDR's review to identify documents that are potentially relevant to soil vapor intrusion includes the 2011 Camp Lejeune Drinking Water Data Mining Technical Work Group as a data source.

ATSDR's Soil Vapor Intrusion Project Team has worked closely with, and benefitted significantly from, the subject matter experts from the Data Mining Technical Work Group, and the soil vapor team is employing the same technologies and procedures developed by the Work Group to identify information that is relevant to the current analysis. If confirmed, I will look into this issue.

- d. **Are the ATSDR personnel who were members of the Data Mining Technical Working Group and who have the subject matter expertise and familiarity with the Camp Lejeune document data bases been formed into a group at ATSDR to examine these more recent documents from the DoN? If not, please explain why.**

Answer: I was not involved in the work associated with these data base as OMB Director but if confirmed, I look forward to working with you on next steps on this issue. I understand that ATSDR's Soil Vapor Intrusion Project Team has worked closely with, and benefitted significantly from, the subject matter experts from the Data Mining Technical Work Group.

2. **If confirmed, please outline the specific steps you will take to improve regulatory transparency, certainty, and predictability at the FDA. Please outline in detail the metrics you believe would best measure the impact of these steps.**

Answer: I understand that FDA's performance goals under all of its user fee agreements provide a set of metrics for assessing the transparency, certainty, and predictability of its regulatory programs. These goals are developed through negotiations between and among the Agency, industry, and Congress. FDA realized higher performance levels and met more procedural goals than ever before in FY 2012, and it continues to strengthen efforts to improve performance in these areas while maintaining a focus on ensuring that safe, effective, and high-quality new drugs, biologics, generic drugs, medical devices, and other product areas under FDA regulatory review are reviewed in an efficient and predictable time frame. I understand that FDA is developing performance metrics that align with program requirements to help drive outcomes. There is always room to improve. If I am confirmed, I will want to better understand these metrics are driving performance, and how we can build on that progress.

- 3. The policies at the Department of Health and Human Services, particularly those at the FDA and CMS, can have a significant impact on patients' ability to access innovation. Do you believe that the potential impact on innovation should be taken into consideration in the Department's policy-making process, including through the regulations issued by the Department? If so, how will you ensure that the Department enacts policies that advance patients' access to innovation?**

Answer: I do believe that innovation is a consideration and it is something that impacts both quality and cost. During my time at OMB, rulemaking review has included economic growth consideration as well as health, safety and environmental consideration. If confirmed, I will want to work to consider key health impacts and innovation.

- 4. Will HHS hold off finalizing the Child Care Development Block Grant (CCDBG) regulations until Congress has the opportunity act on the bipartisan legislation I authored with Senator Mikulski to reauthorize this program?**

Answer: In the event Congress passes and the President signs legislation to reauthorize the Child Care and Development Block Grant program, the Administration would revisit the rule as part of its work to implement the new statute.

- 5. Please outline the specific opportunities you see to improve program clarity and integrity for HRSA's 340B program. If confirmed, how would you seek to work with patient groups, pharmaceutical manufacturers, and 340B covered entities with respect to these opportunities as well as concerns that may arise in the future?**

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. The management of the Strategic National Stockpile (SNS) directly impacts our nation's medical and public health preparedness and response capabilities.**
- a. Please explain how HHS identifies the full range of products and medical assets necessary to stockpile in the SNS and executes contracts and awards to ensure that these needs are met under the full range of scenarios, including for products procured by BARDA and CDC.**

Answer: It is my understanding that HHS determines essential medical countermeasures (MCM) for chemical, biological, radiological, and nuclear (CBRN) threats while considering public health scenarios delineated in the Project BioShield Act (2004) and based on Terrorist Risk Assessments (TRA) and Material Threat Assessments (MTA) determined by the Department of Homeland Security (DHS). As directed by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), the principles, goals, and priorities for the development and acquisition of MCMs are defined in the PHEMCE Strategic and Implementation Plan (2012). Under Project BioShield, managed by the Biomedical Advanced Research and

Development Authority (BARDA), MCMs may be developed and purchased using the Special Reserve Fund (SRF). This includes MCMs for CBRN threats that are not licensed or approved by the FDA, yet have sufficient data to warrant utilization under the FDA's Emergency Use Authorization (EUA). The results of Project BioShield are provided in annual Congressional reports (2005-2013).

I further understand that upon licensure or approval of these MCMs, the responsibility of stockpiling transitions to the Centers for Disease Control and Prevention (CDC)/Strategic National Stockpile (SNS). The CDC's SNS inventory assessments are also available to Congress in annual reports (2007-2013). MCM development and acquisition by ASPR/BARDA and CDC/SNS are in full alignment with the PHEMCE SIP (2012) and MCM requirements. If confirmed, I look forward to understanding how these steps translate to potential action.

How do these align with the full range of projected needs, including those that might not be explicitly identified through the 5 year budget plan, such as drug delivery devices that would be necessary as part of vaccine administration during a public health emergency?

Answer: My understanding from HHS is that the Strategic National Stockpile (SNS) program at CDC maintains stockpiles of vaccine against certain threats, as well as ancillary supplies to support administration of these products. In addition to ancillary supplies procured for specific vaccines, CDC/SNS also maintains ancillary supplies (28 million unit requirement and inventory on hand) that could be distributed during a public health emergency (e.g. flu vaccines). The annual review of the CDC/SNS inventory that is conducted by the Public Health Emergency Medical Countermeasures Enterprise and submitted to Congress addresses these needs using available annual funding to the CDC.

In the case of a pandemic, HHS pandemic influenza response plans designate CDC as the responsible organization for distribution of vaccines, as was done during the H1N1 2009 pandemic. During an influenza pandemic, BARDA would utilize its existing contracts with multiple manufacturers of influenza vaccines and ancillary to purchase these products for delivery to the CDC's distribution hubs. CDC, based on ordering from states and territories, will instruct the distribution hubs to deliver these products to the designated sites.

b. For those products that are part of a “one portfolio” approach that seeks to address both U.S. military and civilian medical countermeasure needs, such as treatment for acute radiation syndrome in the event of a nuclear incident, how does HHS adjust its SNS procurement to ensure that both the military and civilian need requirements are accounted for and there will be enough product procured to protect both populations?

Answer: It is my understanding that together, HHS and the Department of Defense (DoD) plan and implement programs to develop and acquire MCMs that address common threats. Moreover, some shared MCM development projects such as Acute Radiation Syndrome therapeutic for gastrointestinal injury, have transitioned from the DoD to BARDA for advanced development with regard to FDA approval or licensure. As MCMs mature towards acceptability by FDA or

availability under an Emergency Use Authorization, BARDA will purchase these MCMs using the Project BioShield Special Reserve Fund to address MCM requirements for the civilian population, including special needs populations (e.g., children). If the MCM is licensed, then CDC/SNS procures the product. If DoD has a requirement to purchase the MCM to address their requirements, then DoD and HHS (BARDA or CDC/SNS) enter into an agreement to use DoD funds and HHS contracts to acquire the products and store the product at the CDC/SNS or forward deploy to the DoD, as needed. Conversely, DoD has contracts that HHS utilizes under the Economy Act to purchase some FDA approved or licensed products (e.g., influenza antiviral drugs) that are stored at the CDC/SNS.

However, not all DoD MCM requirements are the same as HHS' civilian population requirements. In this situation, I understand that HHS and DoD pursue development and acquisition together for the therapeutics. NIH may support early development of the DoD product, but BARDA does not pursue advanced development and acquisition of MCMs that are not required for the civilian population.

For the products under development as part of the “one portfolio” coordinated approach, does HHS consider a requirement to be addressed when the SNS has procured enough product for just the civilian population need requirement, or both the military and civilian population need requirements?

Answer: Please refer to the previous response.

Questions from Senator Hatch

Liver Allocation

- 1. In June 2013, the United Network for Organ Sharing (UNOS), which serves as the nation’s Organ Procurement and Transplantation Network (OPTN) through a contract with the Department of Health and Human Services, implemented a new policy for liver allocation. I am concerned that this new policy, “Share 35,” may be worsening the liver allocation process in the United States. Indeed, in my home state of Utah, the new policy is worsening outcomes following liver transplantation, causing a higher post-transplant mortality. This is in part due to longer times outside the body for donated livers because a much higher proportion of donor organs from the local region in which they were donated are being moved to transplant centers a state or several states away. Often, these out of state patients have no more medical urgency than do the local patients. I am particularly concerned about the impact of the Share 35 policy on liver donation rates, including the historically high rates in my home state of Utah. Given that a 1% increase in donation rates equates to 60 donor livers, even small improvements in the rate of organ donation can have a large impact on transplant and waitlist mortality rates. Conversely, even a 1% decline in donation rates would negate any national decline in waitlist mortality attributable to Share 35. It seems to me that time would be well spent on working to increase the number of organ donors in our**

country. The state-by-state variation is dramatic, with a low of less than 5% and a high of more than 90%.

- a. Has OPTN conducted an analysis to determine the impact of the new policy on liver donation rates in those areas with historically high donation rates and historically low donation rates? If not, I urge that the Department direct OPTN to conduct such an analysis.**

Answer: There are currently more individuals in need of a transplant than for which a donor organ is available. While I have not been directly engaged in these issues as OMB Director, my understanding from HHS is that in order to continue to raise awareness about the importance of registering to be an organ donor, the Department has engaged in comprehensive educational campaigns about the importance of organ donation, as well as partnered with others in the private sector to raise awareness about how to sign up to become an organ donor.

I understand from HHS that the Organ Procurement and Transplantation Network, which is tasked with developing organ allocation policies, is currently discussing liver allocation policies with experts in the field, transplant recipients, candidates, donor family members and living donors. These discussions will continue to be governed by clear regulatory requirements, including a strong emphasis on transparency and opportunity for public comment. If confirmed, I look forward to understanding more about the work and outreach OPTN is doing in the liver space.

- b. Has the Department done any work with its sister agencies to ensure steps are taken to increase organ donation rates through, for example, requiring that all those who receive a driver's license are educated about organ donation and asked whether or not they would like to be an organ donor?**

Answer: While I have not been directly engaged in these issues as OMB Director, my understanding from HHS is that the Department supports a national initiative to increase enrollment in state donor registries through public service announcements, social media campaigns, and targeted outreach to specific populations. In addition, the Department works with states to improve donor registration and direct outreach activities occur at local motor vehicles offices. If confirmed, I will work to increase organ donation rates.

- c. Can you please tell me if Share 35 policy was tested in a regional demonstration prior to implementation, as required by the 2010 HHS funding bill? If not, please explain how the new policy was evaluated and how any such evaluation provided data equivalent to what could have been obtained through a regional demonstration? Please provide copies of all evaluation (and other) reports associated with the testing of the Share 35 policy (including the exemption for patients with liver cancer).**

Answer: While I have not been directly engaged in this issue as OMB Director, my understanding from HHS is that the policy was tested through the implementation of a "variance" policy ("Share 29") in Region 8 through 2011. While the policy variance demonstrated some decrease in risk-adjusted waiting list mortality, the results were not

statistically significant due to the small number of patients included in the analysis. However, the OPTN liver committee determined that a change targeting a smaller subset of very sick patients with similar waiting list mortality would lead to an increase in access to livers for patients with the most medical urgency and a decrease in geographic disparity for such patients. A report on the potential impact of the Share 35 changes to broaden the geographic allocation of livers, required by the 2010 Appropriations Conference Report, was submitted to the House and Senate Appropriations Committees in November 2011.

If confirmed, I look forward to learning more about these issues and sharing additional information about the Share 35 policy.

- d. UNOS had made clear that data on this new Share 35 policy would be reviewed after six months of implementation. The six-month deadline passed on January 16, 2014 and I have yet to learn the status of this essential post-implementation data review. If this post-implementation review has not been initiated or has not yet been completed, please provide a status report, including a timeline, and an in-person briefing by OPTN with HRSA in attendance.**

Answer: I understand that changes to the liver allocation policy were implemented beginning in June 2013. A six-month post-implementation analysis indicates that, overall, the goals of this liver allocation policy change are being met, and implementation is proceeding as expected. For instance, since implementation of the new policy the number and percentage of livers shared regionally increased and death rates for adult candidates on the liver waiting list have been reduced.

On March 31, HHS/HRSA staff briefed Senate Appropriations staff on these results. If confirmed, I would be pleased to ensure further briefings occur as needed.

- e. I would also like to better understand HRSA's oversight of liver allocation. Does the Department have to approve of or in any way review a new national liver organ allocation policy?**

Answer: If confirmed, I look forward to learning more about HRSA's oversight of liver allocation policies. My understanding from HHS is that HRSA contracts with the United Network for Organ Sharing (UNOS) for the operation of the National Organ Procurement and Transplantation Network. HRSA is responsible for overseeing the operation of the OPTN to ensure equitable allocation of donor organs for transplantation, including the equitable allocation of livers. OPTN organ allocation policies are developed through a deliberative process with input from a wide range of stakeholders and must be consistent with the principles established in the National Organ Transplant Act of 1984, as amended, and the regulations governing the operation of the OPTN.

If confirmed, I look forward to further understanding your concerns and sharing additional information about national liver organ allocation policy.

- f. **Does the Department have the authority to address the ongoing and widely-recognized problem of “over-prioritization” of liver cancer patients for liver transplant? Liver cancer patients are automatically assigned a high score, which increases automatically (equating to a higher place on the transplant list) simply because they have liver cancer, even though they have no higher potential benefit from transplant than do patients with the same MELD score calculated based on lab values. A substantial and growing portion of livers that are transplanted under Share 35 are given to patients with these “exception” scores. I urge that the Department take action to address this inequity, and that the Department insist that UNOS review their exception process and ensure that waitlist positions are based on objective lab scores, and that liver cancer or other types of patients are not “over prioritized” in contraindication of science.**

Answer: As OMB Director, I have not been involved in the current determination. My understanding from HHS is that candidates with a MELD/PELD score exception for hepatocellular carcinoma receive high priority on the liver wait list. As with all allocation policies, HRSA and the OPTN analyze and monitor any emerging issues and there is currently a policy proposal in public comment that would restrict automatic extensions for patients with HCC exceptions. If confirmed, I look forward to working with you and OPTN on this important issue.

Meaningful Use Electronic Health Record Incentive Program

1. **Although very few providers have achieved Meaningful Use Stage 2, CMS and the Office of the National Coordinator for Health Information Technology (ONC) are already engaged in preliminary steps toward Stage 3 rulemaking. Frankly, it is difficult for me to understand how Stage 3 decision making can be underway when there has seemingly been absolutely no opportunity to learn from the experience of Stage 2. Can you please share the evidence base about Stage 2 that the Department is using to inform Stage 3 rulemaking?**

Answer: It is my understanding that HHS is drawing on a range of quantitative and qualitative data to inform Stage 3 rulemaking. As has been the case in 2011, 2012, and 2013, it is expected that most providers who attest in 2014 will Attestation data from providers who attest to Stage 2 will be used as it is available to inform Stage 3 rulemaking. In addition to administrative data from the Medicare and Medicaid EHR Incentive Programs, HHS is using data from national surveys of physicians and hospitals on the rate of adoption of specific health IT functionalities and the impacts of EHR use on health care outcomes. HHS is also taking into account qualitative data gathered from key stakeholders including information from hearings and listening sessions held by the Health IT Policy Committee on provider and vendor experience preparing for and meeting Stage 2.

An overview of the data being used to inform Stage 3 rulemaking can be found in presentations to the Health IT Policy Committee, including:

- http://www.healthit.gov/facas/sites/faca/files/HITPC_Data_Analytics_Update_2014-04-08.pdf

- http://www.healthit.gov/facas/sites/faca/files/HITPC_DataAnalyticsUpdate_2014-05-06.pdf
- http://www.healthit.gov/facas/sites/faca/files/HITPC_ListeningSessionsUpdate_2014-04-08.pdf

2. **Interoperability of Electronic Health Records (EHRs) and the care coordination enabled by the successful use of Health Information Technology (HIT) are critical to the nation’s ability to move to an efficient, high value health system. The Medicare and Medicaid Electronic Health Record incentive program, known as the “Meaningful Use” program, seeks to facilitate the widespread utilization of EHRs by hospitals and physicians. This program is meant to eliminate – not perpetuate – the digital divide.**

Over the next five months (May through September), more than 5,000 hospitals and 550,000 physicians and other eligible professionals must adopt the 2014 Edition of Certified EHR Technology (CEHRT) and meet a higher threshold of Meaningful Use criteria. Failure to do so will not only result in a loss of incentive payments, but also the imposition of significant penalties. I understand from providers that the 2014 Certification and Stage 2 Meaningful Use requirements (which include both an upgrade to the 2014 Edition Certified EHR and an increase in the performance requirements) are simply too much change all at once.

The American Hospital Association (AHA) recently determined that if current timelines remain, approximately 40% of hospitals are at risk of failing to meet Meaningful Use in FY 2014. Only a fraction of the technology used to achieve Meaningful Use has been certified as required for 2014. The AHA and the American Medical Association joined with more than 40 national hospital and physician groups in a February 21, 2014 joint letter to you, Secretary Sebelius, urging that additional time and flexibility be afforded to providers with respect to Stage 2 Meaningful Use requirements and 2014 Certification requirements. Similar recommendations were made to your predecessor beginning last summer by the College of Healthcare Information Management Executives (CHIME), the Healthcare Information and Management Systems Society (HIMSS), the National Rural Health Association (NRHA), the American College of Physicians (ACP), the Medical Group Management Association (MGMA) and the American Academy of Family Physicians (AAFP). It is abundantly clear that there is significant and widespread continuing concern about the timing of Meaningful Use Stage 2.

CMS responded to these concerns with broadened hardship exceptions from the program’s penalties on March 10, which potentially excuse providers from penalties due to difficulties with their vended HIT product. This action did nothing to provide additional time so that providers could reach Stage 2 safely and effectively and still earn incentive dollars. I believe that additional time and flexibility for those who need it to safely attest to Stage 2 of Meaningful Use is needed.

Can you please provide specific reasons along with the evidence base that resulted in your rejection of the views of these stakeholders and the quantifiable information they shared with the Department? I would particularly be interested in seeing the data on which you based your decision, including information about the dates on which 2014 Edition CEHRT arrived at hospitals and eligible professionals, whether the certified components worked as intended, what percentage of the CEHRT needed upgrades or other fixes, how many modules were missing from delivered product as well as your sense of how long a safe implementation of CEHRT should take.

Should this data support the provision of additional time and flexibility for providers to reach Stage 2, I urge that you provide it. Indeed, additional time for Meaningful Use Stage 2 would not only be positively received but it would also allow the Meaningful Use program to succeed and would demonstrate the Administration's willingness to listen to the market and understand the importance and time intensity of testing software, addressing inadequacies, adjusting workflows, and training clinicians.

Answer: HHS believes it has made an effort to listen 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 allows 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.

By extending Stage 2 until 2017, CMS and 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 and to implement a Stage 3 that through interoperability and clinical decision support capabilities would help lead to improved health outcomes.

CMS and ONC announced in February 2013 that additional flexibility would be provided for payment adjustments and hardship exceptions so that providers can avoid penalties for reasons beyond their control. For example, eligible professionals and hospitals may 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.

340(b) Program

- 1. In her testimony before the Finance Committee, Secretary Sebelius stated that the 340B program had "expanded beyond its bounds." 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: 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.

- 2. 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.

- 3. 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.