

**UNITED STATES SENATE
COMMITTEE ON FINANCE
NOMINATION HEARING FOR MARILYN B. TAVENNER TO BE ADMINISTRATOR
OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES
APRIL 9, 2013
QUESTIONS FOR MARILYN TAVENNER**

Questions from Senator Baucus

Question 1

Arguably, the single most important provision of the ACA was the creation of health insurance Marketplaces (also known as Exchanges). These marketplaces, where individuals can compare and shop for health insurance, need to work seamlessly come 2014 if the law is to be considered a success. Consumer outreach and branding are essential to ensuring people are aware of their options and able to enroll in these new Marketplaces. How will CMS help businesses work in the Marketplaces? Can you describe the different types of outreach activities are CMS conducting to ensure consumers know about the Marketplaces?

Answer: CMS has been busy implementing a 4 step plan for outreach. The Preparation phase began last year and continues until Open Enrollment begins. This includes conducting consumer research and building infrastructure for our customer service channels like the call center and website. The Education phase began in January 2013 and goes through June. It includes building awareness of the new Health Insurance Marketplace, by creating content for consumers, and training personnel and partners.

The Anticipation - or "Get Ready" - phase of work begins this summer. It includes additional details about program operations (like web and call center) as they come online, as well as training for navigators and other certified assisters who will help consumers through the enrollment process. The Enrollment phase will run from October 2013 to March 2014. It includes a major launch effort that will engage all media channels, as well as provide new customer service channels and in-person assistance.

An additional component of our efforts to enroll Americans in the Marketplace is the Navigator program. Through this program, CMS will ensure that consumers who need customer service can receive it from trained professionals. Navigators provide unbiased and impartial information to consumers about health insurance, the new Health Insurance Marketplace, qualified health plans, and public programs including Medicaid and the Children's Health Insurance Program. Navigators will serve an important role of ensuring that people understand the health coverage options available to them. The Navigators will also provide fair and impartial assistance to consumers to help them review their health coverage options as they learn about the new Marketplace.

In addition to Navigators, consumers will also have access to assistance through services such as a call center, where customer service representatives can provide referrals to the appropriate state

or federal agencies, or other assistance programs such as in-person assistors and certified application counselors. To help educate small businesses, we plan to work with regions to provide updates on recent rollouts and to conduct business outreach. We held meetings in March – in Dallas, TX and Atlanta, GA – and look forward to working with other regional offices to provide more specific information on the impact of the Affordable Care Act on businesses.

Question 2

The Office of the Inspector General recently released a report describing problems with CMS’s use of surety bond requirements. CMS currently requires durable medical equipment (DME) suppliers to have a \$50,000 surety bond for each location. CMS can then use these bonds to collect payment from overpaid or fraudulent providers. However, as noted by the OIG, CMS has not effectively utilized surety bonds to collect overpayments. For example, CMS has not used authority granted to it under the Affordable Care Act to increase the size of the surety bond for providers with a high billing volume. What are you doing to make sure CMS is using all available tools to fight and prevent health care fraud?

Answer: I challenge my management team each and every day to improve the way we do business and I have made it clear that combatting fraud, waste and abuse in all of our programs is a top priority. We are continually looking at ways our Center for Program Integrity can leverage the expertise of other CMS components, our contractors and law enforcement partners. CMS understands the importance of surety bonds as a program integrity tool and is exploring multiple avenues to strengthen this important tool. Since January 2012, CMS has been working to recover overpayment debts from Durable Medical Equipment (DME) suppliers by asserting claims against the surety companies. As of July 2012, CMS has collected \$263,000 from surety companies for DME supplier debts. In addition, there have been cases where DME suppliers have repaid overpayments voluntarily once they become aware CMS referred their debt to the surety company for collection. CMS believes its efforts to collect outstanding obligations from surety companies will continue to spur DME suppliers to satisfy their Medicare debts.

In addition to the surety bond requirement, CMS has implemented enhanced screening requirements for DME suppliers. All newly enrolling DME suppliers are in the highest risk category for screening and are subject to unannounced site visits and criminal background checks. These efforts will ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries. We are also leveraging other tools to more effectively combat DME fraud, waste and abuse through the use of the Fraud Prevention System and DME competitive bidding.

Question 3

The Affordable Care Act originally envisioned every state expanding Medicaid to cover all non-elderly individuals with incomes up to 133 percent of poverty. But following the Supreme Court’s ruling in July, states may choose whether to expand Medicaid. Creating this choice for states gave CMS considerable power, because CMS must approve or deny every Medicaid state plan. For example, in the past few months, CMS has decided that states must expand all the way to 133 percent of poverty to qualify for the increased FMAP, rather than allowing states to stop at some lower coverage level, like 100 percent of poverty. Currently, CMS is deciding whether states can buy into the Exchange through Medicaid premium assistance, as contemplated by Arkansas and Montana. All of the

decisions significantly impact the shape of Medicaid today and in the future, so they must be made carefully and transparently. How is CMS approaching some of these tough decisions? How is CMS engaging the public in the process?

Answer: As with all regulations and guidance developed by CMS, our first obligation is to ensure we faithfully implement Medicaid's statutory requirements. Our guidance to states on the Medicaid expansion has been rooted in the statute and Congressional intent. Additionally, implementation of the Affordable Care Act has required CMS to issue new regulations and Medicaid demonstration waiver transparency and public input process. Through these processes, we have meaningfully engaged the public and have drawn from their comments to shape final regulations and demonstrations. CMS is also in close contact with states and has used their experiences, questions and suggestions to develop and inform our policy guidance. As implementation continues, CMS will continue to engage our stakeholders to inform future decisions and the need for additional guidance.

Question 4

The Affordable Care Act (ACA) created a number of delivery system reform demonstrations and established the Center for Medicare and Medicaid Innovation (CMMI) within CMS. These demonstrations are intended to test and evaluate new models to reduce Medicare and Medicaid spending while preserving or enhancing the quality of care. CMS is running a number of demonstrations, but has performed few in rural areas. What more can be done at CMS to lower the cost and improve the quality of care in rural areas?

Answer: CMS has worked very hard to ensure that its models have geographic distribution so that each model is tested in variety of communities nationwide.

The Advance Payment Accountable Care Organization (ACO) model was designed for physician-based and rural providers with less access to capital to help increase the participation in the Shared Savings Program by these groups. Currently, there are 35 ACOs participating under this demonstration. The application for the Advance Payment ACO was designed with ACO's that serve rural populations in mind.

Additionally, there are a number of rural participants in the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration. This demonstration is testing enhanced support to FQHCs to help them become medical homes. Finally, we are also testing models in rural areas through the Health Care Innovation Awards: 49 of our awards (nearly half) serve both urban and rural areas, with 16 serving exclusively rural areas. The Health Care Innovation Awards are funding grants to applicants who will implement compelling new ideas to deliver better health, improved care and lower costs to people enrolled in Medicare, Medicaid and Children's Health Insurance Program (CHIP), particularly those with the highest health care needs.

We are aware that some rural stakeholders have had difficulty meeting some of the requirements of the existing programs and models. To address these concerns, we are working with them to find new models that might be appropriate for rural communities. For example, CMS is currently developing the Frontier Community Health Integration Demonstration Program for

very small critical access hospitals with an inpatient census of less than five in sparsely populated states.

Question 5

Unlike Medicare, most delivery system decisions in Medicaid are made at the state level. Within broad federal parameters, states decide which services to cover and how much to pay. This makes it much harder to promote delivery system reforms in Medicaid than in Medicare, because the federal government cannot simply change payment policies to incentivize certain care delivery models. However, states have made a lot of progress in changing how care is delivered – to promote prevention and higher quality, lower cost care – and CMS has been helpful in the process. Unfortunately, these efforts have not gotten a lot of attention and Medicaid continues to be criticized as an old, broken program. Please highlight some of these innovations, especially as they relate to individuals with disabilities and kids. Please also tell us how you plan to do more to improve Medicaid.

Answer: We believe there are a number of important opportunities to test reform models in the Medicaid program and we are actively working with states to undertake these initiatives. The Innovation Center is currently carrying out three initiatives that include State Innovation Models initiative, the Strong Start initiative and the Comprehensive Primary Care initiative, all of which allow the participation of state Medicaid programs. In addition, the Innovation Center is overseeing the Medicaid Emergency Psychiatric Demonstration and the Medicaid Incentives for the Prevention of Chronic Diseases Model.

We have a number of initiatives and programs that focus on improving the health and healthcare outcomes for pediatric populations, including the Strong Start for Mothers and Newborns initiative. The Strong Start initiative is an Innovation Center project focusing on reducing early elective deliveries and reducing the rate of preterm births among high-risk women in Medicaid and CHIP. Additionally, we have released the Initial Core Set of Child Health Care Quality Indicators for Medicaid and CHIP, established for voluntary use by state Medicaid and CHIP programs, which includes a range of children's quality measures encompassing both physical and mental health, including chronic conditions such as asthma and diabetes. CMS is pursuing several other initiatives to improve the health care that children enrolled in our programs receive, including the Pediatric Quality Measures Program and the Pediatric Electronic Health Record Format to help improve the health care that children enrolled in our programs receive. Additionally, the Innovation Center is testing medical homes for individuals with disabilities and complex health conditions, high-risk chronically ill children, and individuals with breast, lung, or colorectal cancer.

As we do in all areas, we continue to look for opportunities to test promising models in the Medicaid program and understand the importance of delivering better, more efficient care to Medicaid beneficiaries.

Question 6

Medicare currently pays physicians on a fee-for-service (FFS) basis, which encourages doctors to maximize the amount of services they provide. As part of efforts to reform physician payment and replace the Sustainable Growth Rate (SGR), some have considered moving physician payment away from FFS and to alternative delivery system models,

including accountable care organizations (ACOs), bundled payments, and medical homes. These models should improve physicians' incentives to provide high quality, low cost care. However, CMS is still testing many of these models and it may be too early to determine their effectiveness. What role are physicians playing in the delivery system models the Innovation Center is testing? How can these new models play in providing an alternative to physician fee-for-service payment?

Answer: One of the goals of the Innovation Center is to create a solid business case for physicians to engage in quality improvement. Therefore, during the development of models, the Innovation Center actively involves and receives ideas from stakeholders, such as physicians, clinicians, and analytical experts. Since its formation, the Innovation Center has held numerous regional meetings, listening sessions, and open-door forums to engage thousands of stakeholders from around the country. In addition, stakeholders have shared more than 500 ideas for improving health care through the Share Your Ideas section of the Innovation Center's website. We have made significant progress in developing these models, and will continue to engage physicians, payers, employers, states, and other stakeholders in our efforts.

We are testing a variety of models through the Innovation Center that could help provide an improved payments system while improving care quality, coordinating care, and reducing the total cost of care. Many of these models are physician led. For example, the Comprehensive Primary Care Initiative is a multi-payer initiative where CMS pays primary care providers monthly care management fees for comprehensive care management on top of their regular Medicare fee-for service payment. After two years, CMS offers the providers the chance to share in any savings they generate. Other payers, often including Medicaid, are also providing enhanced payment for primary care services in alignment with this program.

Another model we are testing is an Accountable Care Organization (ACO). The development of ACOs is one of the Affordable Care Act's key reforms to improve the delivery of care. ACOs are groups of doctors and other health care providers that have agreed to work together to treat beneficiaries and better coordinate their care across care settings. They share – with Medicare – a portion of savings generated from lowering the growth in health care costs while furnishing high quality care including providing patient-centered care.

Working in concert with the Medicare Shared Savings Program (Shared Savings Program), which is a permanent part of the Medicare program, the Innovation Center is testing two alternative ACO models—the Pioneer and Advance Payment model ACOs—both of which can inform future changes to the Shared Savings Program. The Innovation Center designed the Pioneer ACO model for health care providers that have experience coordinating care for patients across care settings. This model tests alternative payment models that include increasing levels of financial accountability. Thirty-two organizations are testing the Pioneer ACO model.

The Advance Payment ACO model examines whether and how pre-paying a portion of future shared savings could increase participation in the Shared Savings Program from entities such as physician-owned and rural providers with less capital. Through this ACO model, selected participants receive upfront and monthly payments, which they can use to make important investments in their care coordination infrastructure. We expect that the assistance the Advanced

Payment model provides to smaller and rural practices will result in expanding access to this coordinated care effort to more fee-for-service Medicare beneficiaries. Thirty-five ACOs are participating in this model.

Finally, the Bundled Payments for Care Improvement initiative is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. We think episode-based payment has great potential to transform the delivery system. We are confident that these initiatives will enable the Congress to build a reformed physician payment system.

Question 7

What do you think is the most pressing issue facing the Medicare program today? What are your biggest concerns around Medicaid? How is CMS planning to address these issues?

Answer: I have three primary focuses for moving this agency forward:

1. We need to operate CMS as a business and act like business partners. This means having an “open door policy” to work together and listen to the concerns of all the groups we work with and work for: beneficiaries, taxpayers, providers, hospitals, members of Congress, states, advocacy groups, insurance companies and our own employees and contractors.
2. We have a responsibility in the months ahead to implement key pieces of legislation to ensure all Americans have access to affordable healthcare coverage, whether it is through the Health Insurance Marketplace, Medicaid, original Medicare, or Medicare Advantage.
3. We need to leverage the tools Congress has provided us to both reduce overall costs of care and improve the healthcare delivery system. These tools include new payment strategies connected to performance, new models of care, and enhanced tools to combat fraud.

Questions from Senator Hatch

Question 1

Regarding Agency Coordination and Inter-Departmental Implementation: It is my understanding that all agencies supplying information for the Federal Data Services Hub have signed service level agreements. Please provide a date for when those agreements were signed by each agency and a copy of each agreement, but have yet to receive a response.

Answer: In order to exchange data among federal agencies, CMS needs to establish a series of agreements, business processes and formatting rules and protocols to ensure that data is exchanged securely and that interfaces between the federal data services hub and our partner agencies work properly. There are multiple types and levels of agreements that work together to facilitate the exchange of data. These include:

- Service Level Agreements, which establish procedures for mutual cooperation between the relevant organizations;
- Business Service Definitions, which ensure that cross agency business processes and data sharing are based on common understandings so that technology decisions and that agency systems development efforts are in-sync;
- Interface Document Controls, which provide a common set of formats, methods, and protocols to effectively define the interface between the Data Services Hub and other partner federal organizations.

CMS began formalizing these processes and rules with our federal partners in July of 2011 and has refined and updated them as the work to design and build the necessary interfaces has progressed.

Question 2

CCIIO has indicated is an inter-departmental working group that includes a wide range of Federal agencies. Please provide a list of the agencies that are members or participants of the inter-departmental working group.

Answer: The purpose of the inter-departmental working group is to leverage available resources across the federal government to ensure that the goals of the Affordable Care Act are met. Since a wide variety of agencies may come into contact with uninsured individuals, they can help CMS reach the broadest audience possible. Below is a list of the agencies or operating divisions:

Department of Agriculture
 Department of Commerce
 Department of Defense
 Department of Education
 Department of Health and Human Services
 Substance Abuse and Mental Health Services Administration
 Centers for Medicare & Medicaid Services
 Department of Homeland Security
 Department of Housing and Urban Development
 Department of Justice
 Department of Labor
 Department of State
 Department of Transportation
 Department of Treasury - Internal Revenue Service
 Department of Veterans Affairs
 Census Bureau
 Corporation for National and Community Service
 Environmental Protection Agency
 Executive Office of the President
 General Services Administration
 Government Accountability Office
 Office of Management and Budget

Office of Personnel Management
Office of National Drug Control Policy
Small Business Administration
Social Security Administration
U.S. Agency for International Development
United States Postal Office

Question 3

The implementation of Exchanges requires the development of complex software and data systems that determine eligibility, facilitate enrollment and manage conversations with the States and territories. Please explain how the Administration has organized itself to implement the Exchange undertaking. Specifically, who has authority to finalize decisions related to policy issues, for translating those decisions into operational requirements, for communicating those decisions to the States and for executing the necessary interfaces with different State systems?

Answer: Marketplace implementation activities follow the same decision and clearance process as other activities relating to CMS programs where decisions are made by CMS leadership and then executed by various components within CMS. The work of implementing the Marketplace crosses several components in CMS. The Center for Consumer Insurance Information and Oversight (CCIIO) is responsible for implementing many provisions of the Affordable Care Act through developing regulatory guidance and coordinating the business side of building systems. The Office of Information Services (OIS) works in collaboration with CCIIO to develop the IT infrastructure of the Marketplace systems. The Center for Medicaid and CHIP Services (CMCS) is responsible for implementing provisions of the ACA affecting Medicaid and CHIP programs. In addition, Marketplace implementation requires cross-component work with the Office of Grants and Management (OAGM), which is responsible for all contracts, and the Office of Communications (OC), which manages the public-facing component of the Marketplace.

Question 4

By what date do you intend to have final the development of all of the necessary software, the building of all necessary Federal information technology (IT) infrastructure and the resolution of all database connectivity issues between Federal agencies and between the Federal government and the States and territories? Is this timeline consistent with the timelines that are considered standard industry practice for an undertaking of this nature? Have you built in a margin of error for various types of problems that may not be anticipated at this time but are common in a project of this scope and breadth, such as interoperability issues or software glitches?

Answer: By September 2013, CMS intends to have finalized the development and testing of the information technology infrastructure for the Federally-facilitated Marketplace, as well as for the Data Services Hub. Testing has already begun and is ongoing, which will ensure sufficient time to address any problems that may arise.

Question 5

Will the eligibility determination for cost-sharing reductions (CSR) be aligned with the same eligibility criteria used by the Internal Revenue Service (IRS) for advance premium tax credits (APTC)? How will CSR payments be administered?

Answer: Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through a Marketplace, and section 1412 provides for the advance payment of these reductions to issuers. Section 1402 further provides that eligibility for cost-sharing reductions is tied to eligibility for the premium tax credit, and uses the same methodologies for household size and household income as are specified for the premium tax credit. As finalized in the 2014 Payment Notice (78 FR 15410), issuers will reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 250 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The statute also directs issuers to eliminate cost sharing for Indians (as defined in section 4(d) of the Indian Self-Determination and Education Assistance Act) with a household income at or below 300 percent of the FPL who are enrolled in a QHP of any “metal” level (that is, bronze, silver, gold, or platinum) through the individual market in the Exchange.

Question 6

How is CCIIO ensuring a level playing field with qualified health plans (QHPs) and Multi-State Plans (MSPs) offered under the Multi-State Plan program (MSPP) since the law states that the Office of Personnel and Management (OPM) has the authority to modify the requirements of plans as it relates to essential health benefits, actuarial value and numerous other authorities allowing for different plan standards?

Answer: CCIIO is working closely with the Office of Personnel Management (OPM), which is charged by Section 1334 of the Affordable Care Act with implementing the Multi-State Plan Program (MSPP). The goal of the MSPP is to foster competition among plans in the individual and small group health insurance marketplaces in all states and the District of Columbia, without providing a competitive advantage or disadvantage to the Multi-State Plans (MSPs).

Accordingly, OPM has established working relationships with officials in state regulatory agencies and Marketplaces.

OPM has also established a dispute resolution process by which a state may request that OPM reconsider a determination that a state law does not apply to MSPs or MSPP issuers. This process will offer a formal avenue for states to raise concerns about the MSPP to OPM and to have those concerns adjudicated. CCIIO is working closely with our colleagues at OPM to ensure a level playing field with QHPs in the Marketplace.

**Regarding Federally-facilitated Exchange (FFE) Infrastructure and Operations:
Information provided by CCIIO in response to my requests for information on the FFE**

has been insufficient. Below is a list of requests I have made that have either not been answered or not answered in full. Please provide the following information:

- a) An annual budget estimate to maintain the FFE, including funding from user fees, mandatory accounts and appropriated accounts.**

Answer: The President's FY 2014 requests \$1.5 billion for costs related to Marketplaces, including operation of a Federally-Facilitated Marketplace in each state that does not have its own Marketplace by January, 2014. The President's budget also estimates that \$450 million in user fees will be collected in FY 2014 to support these Marketplaces.

- b) An accounting of all funds obligated related to the establishment of the FFE and the Federal Data Services Hub to date.**

Answer: The total spending on the FFE and Data Services Hub through March 31, 2013 is below.

FFE and Data Hub Totals	
FY 2010	\$ 4,224,557
FY 2011	\$ 112,656,217
FY 2012	\$ 248,380,535
FY 2013	\$ 28,384,919

- c) A flow chart that describes what will occur once an individual application is submitted and begins to go through the eligibility determination process all the way through to when the application is approved.**

Answer: Please see attached chart that provides an overview of the application and eligibility process. After consumers submit their Marketplace application, the following steps occur:

1. The Marketplace IT system certifies Social Security Numbers and citizenship or immigration status by receiving data through the Data Services Hub from the Social Security Administration (SSA) and the Department of Homeland Security (DHS).

(Note: The Marketplace IT system and the Data Services Hub will not store or retain the data used to certify the application.)

2. If the consumer requested help paying for health coverage, the Marketplace IT system certifies income data by receiving data through the Data Services Hub from the Internal Revenue Service (IRS), and confirms income data contained in IRS records.

3. With this certified data, there is a preliminary eligibility determination. A consumer can be eligible for:

- A qualified health plan selected through the Marketplace purchased with the advanced premium tax credit (and will therefore answer question about available employer-sponsored coverage or access to other health insurance);

- Medicaid (and will therefore answer specific Medicaid-eligibility questions); or CHIP (and will therefore answer specific CHIP-eligibility questions).

4. After the preliminary eligibility determination is made and the application is signed, a final eligibility determination will be displayed. The applicant will then either proceed to the Plan Compare section of the Marketplace or the State-specific process for Medicaid or CHIP, depending on the final eligibility determination.

d) An outline of the operational capabilities and functions of the FFE.

Answer: The Federally Facilitated Marketplace (FFM) system enables individuals to find and purchase affordable coverage. CMS designed the Federally Facilitated Marketplace for use in states that do not operate a State Based Marketplace. Additionally, the Federally Facilitated Marketplace provides those functions that are that CMS performs for all states, regardless of whether they operate a State Based Marketplace or are part of the Federally Facilitated Marketplace.

The FFM includes the following functions and capabilities:

- **Plan Management.** Accept applications from issuers to offer Qualified Health Plans (QHP) and evaluate the applications with support from CMS and state Departments of Insurance (DOI). Display the QHPs on the Marketplace portal for consumer shopping.
- **Enrollment and Eligibility.** Facilitate determination of individual eligibility for coverage, including interfacing through the Data Services Hub for verifications with other federal and state agencies such as income, citizenship, and enrollment in other health insurance programs. Facilitate individual enrollment into a Qualified Health Plan. Accept and process employer applications for SHOP.
- **Financial Management.** Support financial management processes including the calculation of advanced premium tax credits and cost sharing reductions; risk adjustment, reconciliation, risk corridors; and reinsurance.

e) A complete list of agencies that will interact with the Federal Data Services Hub.

Answer: SSA, Treasury/IRS, DHS, VA, OPM, DoD/Tricare, Peace Corps

f) A date for when we can expect to have the Federal Data Services Hub operational and available to stakeholders for testing.

Answer: We expect the eligibility and enrollment services the Hub performs to be ready by October 1, 2013.

Interagency testing with federal agencies leveraging the Data Services Hub, including IRS, SSA, and DHS began testing:

- We have been engaged in functional testing with IRS since November 2012

- We have been engaged in functional testing with SSA scheduled since February 2013
- We have been engaged in functional testing with DHS since February 2013
- Formalized testing that includes tracking readiness indicators began in mid-March 2013 with a small group of states.

CMS will be on-boarding states for testing in approximately 4 phases starting in mid-March.

g) How CCIIO will interact with State Insurance Commissioners in FFE States that are not implementing the law.

Answer: As CMS articulated in the May 2012 in the FFE guidance (<http://www.cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>), there are four guiding principles in the implementation of the FFE. They include: commitment to consumers, market parity, leveraging the traditional state role, and engagement with states and other stakeholders. To the greatest extent possible, CMS intends to work with states to preserve the traditional role and responsibilities of state insurance departments, and we will seek to harmonize policies in the Federally Facilitated Marketplace (FFM). For example, CMS will not duplicate as part of its QHP certification process reviews conducted by state departments of insurance under state law and authority. CMS has been engaged in state-specific consultations with a variety of state staff, including but not limited to staff at state departments of insurance, to plan the QHP certification process and jointly identify potential interactions between state laws and processes and federal standards. In addition, CMS continues to provide technical assistance to state departments of insurance to assist these staff in preparing for the 2014 plan year.

h) If a decision is not provided in real time, how long consumers will need to wait for the agencies to reconcile enrollment application information and make a final decision.

Answer: We are striving to process as many applications in real time as possible. When there is an inconsistency between an applicant's attestation regarding a factor of eligibility and a data source, the Marketplace, Medicaid agency, or CHIP agency will notify the individual and provide him or her with a period of time to provide satisfactory documentation or otherwise resolve the inconsistency. This can include working with SSA or DHS, for example, to correct information in their records. The processes for inconsistency are laid out in the Exchange Final Rule at 45 CFR 155.315(f). When an inconsistency is related to SSN, citizenship, or immigration status, the applicant has 90 days to resolve the inconsistency, with the possibility of a "good faith" extension. The statute and regulations specify that, during this period, the applicant will receive a determination about eligibility for enrollment in a qualified health plan, advanced premium tax credit (APTC), cost-sharing reduction (CSR), Medicaid, or CHIP. This is also the process specified in statute for inconsistencies that are related to other factors of eligibility for individuals who are otherwise eligible for enrollment in a QHP with or without APTC and CSR. For inconsistencies that are related to factors of eligibility other than SSN, citizenship, and immigration status for individuals who are otherwise eligible for Medicaid or CHIP, pre-Affordable Care Act regulations provide for a shorter resolution period, and a determination regarding eligibility for Medicaid or CHIP is not provided until the inconsistency is resolved.

i) How application data will be protected to ensure no unauthorized access to such data.

Answer: The privacy and security of consumer data in the Marketplace is a top priority for CMS and other federal and state agencies. Consumer data in the Marketplace is safeguarded and secured through processes, controls, and standards that will be used not only by CMS, but also by federal agency partners including IRS and SSA. CMS will use a layered security approach to protect personal information which includes presentation of a secure web interface, use of secure transmission protocols, and validation of identity. Once information is captured, it is then protected through a wide variety of security measures and counter-measures during the entire time the data is being used within the Marketplace. CMS also reviews its internal security policies and procedures each year, and updates them accordingly to ensure a comprehensive information security program is in place and remains relevant and responsive to today's emerging threats. In addition, CMS and IRS have worked together to develop additional safeguards to protect sensitive tax return data that will be accessed in the Marketplace. CMS is also making use of commercial sources of information as an additional identify-proofing measure. This approach has been successful with other Federal government websites, such as SSA's MyAccount.

j) How CCIIO was able to provide an example of an individual purchasing insurance through the FFE in 30 minutes when the exchange is not fully operational and the eligibility determination system has yet to be built.

Answer: CCIIO has provided hypothetical examples, designed to illustrate how consumers will interact with the Marketplace starting on October 1, 2013.

Question 8

CCIIO has identified Section 1311(d)(5)(A) of the Patient Protection and Affordable Care Act (PPACA) as the statutory authority to collect user fees and indicated that funds provided through the user fee will be used for "qualified health plan certification, administration of APTCs, cost-sharing reductions, Navigators, and other functions." Please provide a complete list of what CCIIO means by "other functions."

Answer: CMS will collect a 3.5 percent of premium user fee on participating issuers in the FFE as specified in the final 2014 Payment Notice, available at 78 FR 15410. The user fees funds the following:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management and operation of a Navigator program;
- Oversight of agents and brokers;
- Eligibility determinations;
- Administration of advance payments of the premium tax credit and cost-sharing reductions;
- Enrollment processes;
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification); and

- Administration of a SHOP Exchange.

Question 9

CCIIO has indicated in testimony before this Committee that States are given options between whether the Exchange is an active purchaser or a passive market facilitator, and other specific policy decisions that are left up to the State related to accreditation and additional QHP standards. When will CMS outline the decision of the FFE as it relates to the options left up to each individual Exchange? Will the decision be made in coordination with each of the 26 FFE States? Will the decision be different for each of the 26 States?

Answer: CMS outlined the FFE purchasing policy for 2014 on May 16, 2012 (<http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>). To ensure a robust QHP market in each state where an FFE operates, and to promote consumer choice among QHPs, in the first year, HHS intends to certify as a QHP any health plan that meets all certification standards. HHS will analyze the QHP certification process and may identify improvements or changes to this process, as appropriate.

CMS released the Letter to Issuers outlining our planned approach for QHP certification, and how CMS will interact with states in the FFE and Partnerships. As noted in previously released guidance, Plan Management State Partnership Marketplaces have some flexibility in their application of QHP certification standards. States in which a State Partnership Marketplace is operating may use CMS's planned approach to conduct QHP certification reviews and arrive at certification recommendations, or adopt another approach that is consistent with the federal standards.

CMS does not intend to duplicate reviews of potential QHPs conducted under state authority or as part of a state's enforcement of 2014 market reforms (e.g., essential health benefits and actuarial value standards). CMS expects that states will enforce 2014 market reforms; accordingly, CMS expects to rely on states' reviews of market reforms as part of its QHP certification process.

CMS is committed to stakeholder consultation as we implement the Affordable Care Act. We have undertaken extensive stakeholder consultation during the Marketplace rule making process, and solicited comments on Federally Facilitated Marketplace guidance. We will enhance our outreach and education efforts as we move toward open enrollment in 2013 and will seek to join state and local partners in that effort.

Question 10

CCIIO has indicated that they are considering contingency plans for "every eventuality." Please provide a comprehensive list of eventualities and contingency plans that CCIIO is analyzing and developing.

Answer: We are moving forward with Marketplace implementation for open enrollment beginning on October 1, 2013. We are also working with states to provide the maximum amount of flexibility to enable them to perform the functions in their Marketplaces. A number of

different systems will be in place by October 1 to accommodate open enrollment, including IT, call center, and plan management systems, and we are carrying out the plans we have in place to ensure that all of these systems are operational and that the Marketplace will be available to all consumers on October 1.

We are also developing mitigation strategies for IT systems as provided in the guidance established by the National Institute of Standards and Technology, Special Publication 800-34, revision 1 (May 2010). The document provides guidance to help personnel evaluate information systems and operations to determine mitigation strategy requirements and priorities.

Question 11

Are you currently planning to implement certain aspects of the Exchanges in a manner that will require non-electronic communications, such as confirming an applicant's Medicaid eligibility status or incarceration status with a State or confirming immigration status or tax credit eligibility with Federal agencies? Can you provide a list organized by State of which of the various functionalities you expect to carry out on a non-electronic basis?

Answer: The Affordable Care Act set up a system of coordinated, streamlined processes to determine eligibility for enrollment in a qualified health plan, advance payments of the premium tax credit, Medicaid, or CHIP. Marketplaces must first rely on electronic data to verify eligibility. CMS expects that the majority of transactions related to eligibility determinations will be electronic. Specifically, with respect to incarceration status, 45 CFR 155.315(e) specifies that Marketplaces must verify applicant attestations regarding incarceration status by relying on electronic data sources; however, if an approved electronic data source is not available, the Marketplace must accept the applicant's attestation regarding incarceration status without further verification, unless it is not reasonably compatible with information from other approved data sources. If the attestation is not reasonably compatible with information from approved data sources, the Marketplace must follow the inconsistency resolution procedure provided at 45 CFR 155.315(f), which is also the procedure for verifying information any time required electronic data is not available.

Question 12

How will manual enrollment work under the FFE model if some of the necessary activities to enroll an individual either cannot be accomplished in real time, require certain steps to verify information, or the individual chooses to not enroll through the FFE website? Who will be conducting manual enrollment activities? What percent of enrollees be required to go through a manual enrollment process?

Answer: In addition to the dynamic Web-based system supporting eligibility determinations for all insurance affordability programs, a paper application will be available, and eligibility workers will handle exceptions and manual processing, including for paper applications and in cases where verification documentation is needed (e.g., immigration documents).

CMS will provide consumer support to help purchasers of health insurance obtain an eligibility determination and select a plan through the FFE. CMS will fund a Navigator grant program in FFE states to provide consumers with fair, unbiased help with determining if they are eligible for tax credits, comparing QHPs, and the application process for health coverage. Training modules are under development and Navigator grants will be awarded in the summer of 2013.

CMS will launch a website with chat capabilities and a 24 hour call center for the Marketplace that consumers can use to identify and compare QHPs, check their eligibility for affordability programs to help them pay for coverage, and enroll in a QHP. As with all Marketplaces, consumers will be able to submit an application online, over the phone, through the mail, or in person at certain locations.

Question 13

In a meeting with members of the Committee, Secretary Sebelius indicated that the Federal Data Services Hub is 40% complete and that a contract will soon be signed established eligibility determinations and enrollment processes. As you are well aware, multiple systems must be complete for open enrollment on October 1. Taking into account all systems necessary for a person to access the FFE website to enrolling an individual in a QHP, what is the total progress to date in having the system 100 percent complete by October 1?

Answer: CMS is creating and integrating several systems to support the business processes necessary for open enrollment on October 1: the Federally Facilitated Marketplace (FFM) system; the Federal Data Services Hub (the Hub); and Marketplace Data Warehouse and Analytics (MIDAS) system. The first major component of the FFM and DSH systems, Qualified Health Plan (QHP) applications, is now complete. The infrastructure for the data hub has been completed and testing has been successful. We met our April 1 deadline for allowing issuers to submit QHP applications, and states have successfully used the Hub in testing. We expect each of these systems to be fully operational and interoperable by open enrollment on October 1.

Question 14

Regarding the Federal Data Services Hub: Please provide a comprehensive list of all categories of data that will be routed through the Federal Data Services Hub.

Answer: The following categories of data will be routed through the Federal Data Services Hub:

- Identity Proofing
- SSN validation
- Income and Family Size
- Calculation of Maximum Tax Credit Amounts
- Citizenship and Immigration Status
- Enrollment in Insurance Affordability Programs and Qualified Health Plans
- Enrollment in Minimum Essential Coverage
- Incarceration Status

Question 15

Please provide a comprehensive report on Federal Data Services Hub testing activities, including a list of all tests, the date of the test, which agency or stakeholder tested the data hub in each event, the results of each test and when testing will be complete.

Answer: CMS is also working with our partners on external testing. CMS is undertaking ‘Secure Communications’ and the ‘FEPS and Partner’ functional testing with the IRS, which has been ongoing since October 2012. These tests have been successful in testing the services between IRS and CMS.

The following federal agencies will begin similar testing in Spring 2013:

- Department of Homeland Security (DHS)
- Internal Revenue Service (IRS)
- Office of Personnel Management (OPM)
- Peace Corps
- Social Security Administration (SSA)
- TRICARE Management Activity (TMA)
- Veterans Health Administration (VHA)

Several State Based Marketplaces and Federally-facilitated Marketplace states will begin ‘Secure Communications’ and ‘FEPS and Partner’ in the spring of 2013. All states will participate in the ‘Regression and End to End’ Testing in August 2013. Plan issuers are scheduled to begin testing plan management templates in the spring of 2013.

Together, internal and external testing will validate system functionality. Performance Stress Testing will examine infrastructure capacity and scalability with the most active trading partners. Security Testing will take place in the same manner as with all CMS systems. We have dedicated significant resources and personnel to work with developing a robust testing infrastructure that will allow for testing to occur once the system is operational.

Question 16

Regarding the QHP Approval Process: It is my understanding that all QHPs, regardless of the exchange model, will be submitting plan and rate information to HHS through the Health Insurance Oversight System (HIOS). Can you please provide information on the capabilities and functions of HIOS? I am also interested in how HHS will be using the information collected from plans through HIOS. It has been said that information will be used to certify health plans, but that it will also be used for “other purposes.” Please provide a comprehensive list of all “other purposes,” and the statutory authority provided to use data for those purposes.

Answer: CMS issued the final Letter to Issuers modeled after the Medicare Part D program call letter. In this letter, we outlined specific application requirements and the appropriate electronic system for QHP certification applications.

In states with Federally-facilitated Marketplaces, an issuer can submit QHP certification applications in HIOS between April 1, 2013 and April 30, 2013. The QHP application will collect both issuer-level and plan-level benefit and rate data and information, largely through standardized data templates. Applicants will also attest to their adherence to the regulations set forth in 45 CFR parts 155 and 156 and other programmatic requirements.

In a Plan Management State Partnership Marketplace, issuers will work directly with the state to submit all QHP issuer application data in accordance with state guidance. Most states are using the SERFF system to collect and review QHP data. The state will review issuer applications for QHP certification for compliance with the standards described above and will provide a certification recommendation for each plan to CMS. In Partnership states, CMS will review and confirm the state's recommendations, coordinate Plan Preview, make final certification decisions, and load certified QHP plans on the Marketplace website for the relevant State Partnership Marketplace. CMS will work closely with states to coordinate this process.

The legal authority for any specific data collection has been articulated in rule making and guidance. Sections 1301 and 1311 of the Affordable Care Act contain the authority for QHP certification.

The Health Insurance Oversight System (HIOS) has been used for various requirements in the Affordable Care Act such as www.healthcare.gov web submission, the medical loss ratio reports, and the rate review program for example. Most issuers and states are familiar with the system and have already registered in HIOS. The system has multiple functional modules and has the capability of accepting QHP certification applications.

Question 17

What considerations were taken into account in determining the QHP approval timeline? Have you heard any concerns from stakeholders regarding the uncertain and short period of time between plan approvals and open enrollment?

Answer: CMS has solicited comment on the QHP certification approval time-frame on multiple occasions. We have worked with issuers, states, and other stakeholders to make certain that consumers in the new Marketplaces have robust choice of plans.

Most recently, CMS solicited comments on the draft Letter to Issuers. In the final Letter, issued on April 3, 2013, CMS expressed willingness to work with issuers to provide them with additional time during the resubmission window. To prepare for this first year of operation, we must sign QHP certification agreements in early September 2013, to display benefits and rates to consumers in time for open enrollment to begin on October 1, 2013.

Question 18

Regarding Program Integrity: The healthcare Exchanges represent the largest program expansion in healthcare since the Federal healthcare programs were created. Given the vast amounts of healthcare fraud that exist under current programs, with estimates of at least \$60 billion being lost each year to healthcare fraud, what program integrity efforts has Centers for Medicare and Medicaid Services (CMS) embedded as part of the infrastructure of the FFE? Are there similar efforts being implemented at the State level with respect to State Exchanges or the Partnership Exchanges? Are there any requirements for program integrity efforts included in either the Federal Exchange or Partnership Exchange guidances or regulations issued to date? Is there a comprehensive program integrity plan in place for addressing vulnerabilities in the Federal and/or State-based Exchanges? Which entity within CMS is coordinating those efforts? How is information obtained from early detection or other program integrity efforts being shared within CMS and what is the plan for developing corrective actions when those instances are identified? How are CMS' program integrity efforts being coordinated with the IRS?

Answer: CMS takes seriously its responsibility to monitor the implementation of these programs to protect consumers, prevent fraud and abuse, and ensure the programs achieve their goals. In addition to the program integrity efforts underway within CMS, CMS and IRS are working on a number of key operational issues which include program integrity matters. We will provide further detail on the oversight of Marketplace programs in future rulemaking and guidance.

In states in which a federally-facilitated Marketplace is operating, CMS will focus on compliance concerns that are specific to the Marketplace and will look to existing state compliance and enforcement efforts for issues that fall under states' regulatory and enforcement authority.

Question 19

A good example of where program integrity will be critical is with respect to eligibility determinations. For those States under the FFE, there are two options: 1) let the FFE make all decisions of eligibility determinations or 2) let the FFE obtain the application and provide an assessment to the States, and the States can make the ultimate eligibility assessment. However, in both cases, my understanding is that the Exchanges will rely 100% on the individual to self-disclose that they live in the State they claim to live in. While this may improve customer experience and make subsidies more easily accessible, numerous Office of Inspector General (OIG) and the U.S. Government Accountability Office (GAO) reports have shown the fraud that occurs when self-reporting is allowed in programs of this size.

- a) What steps will CMS and/or the IRS implement to verify that the self-reported information is accurate?**

Answer: With respect to residency, the Exchange final rule, at 45 CFR 155.315 (d) details Marketplace procedures for verifying residency. These rules apply to all Marketplaces, regardless of governance model.

In general, Marketplaces have two options. First, a Marketplace may accept attestations that an individual resides in a Marketplace service area. Second, a Marketplace may examine electronic data sources that are available to the Marketplace for this purpose, based on evidence showing that such data sources are sufficiently current and accurate, and minimize administrative costs and burdens.

If an Marketplace chooses to accept attestations regarding residency, the regulations provide that if residency information provided by an applicant is not reasonably compatible with other information provided by the individual or in the records of the Marketplace (e.g. information from last year's eligibility determination), the Marketplace must examine available data sources. If this data matching cannot reconcile the discrepancy, the Marketplace must notify the individual and request an explanation or documentation. CMS will provide additional guidance in the future regarding policies and procedures for data matching.

b) If a recipient falsifies an application and receives tax credits, who will investigate that fraud?

Answer: Under section 1411 (h) of the Affordable Care Act, the Secretary of Health and Human Services may impose civil penalties on any person who fails to provide correct eligibility information if such failure is attributable to negligence or disregard of rules and regulations.

Question 20

Regarding Risk Programs: The proposed regulation pertaining to the Notice of Benefit and Payment Parameters eliminates the option for States to operate the temporary reinsurance program. Why was this change made? What stakeholder comments were taken into account in making this determination? Why are reinsurance funds collected and distributed nationally? Will not this lead to lower-cost States, like Utah, subsidizing higher-cost States?

Answer: The final 2014 Payment Notice (78 FR 15410) does not eliminate the option for states to operate the temporary reinsurance program. States still retain this option under 45 CFR § 153.210. The Affordable Care Act directs that a transitional reinsurance program be established in each state to help stabilize premiums for coverage in the individual market. The reinsurance program is designed to alleviate the need to build into premiums the risk of enrolling individuals with significant unmet medical needs and to lower premiums across the country.

Federal collections will leverage economies of scale, reducing the overall administrative costs of the reinsurance program. The final payment policy provides reinsurance payments in an efficient, fair, and accurate manner, where they are needed most, to effectively stabilize premiums nationally. The cost of medical care is one variable, but CMS analysis indicates that other variables are also important. The extent to which issuers receive payments under the reinsurance program depends on their actual claims experience in plan year 2014.

Question 21

Regarding State Coordination: In public statements and guidance documents, CMS has said that it will try to harmonize Exchange policy with existing State programs and laws whenever possible. However, with 26 States relying on the FFE, limitations on resources and time running out, it would seem difficult for the agency to tailor an Exchange to meet each State's unique insurance market needs. What are the specific details of the plan to harmonize these laws and regulations in States under the FFE model? What are the necessary steps to ensure FFEs will be available to consumers in the 26 States as it relates to harmonizing State laws and regulations?

Answer: CMS has been coordinating plan management activities with states, including QHP certification, monitoring and oversight, account management, and recertification. States that are enforcing market-wide standards that are part of QHP certification will be able to submit their findings for the Federally Facilitated Marketplace for use in its QHP certification reviews; the Federally Facilitated Marketplace does not intend to duplicate those reviews. The Federally Facilitated Marketplace will work with the state to review the state's recommendation and to provide a coordinated application process.

CMS has worked with the National Association of Insurance Commissioners to standardize the collection of data needed to certify qualified health plans. We have also already released the data elements that insurance plans will need to integrate into this application. CMS will continue to work with states to ensure coordination with state eligibility processes.

The Marketplace developed by CMS will be adapted to meet the needs of any state that chooses to utilize this model. The Federally Facilitated Marketplace will support the following operation functions; Eligibility and Enrollment, Plan Management, Financial Management, and Consumer Support.

CMS is already testing IT data information exchange functions and expects to complete testing in the spring of 2013. Consumer call centers are on track to open in the summer of 2013.

CMS is committed to stakeholder consultation as we implement the Affordable Care Act. We have undertaken extensive stakeholder consultation during the Marketplace rule making process, and solicited comments on FFE guidance. We have also begun consultation specifically in the Federally Facilitated Marketplace and partnership states through our regional offices. We will enhance our outreach and education efforts as we move toward open enrollment in 2013 and will seek to join state and local partners in that effort.

Question 22

It is anticipated that plans will begin submitting QHP applications starting March 28th for approval either through the National Association of Insurance Commissioners' (NAIC) System for Electronic Rate and Form Filing (SERFF) and through HHS's Health Insurance Oversight System (HIOS). Can you please explain the purpose behind plans submitting QHPs to both systems in States with State-based Exchanges? Is this not duplicative, unnecessary, contrary to the goals of limiting administrative costs and an encroachment of State authority to regulation insurance in the State?

Answer: CMS issued the final Letter to Issuers modeled after the Medicare Part D program call letter. In this letter, we outlined specific application requirements and the appropriate electronic system for QHP certification applications.

In states with Federally-facilitated Marketplaces, an issuer can submit QHP certification applications in HIOS between April 1, 2013 and April 30, 2013. The QHP application will collect both issuer-level and plan-level benefit and rate data and information, largely through standardized data templates. Applicants will also be required to attest to their adherence to the regulations set forth in 45 CFR parts 155 and 156 and other programmatic requirements.

In a Plan Management State Partnership Marketplace, issuers will work directly with the state to submit all QHP issuer application data in accordance with state guidance. Most states are using the SERFF system to collect and review QHP data. The state will review issuer applications for QHP certification for compliance with the applicable standards and will provide a certification recommendation for each plan to CMS. CMS will review and confirm the state's recommendations, coordinate the plan preview period during which issuers may review their QHP data before it becomes public, make final certification decisions, and load certified QHP plans on the Marketplace website for the relevant State Partnership Marketplace. CMS will work closely with states in State Partnership Marketplace to coordinate this process.

Question 23

Regarding Application Counselors: The latest proposed regulation creates a new category of assisters called "Application Counselors." The proposed regulation says these assisters could be in hospitals or other provider offices. Can you shed more light on what role these Application Counselors will play? What would prevent such a counselor in a hospital from steering people to plans that benefit the hospital?

Answer: We believe that making such assistance available for the Marketplaces will be critical to achieving a high rate of enrollment. Accordingly, the proposed regulation seeks to ensure that application counselors will also be available in the Marketplace to help individuals and employees apply for enrollment in Marketplace coverage and for insurance affordability programs. Under the proposed regulation, certified application counselors would provide help to consumers in applying for health insurance in the Marketplace beginning on October 1, 2013. These counselors would serve as resources that individuals could turn to for help with filling out their applications and exploring their coverage options. Many organizations, like hospitals, community health centers and other social service organizations, already employ individuals in a similar capacity. These individuals, for example, may assist in patient registration, with the objective of determining eligibility for medical coverage under the terms of various private and public health care and financial assistance programs including Medicaid and Medicare to facilitate patient care.

The proposed rule also would requires that these counselors act in the best interest of the consumer, and mandates that they will would be trained regarding qualified health plan options,

insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the state, as implemented in the state, prior to providing assistance. CMS is currently developing this training, and it will begin this summer.

Question 24

Regarding Outreach and Education: What source of funding provided under PPACA or other laws will be used to fund outreach and education activities? What is the total budget for outreach and education activities? Will CMS fund outreach and education activities for all states, or just those under the FFE model?

Answer: The President's Budget for FY 2014 requests \$554 million for Marketplace-related Consumer Information and Outreach. We expect that other forms of consumer engagement, such as traditional and social media, will promote awareness of new insurance options across the nation. This funding will primarily support efforts in the Federally-facilitated and Partnership Marketplaces such as the Marketplace Contact Center and Navigator grants.

Question 25

Are you developing a communications plan to guide the public and manage expectations prior to the October 1 or January 1 deadline for enrollment and coverage? If so, please provide a copy of the plan with the Committee?

Answer: CMS is developing and implementing an outreach and education plan to help ensure that Americans have access to quality, affordable health insurance. The plan seeks to raise awareness of the Marketplace as the official, objective source for finding affordable health coverage. A timeline describing the plan is attached.

Question 26

Regarding Pre-existing Conditions Insurance Plan (PCIP) program: The President's budget indicates that the PCIP program a total of \$312 million in total unobligated balances but \$937 million in total outlays. Given the flexibility under the law to address budget shortfalls, what plans does CMS have in place to ensure the program is funded through December 31, 2014?

Answer: CMS is aggressively managing costs in the federal PCIP program and has taken a variety of steps to ensure that the limited funds provided by the Affordable Care Act are applied efficiently in funding patient care and program administration. These include a change in provider networks used by the federally-administered PCIP, reducing both its negotiated and out-of-network payment rate for providers; negotiation of additional discounts on reimbursement rates with targeted hospitals that were treating a disproportionate number of PCIP enrollees; limiting the specialty drug benefit to provide coverage only if the specialty drug is dispensed by an in-network pharmacy, and consolidation of three benefit plan options into one, increasing the maximum out-of-pocket limit from \$4,000 to \$6,250 for in-network services. In February and March 2013, the PCIP program suspended enrollment to manage costs in the last year of the

program as another step to ensure that current enrollees will have coverage through December 31, 2013.

Question 27

Regarding Enrollment Process: Please explain how the Federal Data Services Hub, Exchanges (of any type) and Medicaid eligibility system will interact.

Answer: When consumers access the Marketplace and fill out the single, streamlined application, the information they provide, including income information, will, via the Hub, be verified against other sources of information, including the IRS, DHS, and SSA. The Federally-facilitated Marketplace will also use the Hub to connect to state Medicaid agencies to check whether an applicant is already enrolled in Medicaid. In the Hub, data will be routed through but not stored in the system, while ensuring that the data flows where it is needed. The Hub will access only the information needed to determine individual eligibility and will not be involved in the selection or certification of health plans. CMS has completed the Hub's technical design, has almost completed the services related to Federal and state agency interactions, and has already begun testing the Hub across agencies. For the Federally-facilitated Marketplace, when an applicant is assessed or determined eligible for Medicaid, the Hub will be used to transfer the applicant's information to the state Medicaid agency to complete the process.

Question 28

Regarding Data Security and Privacy: CMS has indicated that information provided in the streamlined application will be subject to strong privacy and security protections, that IRS data used to verify eligibility through the Federal Data Services Hub will be used in a manner consistent with existing IRS safeguards and that the agency has completed the framework for security across agencies to establish protocols for connectivity. Could you please elaborate on how information provided through an application, to the IRS for eligibility determinations and as other data shared between agencies will be protected from unauthorized uses?

Answer: The privacy and security of consumer data is a top priority for CMS and other federal and state agencies. Consumer data is safeguarded and secured through processes, controls, and standards that will be used not only by CMS, but also by federal agency partners including IRS and SSA. CMS will use a layered security approach to protect personal information. This layered approach includes presentation of a secure web interface, use of secure transmission protocols, and validation of identity. Personal information is protected through using a variety of security measures and counter-measures during while the data is being used within the Hub. CMS also reviews its internal security policies and procedures each year, and updates them to ensure a comprehensive information security program is in place and remains relevant and responsive to today's emerging threats. In addition, CMS and IRS have worked together to develop additional safeguards to protect sensitive tax return data that will be accessed through the Hub. CMS is also making use of commercial sources of information as an additional identify-proofing measure. This approach has been successful with other Federal government websites, such as SSA's MyAccount.

Question 29

Regarding Navigators: CMS recently published a \$54 million funding announcement to eligible self-employed individuals and private and public entities applying to serve as Navigators. How many Navigators did CMS estimate will be trained in determining the amount to transfer from the Prevention and Public Health Fund to the Navigator program? What is the target number of Navigators needed to enroll the estimated 7 million new enrollees in exchanges? What is the target Navigator to enrollee ratio and how will the Administration ensure that training continue to meet the demand as the number of exchange-enrollees increases over time?

Answer: Navigators are charged with providing impartial education and guidance to consumers about the public and private health insurance options available to them in the Marketplaces. Navigators will play a significant role in enrolling Americans in coverage and in ensuring that all consumers who need customer service can receive it from trained professionals.

The Funding Opportunity Announcement (FOA) is available for self-employed individuals, as well as public and private organizations that are interested in becoming Navigators in the federally facilitated and state partnership Marketplaces. At this time CMS has not estimated the total number of Navigator grantees and applicants or the number of that will receive funding through the FOA, although the regulation governing the Navigator program, 45 CFR 155.210, requires that at least two types of entities serve as Navigators in each Marketplace service area, and that at least one of those entities be a community and consumer-focused nonprofit

CMS apportioned \$54 million for the FOA based on the total number of uninsured (under age 65) legal residents in each state with a Federally-facilitated Marketplace/State Partnership Marketplace, with a minimum award of \$600,000 available per Federally-facilitated Marketplace/State Partnership Exchange service area. We invite public comments on the number of Navigator grantees that would be appropriate, as well as on the number of consumers expected to receive assistance in a particular state.

In addition to Navigators, consumers will have access to assistance through services such as a call center, where customer service representatives can provide referrals to the appropriate state or federal agencies, or other forms of assistance, including certified application counselors and agents and brokers.

Question 30

Durable Medical Equipment (DME) Guidance re: Minimum lifetime requirement: In November 2011, CMS issued a Final Rule on the Medicare Program which impacted DME. This regulation, revised the definition of DME to add a 3-year “minimum lifetime requirement” (MLR). As a result, items classified as DME after January 1, 2012, must have an expected life of at least three years. In subsequent communications with Congress, you wrote that CMS will be providing additional guidance “in the near future.” To this date, CMS has not yet provided guidance sought by members of the Finance of the Committee on how it will apply the Final Rule’s 3-year MLR requirement to multi-

component devices (which may have both durable and non-durable components). When will CMS issue a proposed rule or guidance on this important issue in order to provide further direction and consistency to innovators?

Answer: CMS strives to promote innovation and competition while maintaining beneficiaries' access to critical items and services. CMS is taking a thoughtful and deliberate approach with respect to this important matter, and will be issuing more detailed guidance on this policy. We hope to move forward as soon as we can. I am happy to work with you to address any concerns regarding a particular product in development that may be impacted, and CMS is happy to discuss that specific product with your constituent.

Question 31

Regarding the use of technology in new provider payment arrangements: The Accountable Care Organization pilot program and other bundling initiatives being deployed by CMS use “benchmarks” that are determined using historical data. Due to this lag, they could penalize doctors that use cutting edge treatments and technologies that are more clinically appropriate for the patient or bring more value and better care outcomes over the longer term. Is there a comparable danger that ACOs and bundling will create incentives to stint on care? Are there technical modifications that can be made to the program that will neutralize the disincentives providers face when they want to use breakthrough treatments and technologies that are more expensive than the standard of care in the short run but will bring higher value to patients in the long term? Could time-limited technical adjustments to benchmarks be permitted to ensure that providers are not penalized by providing patient care with new technologies?

Answer: Medicare accountable care organizations (ACOs) and organizations participating in the Bundled Payments for Care Improvement initiative must meet rigorous standards for care quality and beneficiary satisfaction. To assess the quality of care furnished by the organizations and safeguard against stinting of care, CMS has created a vigorous monitoring program that includes asking beneficiaries about their experiences as well as measurement of the quality provided by participating organizations. ACOs and organizations participating in the Bundled Payments for Care Improvement initiative must achieve certain quality thresholds in order to continue participating in the initiatives.

Beneficiaries retain their original Medicare benefits and may choose to receive care from providers not participating in the initiative. Nothing in the initiatives will in any way restrict the ability of beneficiaries to access care from participating or non-participating providers, nor will it restrict the ability of participating ACOs to offer the latest medical technologies.

We will continue to carefully assess the progress of our ACO program and we welcome your continued input on how we can improve the program.

Question 32

Regarding Molecular Diagnostic Coverage and Payment: Medicare contractors have been establishing payment rates for 2013, but we understand that the methodology used by the contractors lacks transparency. What steps is CMS taking to provide greater clarity

regarding the methodology used to establish specific payment rates, such that interested stakeholders are able to clearly understand how the rate was derived? Is there a way to allow stakeholders to participate in this process, particularly when there is disagreement regarding the level of payment that has been established? If not, what steps will CMS take to provide a public process for stakeholders?

Answer: CMS uses CPT codes developed by the AMA in establishing payment rates for Medicare services. The AMA CPT Panel developed 114 new single CPT codes to replace multiple “stacking codes” (based on component steps) that were previously used to bill for molecular pathology tests. The old “stacking codes” were deleted at the end of 2012 and are no longer available.

While the new codes were issued in 2012, CMS decided to delay their use for a year to carefully consider whether they should be paid under the physician fee schedule (as pathologists preferred) or the clinical laboratory fee schedule (as preferred by laboratories). After requesting comments as part of the 2013 physician fee schedule rule, we decided to keep them on the lab fee schedule, with an additional payment available for interpretation by a pathologist. New rates for these tests (generally genetic tests) are being established through the “gap-filling” process, which enables the Medicare contractors to collect a wide range of relevant data. While this process is underway, the tests are being paid interim rates set by the contractors, which may reflect invoice amounts, old “stacking code” prices, or case-by-case determinations by the contractor medical directors.

The local gap-fill prices will be submitted to CMS this month and will be open to public comment for 60 days. CMS will post final prices in September, at which point stakeholders may request reconsideration, with supporting evidence. The 2014 fee schedule, including national limitation amounts for the new test codes, will be issued in November.

Question 33

Regarding Access to Diagnostic Imaging Services: According to data compiled by the Food & Drug Administration in 2013, there are now 200 fewer mammography facilities and nearly 1,000 fewer mammography scanners available to American women than in 2007, when several major Medicare imaging payment reductions were implemented. In addition, data from the FDA suggests that mammography imaging facilities that remained open have cut back the scope of services offered in order to remain in practice and combat lost revenue that resulted from reductions in payment rates. Centers for Disease Control and Prevention data also indicates that mammography screening rates have fallen slightly over the 2003 through 2010 period, which could attributed to a variety of causes, including Medicare payment policies. Is CMS monitoring the impact that Medicare payment rate cuts may be having on beneficiary access to important diagnostic imaging services, like mammography? If not, will CMS take steps to ensure we are monitoring access to these services for beneficiaries?

Answer: Medicare covers screening mammograms to check for breast cancer once every 12 months for all women with Medicare age 40 and older. Beneficiaries pay nothing for the test if the doctor or other qualified health care provider accepts assignment.

We believe access to these preventive services is important and we are monitoring access to care.

Question 34

Regarding Compounded Drugs: As we've all become aware in recent months, compounded drugs are commonly used, but can pose serious health risks if Good Manufacturing Procedures are not followed. Since a marked percentage of all hospital intravenous medications and those administered in the physicians' office are compounded or repackaged, could you elaborate on what CMS is doing to protect beneficiaries from risk? The CMS Benefit Policy Manual states that if FDA has determined that a drug is compounded in violation of the Federal Food, Drug and Cosmetic Act (FFDCA), that they do not meet the approval requirements of the Medicare program and thus not covered. How will CMS ensure appropriate oversight of reimbursement for these types of drugs?

Answer: We share your concern for the safety of drugs used by Medicare beneficiaries. We will continue to work with the FDA to ensure the denial of Medicare payments for compounded drugs that violate the FFDCA.

With the exception of compounded drugs and some repackaged items, the majority of drugs paid under Part B are commercially available, FDA approved products that are purchased by a physician's office, administered in the office or clinic setting, and billed by the physician or other provider.

Question 35

Regarding Short Cycle Dispensing in Long-Term Care (LTC) Facilities: Under the Affordable Care Act, a provision was included to require so-called "short-cycling" of certain high-cost drugs in LTC facilities in order to eliminate waste. The CMS final rule only required short-cycle dispensing of brand name drugs. It did not require short-cycle dispensing of low cost generics, however, because the added cost of extra dispensing outweighed the cost benefit of reducing the wastage of cheap generic drugs. It seems unintentional that the final rule's definition of a "brand name" drug is being interpreted by some plans to require short-cycle dispensing of select generic drugs that were approved prior to 1984, before the creation of the ANDA process for approving generics, and thus, do not have an ANDA number. Isn't this interpretation of the policy, requiring short-cycle dispensing for the oldest and least expensive generics, inconsistent with the goal of saving costs for the Medicare program? What is CMS' justification for the policy? Are you open to a reconsideration of this policy for this subset of drugs?

Answer: Part D regulations at 42 CFR 423.154 require 14-day-or-less dispensing cycles in the LTC setting for oral solid brand name drugs. In order to simplify administration of these requirements for Part D sponsors, CMS adopted in regulation the same definition of brand name drugs and generic drugs at 42 CFR 423.4 that sponsors are required to use when administering

other program requirements, including the statutory Low Income Subsidy copayments. We recognize the distinction between brand name drugs approved as NDAs and generics that were approved before the creation of the ANDA process. However, any such reconsideration of the regulatory definition of brand name drugs and generics would require notice and comment rulemaking.

Question 36

Regarding Physician Quality Reporting Feedback: The success of quality initiatives to influence physician behavior depends largely on the timeliness of the feedback they receive from CMS. Yet the data from Physician Quality Reporting System isn't made available to physicians for nearly two years after the fact. What is CMS' plan to address the data lag that currently exists from CMS to physicians? Has CMS determined an appropriate timeline for feedback that provides for an equitable determination of physician's quality performance? When will CMS provide public comment on a plan to disseminate quality information?

Answer: Section 609(b) of the American Taxpayer Relief Act of 2012 requires the Secretary to develop a strategy to provide providers with data on quality performance and utilization in a timely manner. The provision requires the Secretary to take into account specified items such as risk adjustment methods and the frequency of providing data so that the data is effective in improving provider performance. The provision also requires the Secretary to develop an interim strategy not later than one year after the date of enactment of the American Taxpayer Relief Act of 2012. Pursuant to Section 609(b), the strategy must take into account feedback from providers and must be updated not later than 18 months after the date of enactment. We will address these questions as we develop the interim and updated strategy as required by the law. In addition, the Administration has proposed in our FY 2014 Budget to allow for greater dissemination of medical claims data directly to physicians through entities participating in the Medicare Data Sharing for Performance Improvement program.

Question 37

Regarding Worker Compensation Set-Asides: During the confirmation of William Schultz, the department's General Counsel, in response to a question about well-documented problems with the CMS review of Worker Compensation Medical Set-aside Accounts (WCMSA), he indicated your agency is taking steps to become more transparent, is considering the adoption of an appeals process in order to ensure fairness and consistency, and is reviewing whether the use of evidence-based guidelines should be expanded. Unfortunately, since his answers were submitted, the agency released some documents that have been used to assess WDMSA submissions. The issue remains unaddressed. Instead, according to some observers, it only highlights the inconsistency and deficiency of the review process for WCMSAs, which continues to put the Medicare Trust fund and the interests of beneficiaries at risk. What additional steps will CMS take to ensure that 1) the review program is operated in a transparent and consistent fashion; 2) utilizes scientific, evidenced-based guidelines when reviewing submissions; and 3) establishes an appeals process in order to, as Mr. Schultz suggested, "ensure fairness and consistency"?

Answer:

On June 15, 2012, we published an Advance Notice of Proposed Rulemaking (ANPRM) to solicit public input on options that could be used to address future medical expenses related to an accident or injury for which there is third party liability, including in workers' compensation cases. We received over 100 comments. As noted in our ANPRM, we anticipate promulgating rules on these issues in the near future, consistent with the SMART Act that was enacted in January.

We are always striving to improve the MSP program so that we operate in a transparent and consistent manner. In the past, we have heard from stakeholders that we should offer additional information about the operation of the MSP program, and we are working hard to provide guidance to help educate stakeholders about the operation of the MSP program. While the informal guidance we recently released does not yet address all of the concerns we have received regarding WCMSAs, it does list the criteria we will consider in making decisions about a particular WCMSA as well as the procedure for receiving and reviewing WCMSAs. We are considering the feedback received on the program as we consider potential improvements.

Question 38

Regarding Diagnostic Laboratory Payment Reform: The President's Budget has proposed additional cuts to the clinical lab fee schedule. Last year, CMS initiated re-pricing for several molecular diagnostics. Due to the antiquated nature of the fee schedule and the increased development of newer advanced diagnostics, the existing coverage and reimbursement platform used by CMS is in need of reform. What is CMS doing to modernize coverage and payment policies to appropriately reimburse for quality tests and create a stable foundation for encouraging the development of new technologies that improve quality and reduce costs? What new legislative authority or legislative guidelines does CMS need to achieve necessary reforms?

Answer: We agree that the current statutory procedures and formulas governing clinical laboratory payment fail to provide the flexibility needed to modernize payment to reflect changes in laboratory practice, pricing, and technology. Toward that end, the President's FY 2014 budget includes a legislative proposal to provide the Secretary the authority to adjust payment rates under the Clinical Laboratory Fee Schedule in a budget-neutral manner, beginning in CY 2014. We welcome ideas on how we can improve our clinical laboratory payment system.

Question 39

Regarding Part B Drug Reimbursement: The reduction of reimbursement for physician-administered drugs that will occur due to sequestration has led to articles highlighting the cost of cancer drugs and the impact on community oncology practices. Market participants have suggested that many patients have been redirected from the clinic to the more expensive hospital outpatient setting. Does CMS have data available that will confirm that this transfer of patient care is occurring? If not, what is CMS prepared to do to make this data available to Congress?

Answer: We share your concern about the potential adverse impacts of the payment cuts mandated by sequestration, both with regard to Medicare payments, and more broadly across all

government programs. That is why the Administration has indicated that we stand ready to work with Congress on balanced approaches to replace sequestration to avoid its adverse impacts.

CMS is committed to preserving Medicare beneficiaries' access to quality health care. We will continue to monitor the impact of provider payment cuts mandated under the Budget Control Act to assess their impact on Medicare beneficiaries and we are happy to share our results.

Question 40

Regarding CMS Coverage of Alzheimer's Diagnostics: An FDA-approved new diagnostic for helping detect if a patient has Alzheimer's is being considered by CMS for national coverage under Medicare (NCD). The Alzheimer's association and thought leaders in that community have endorsed the technology and have urged CMS to institute coverage without coverage with evidence development. The Alzheimer association and clinical community have adopted appropriate use criteria for the diagnostic to assure appropriate utilization. However, CMS has also discussed the potential additional use of coverage with evidence development (CED) for this diagnostic test. Can you provide an update on this NCD? Why is the appropriate use criterion developed by the medical community insufficient to protect from over utilization of this diagnostic? What will CMS do to ensure this diagnostic is available to the Medicare patients in need?

Answer: CMS is actively engaged in reviewing new technology to ensure timely access to innovation for our beneficiaries. In October 2012, we opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans, which provided national coverage of PET using only specified radioisotopes for certain indications, and conditional coverage for additional uses under the process known as Coverage with Evidence Development (CED). Reconsideration of this NCD was requested by a stakeholder who advocated coverage of PET using a new type of radiopharmaceutical approved by the FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline. To help inform this evidence review, we convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in January 2013. A proposed coverage decision is expected by July 2013, with a final decision (including consideration of public comments) expected by October 2013.

Question 41

Regarding State Authority to define qualified providers: Section 1902(a)(23) of the Social Security Act states that Medicaid providers must be "qualified to perform the service or services required," and the federal regulations implementing this statute (42 CFR Section 431.51) allow states to set "reasonable standards relating to the qualifications of providers." Additionally, Section 1902(p)(1) infers that states have broad authority to exclude certain providers, and the legislative history from Senate Report 100-109 states "This provision is not intended to preclude a State from establishing, under State law, any other bases for excluding individuals or entities from its Medicaid program." A First Circuit court ruling in *First Medical Health Plan, Inc. vs. Vega-Ramos* found that Section 1902(p)(1) "permit[s] a state to exclude an entity from its Medicaid program for any reason establish by state law." Do you agree with the premise of this court's ruling that states have broad authority to exclude certain provider entities from its program? If not, how do

you interpret “reasonable standards relating to the qualifications of providers” that may be set by a state to set in order to exclude certain providers from its Medicaid program? What are the limits on this state authority?

Answer: Our regulations codified at 42 CFR 431.51 provide that beneficiaries may obtain services from any qualified Medicaid provider that undertakes to provide services to them, pursuant to section 1902(a)(23) of the Act. 42 CFR 431.51(a)(6) codifies section 1932(a) of the Act, which permits a state to restrict the freedom of choice required by section 1902(a)(23) of the Act under specified circumstances related to enrollment in managed care, for all services except family planning services. States are required to comply with the freedom of choice requirements as dictated by statute and codified in regulation. We do not believe that it is consistent with Section 1902(a)(23) for states to exclude providers for reasons unrelated to their ability to furnish the services at issue, or bill for the services properly and ensure program integrity. In context, section 1902(p)(1) of the Act permits states to have independent authority to protect program integrity, similar to the authority the Secretary exercises under sections 1128, 1128A or 1866(b)(2) of the Act. In the case you reference, we note that Puerto Rico is explicitly exempted from the freedom of choice requirement as codified in 42 CFR 431.51(b)(1).

Question 42

Regarding Per Capita Caps: As you know, Medicaid consumes the largest health-related share of federal revenues and federal spending as a share of the economy is set to grow by 25 percent over the next 10 years. Clearly, Medicaid – like our other entitlement programs – must be reformed if we are to make a meaningful impact on our debt and deficit problems. President Clinton proposed Medicaid per capita caps back in the 1990s, and to quote the former Secretary of Health and Human Service when she testified in this Committee back in March of 1997, per capita caps mean “there are absolutely no incentives for States to deny coverage to a needy individual, or to a family...It is a sensible way to make sure that people who need Medicaid are able to receive it.” Given the need to address health care entitlement spending and the bipartisan history behind Medicaid per capita caps, would you work with us on developing the details of this proposal to ensure we enact reforms that both protect taxpayers and patients?

Answer: CMS strives to ensure that the current Medicaid program is run as efficiently as possible while ensuring that our beneficiaries have access to services delivered through a high-quality health care delivery system. We view the Medicaid program as a partnership between CMS and the states and strive to use statutory and regulatory flexibility and the ingenuity of the states to regularly make improvements to the program. We have effectively managed Medicaid spending growth. The latest Medicaid Actuarial Report shows that Medicaid benefits spending per beneficiary is estimated to have decreased by 1.9% from 2011 to 2012. The Affordable Care Act has provided both CMS and the states with opportunities to enhance the quality of care delivered to Medicaid beneficiaries in a more efficient and coordinated manner. We are transforming our data systems so we have better and more accurate information about expenditures, we are moving beneficiaries from traditionally expensive long-term care settings to home and community based services, we are exploring new delivery system models like integrated care to replace more expensive delivery systems, and we are implementing incentives for states to comprehensively address the needs of their most chronically ill and expensive

beneficiaries. The President’s budget proposes additional ideas to improve Medicaid efficiency without shifting costs to states or beneficiaries.

Question 43

Regarding Medicaid Premium Assistance: CMS recently released “Frequently Asked Questions” regarding Medicaid premium assistance proposals. I understand that you intend to approve some of these proposals under Section 1115 waiver authority. Do you believe that 1115 waiver authority gives the Secretary of Health and Human Services the ability to waive the “wrap-around” benefit requirements, if benefits offered under qualified health plans differ from those traditionally offered in Medicaid?

Answer: As described in the Frequently Asked Questions (FAQs) released by CMS regarding the use of premium assistance, we will only consider demonstration proposals that make arrangements with qualified health plans (QHPs) to provide any necessary wrap around benefits and cost sharing.

Questions from Senator Rockefeller

Question 1

On April 2, 2013, Governor Beebe announced that Arkansas received written approval from Secretary Sebelius for the state’s Medicaid expansion “concept,” which would use Medicaid funding to enroll beneficiaries into private coverage. However, many important details still must be sorted out in a more comprehensive demonstration proposal. Does CMS plan to use this process—first approving a concept memo and then approving a more detailed demonstration proposal—for all states interested in using the premium assistance model? What outstanding issues is Arkansas expected to address in the demonstration proposal before they can move forward with implementation?

Answer: As a regular course of business, CMS provides technical assistance and informal guidance to states as they develop proposals at the state level. States often request this assistance from CMS prior to making a formal proposal, in order to better understand applicable statutes and regulations and the impacts of those provisions on their proposals. CMS recently issued a set of Frequently Asked Questions (FAQs) regarding the use of premium assistance, providing more information to all states considering such an option. We would expect states that are interested in this option to use these FAQs as a guide when developing their proposals. Arkansas has yet to make a formal submission to CMS and without such a proposal it is premature to speculate on the items that may require additional information from CMS.

Question 2

How will HHS address the additional costs generated by enrolling Medicaid beneficiaries into private coverage in Arkansas and other states that are interested in using the premium assistance model for Medicaid expansion? How much of those additional costs be assumed by the federal government versus the states?

Answer: CMS recently released a set of Frequently Asked Questions (FAQs) that provide additional information to states interested in pursuing the use of premium assistance. Specifically, the FAQs described that the current Medicaid statute requires that premium assistance arrangements be “cost effective.” “Cost effective” generally means that Medicaid’s premium payment to private plans (plus the cost of additional services and required cost sharing assistance) will be comparable to what Medicaid would otherwise pay for the same services. Such a standard would need to be met if a state pursued the use of premium assistance through their State Plan.

Additionally, some states have expressed interest in section 1115 demonstrations to provide premium assistance. CMS has indicated that we will consider approving a limited number of premium assistance demonstrations and that as part of such demonstration would consider states’ ideas on cost effectiveness that include new factors introduced by the creation of Health Insurance Marketplaces and the expansion of Medicaid. As with all demonstration proposals, the actuarial, economic and budget justification (including budget neutrality) would need to be reviewed and, if approved, the program and budgetary impact would need to be carefully monitored and evaluated.

Question 3

There seems to be a trend toward Medicaid managed care organizations both in the Medicaid expansions and in the duals demonstration projects. I continue to hear complaints from beneficiaries about transitions to managed care. Assurances of continuity of care are not being met, and the result can be patient care ending mid-treatment, with negative health consequences. What steps is HHS taking to monitor quality, plan performance and patient experience under these new Medicaid models? Will beneficiaries in these states have real options to opt-out of private coverage into traditional Medicaid?

Answer: Ensuring quality of care for our beneficiaries is CMS’ top priority. Managed care is not new for Medicaid; most states contract with private managed care organizations to deliver services to their beneficiaries. More recently, states have expanded managed care to new populations and to new services, including long term care services and supports. States have the flexibility under the statute to adopt managed care without a waiver, but some have pursued the use of managed care to deliver benefits through 1115 demonstrations. CMS has worked with states to ensure the appropriate use of this delivery system, to promote quality and improve health outcomes. In approving demonstrations, CMS has exempted certain populations and ensured the readiness of the new delivery system prior to allowing enrollment in managed care. Additionally, demonstrations include ongoing monitoring plans to assure contract compliance, network and benefit adequacy and the quality of care provided and, particularly with respect to long term services and supports, we have worked with states to create or expand ombudsman offices to help beneficiaries with transition. In cases where the use of managed care has been approved through an 1115 demonstration, CMS and the state have agreed to a specific set of special terms and conditions whereby the state agrees to monitor and report on demonstration requirements.

Question 4

I was pleased to see that the memorandums of understanding on duals demonstrations include some requirements for consumer engagement. However, I am concerned about whether and how that engagement will actually take place in the states. Can you speak to the importance of consumer engagement in the duals demonstration projects and how HHS will make sure that the M.O.U. provisions to safeguard consumers are satisfied on the ground?

Answer: As you know we've worked with each state to incorporate the most robust beneficiary protections from Medicare and Medicaid and will integrate and enhance the current protections to create a more accessible, seamless system of care for Medicare-Medicaid enrollees. Continuity of care provisions will ensure beneficiaries have access to their existing doctors and other providers for a specified period of time while they transition into demonstration plans, and Demonstration enrollees will retain all Medicare Part D beneficiary protections.

In addition, beneficiaries will receive clear, understandable notices that have been reviewed by advocacy organizations and field tested with beneficiaries. Outreach and education will proceed through multiple channels at multiple points in time and will take into account the prevalence of cognitive impairments and mental illness in this population as well as the incidence of limited English proficiency. Independent resources, such as choice counselors and enrollment brokers, will assist beneficiaries in making enrollment choices. We will also leverage existing resources, such as State Health Insurance Programs and Aging and Disability Resource Centers, to provide one-on-one counseling on enrollment options. We will provide specialized training for 1-800-Medicare operators to enable them to effectively assist beneficiaries.

CMS will be working with each state to ensure that they comply with the terms of the Memorandums of Understanding, other related Demonstration agreements and all applicable laws and regulations. CMS is funding and managing the evaluation of each approved Demonstration. CMS has contracted with an external independent evaluator to measure, monitor, and evaluate the overall impact of the Demonstrations, including impacts on Medicare-Medicaid enrollees, expenditures, and service utilization. The evaluator will design unique, state-specific evaluation plans for each individual state participating in the Demonstration, as well as an aggregate analysis that will look at the Demonstration overall including Demonstration interventions and impact on key subpopulations within each state. The evaluation will use a mixed methods approach to capture and analyze quantitative and qualitative information.

The Memoranda of Understanding for Massachusetts, Ohio, Washington, Illinois, and California provide examples of the types of areas that will be measured in all Demonstrations, including beneficiary experience with care and care transitions, the support afforded by community living, beneficiaries' access to services, and shifts in service utilization patterns. Additional quality measures, as well as qualitative evaluation components such as beneficiary focus groups and key informant interviews, will be included in the state-specific evaluation plans. CMS will apply Medicare Part D requirements regarding oversight, monitoring, and program integrity to Demonstration plans.

Question 5

I strongly believe that Independent Payment Advisory Board will allow necessary, cost-saving changes to Medicare without harming beneficiaries. The Board would need to start its work this year and yet there have been no nominations yet. Where does this stand and what can you do to move it forward?

Answer: We agree that the Independent Payment Advisory Board (IPAB) will help to ensure that Medicare continues on a sustainable financial footing. The President looks forward to working with Congress to begin the nomination process for IPAB Board members in the near future. We are encouraged to see that our recent efforts to improve quality and efficiency in Medicare are contributing to historically low cost growth in the program. Under current assumptions, projected per capita Medicare spending will not exceed the statutory target for several years.

Question 6

As the marketplaces become up and running, it is important to make sure that children maintain access to the most affordable and comprehensive coverage. Can you discuss how CMS plans to navigate the intersection between the Medicaid and CHIP programs with marketplace coverage, while placing a priority on making sure that children are provided with the most comprehensive and affordable care?

Answer: CMS is fully committed to helping providing high quality, affordable coverage to all children, including those with private insurance and in the Medicaid and CHIP programs. We are also fully aware that some families may receive coverage from different sources, for instance, a child may be enrolled in CHIP, while the parents purchase private insurance on the Marketplace. Whenever possible, we try to align the essential health benefits required for Marketplace plans with the comprehensive coverage received by Medicaid beneficiaries.

CMS' final eligibility rules for both Marketplaces, Medicaid and CHIP outline standards for mutual agreements including the clear delineation of the respective responsibilities of programs in support of a coordinated and streamlined eligibility and enrollment process. There are additional agreements needed to exchange data among insurance affordability programs, and between states and the federal government in support of verifications. Development and finalization of those agreements is proceeding concurrently with operational and technical modeling and testing.

Question 7

According to pharmacy benefit manager Prime Therapeutics and Blue Cross and Blue Shield of Minnesota, specialty drugs will likely account for 50% of all drug costs by 2018, up from 28.7% of total prescription drug costs in 2012. In many cases these drugs account for more than half of the treatment costs for an illness (no opportunity for medical offset). Medicare will see these costs largely under Part B. How specifically is the agency responding to this financial threat?

Answer: CMS agrees that prescription drugs play a large role in Medicare spending as well as a person's interaction with the health care system.

Improved medication adherence through policies like ACOs can help reduce other health care costs and improve quality.

In addition, the recently released President's budget proposal for fiscal year 2014 includes proposals for reducing overpayments for drugs paid under Parts B and D. The Part D proposal would require manufacturers to pay the difference between rebates they negotiate with Part D plans and Medicaid rebate levels, beginning in 2014. This proposal would 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 2014. The proposal would require manufacturers to pay the difference between rebate levels they already provide Part D plans and the Medicaid rebate levels. The Part B proposal would reduce payments of Part B drugs from the current methodology of average sales price (ASP) plus 6 percent to ASP plus 3 percent. In order to preserve access to care, manufacturers would be required to provide a specified rebate in certain instances as determined by the Secretary.

Questions from Senator Menendez

Question 1

Regarding Imputed Rural Floor - As you're aware, New Jersey and Rhode Island are unique among the states because they're considered "all urban" for Medicare wage indexing purposes. This means that hospitals in my state are ineligible for the myriad special payments available to hospitals located in rural areas or which have been specially classified as being in rural areas. As an attempt to provide some equity in the system, CMS devised the imputed rural floor. This policy serves the same purpose as the regular rural floor available to every other state and provides New Jersey hospitals with a more equitable payment structure that reflects the unique health care market in the state. The imputed rural floor is set to lapse at the end of the current fiscal year, but can be extended as part of the 2014 Inpatient Prospective Payment System (IPPS) rule.

New Jersey hospitals are struggling to recover from Superstorm Sandy, facing significant payment reductions from sequestration, and working tirelessly to implement significant delivery system reforms. It would be devastating to New Jersey's health care infrastructure for CMS to cherry-pick the imputed floor out of the entire Medicare wage index system for expiration, especially while the rest of the system is allowed to remain as is. Earlier this year I sent a letter, signed by the entire New Jersey delegation, urging the extension of this vital policy.

If confirmed, can you assure me that the imputed rural floor will continue until such time as Congress acts on a comprehensive overhaul of the wage index system?

Answer: In FY 2005, CMS adopted the "imputed" floor as a temporary 3-year regulatory measure to address a concern that hospitals in all-urban states were disadvantaged by the absence of rural hospitals to set a wage index floor in those states. The imputed floor was originally set to expire in FY 2007 but was extended for an additional year in FY 2008. In FY 2009, CMS extended the imputed floor for an additional 3 years through FY 2011. In FY 2012, CMS

extended the imputed floor again through FY 2013. We will issue the FY 2014 IPPS proposed rule in short order, along with our decision on whether to propose extending the imputed floor.

Question 2

Regarding Essential Health Benefits and Behavioral Health Services - In following up to my question during the hearing, I wanted to provide you with some additional information about the concerns I have regarding the essential health benefits (EHB) rule and the statutory requirement that qualified health plans (QHPs) offer behavioral health services, such as those used to treat autism spectrum disorders.

The underlying reason I fought to have “behavioral health” explicitly codified in the EHB was because of the countless instances of people being denied access to needed behavioral health services because these services weren’t deemed as being “medical” or “mental health” services covered under their insurance policy. The final EHB rule issued on February 25, 2013 does not adequately protect against this practice nor provide assurances that everyone enrolled in a QHP will have access to behavioral health services, as prescribed in law.

The primary area of concern is that the rule allows plans to substitute benefits. While the rule ensures that substitution is only allowed within each benefit category, and that it be actuarially equivalent, there is still a strong likelihood that substitution could lead to limitations on the availability of behavioral health services. Because this benefit category also includes mental health and substance use disorder services, there are concerns plans could simply increase the availability of mental health or substance abuse services and decrease or essentially eliminate, in an actuarially equivalent manner, the availability of behavioral health services. This has the practical effect of continuing to allow issuers to deny access to these important services.

Additionally, in a paragraph of the rule that explains the requirements needed to satisfy this benefit category the rule states that services “must be provided in a manner that complies with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).” (78 FR 12843) However, a 2012 Report to Congress on the implementation of MHPAEA states that, when it comes to behavioral health services, the “impact and protections” of MHPAEA are being interpreted and implemented as part of ACA. This circular logic provides no real assurances that behavioral health services are being meaningfully addressed in either case.

In another section discussing the impact on issuers, the final rule reiterates that the statute requires “that all plans covering EHB offer mental health and substance use disorder service benefits, including behavioral health treatment and services.” (78 FR 12861) However, the rule fails to elaborate further on the behavioral health aspect, only focusing on mental health parity. This again fails to address how issuers are to ensure access to these services in a meaningful way.

Finally, when asked about the lack of assurances regarding behavioral health services CMS and CCIIO stated that any shortcoming in coverage under the mental health and substance

abuse category will be made up in the rehabilitative and habilitative services benefit category. However, the rule itself clearly recognizes habilitative benefits “are not well defined.” (78 FR 12844) The lack of an established definition of habilitative service provides no assurances that behavioral health services will be included in any future definition, especially since issuers will (rightly) claim they belong in the mental health and substance use disorders category. The rule continues by saying states will “have the first opportunity to determine which habilitative benefits must be covered... [and] if states have not chosen to define habilitative benefits, the issuer’s choice remains.” This is understandably causing concern because states that do not yet have a definition of habilitative services are likely to be those that also lack a requirement for behavioral health services, meaning issuers in those states are likely to lack both.

Please address the concerns outlined above, including the lack of consistency within the EHB and MHPAEA rules; how substitution of benefits does not equal discrimination or access limitation; and how the definition of habilitative services could come to include behavioral health services.

What specific policies and procedures are in place to ensure behavioral health services, including those for autism spectrum disorders, are included in every QHP offered in every state, as required by statute? Additionally, what are the specific policies to ensure this is the case in states with a federally-facilitated exchange and/or no existing state-based behavioral health requirements?

Will CMS overrule the certification of a plan as a QHP if it substitutes benefits that diminishes coverage of, or limits access to, behavioral health services, even if it’s done within the same benefit category and in an actuarially equivalent manner?

Answer: Throughout the implementation of the essential health benefits (EHB), we have taken great care to ensure that the law is implemented consistently. The statute contains many provisions that affect how EHB and MHPAEA interact. Section 2707 of the PHS Act requires health insurance issuers offering non-grandfathered coverage in the individual and small group health insurance markets to cover the EHB package required under section 1302 of the Affordable Care Act. The Affordable Care Act grants the Secretary authority to define EHB. The EHB final rule stated that plans are required to comply with the parity standards set forth in 45 CFR 146.136 – the MHPAEA regulations - in order to satisfy the requirement to provide EHB. Section 1311(j) of the Affordable Care Act specifies that section 2726 of the PHS Act – the portion of the statute that contains the MHPAEA amendments to the Public Health Service Act - shall apply to qualified health plans in the same manner and to the same extent as such section applies to health insurance issuers and group health plans. For these reasons, HHS has concluded that plans must comply with the parity standards applicable to mental health and substance use disorder benefits set forth in 45 CFR 146.136 in both the individual and the small group markets in order to satisfy the requirement to cover EHB.

As you know, the essential health benefits rule permitted states to select a benchmark plan from among several plans that currently exist in the market. This benchmark plan, known as the EHB benchmark plan, must include ten categories of items and services identified in the statute.

Among these categories is mental health and substance use disorder services, including behavioral health treatment. If a benchmark plan chosen by a state does not contain any benefits in a benefit category, it must supplement those benefits with the benefits from another benchmark plan option. The essential health benefits final rule requires that all qualified health plans provide benefits that are substantially equal to the EHB benchmark plan including both covered benefits and limitations on coverage including coverage of benefit amount, duration and scope.

As you note, qualified health plans are permitted to substitute benefits only within categories and such substitution must be actuarially equivalent. The EHB final rule permits substitution to provide greater choice to consumers, and promote plan innovation through the use of various coverage and design options. We note that even if qualified health plans have substituted benefits those plans would still be subject to the non-discrimination provisions of the Affordable Care Act including section 1302 , which is codified in 45 CFR 156.125 providing that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Finally, under the EHB final rule, states may, at their option, limit or prohibit benefit substitutions that would otherwise be permissible under our regulations,

With respect to certification, a state implementing a state-based Marketplace is responsible for QHP certification. CMS will be responsible for certifying all QHPs in Federally-facilitated and State Partnership Marketplaces.

Question 3

Regarding Molecular Pathology Tests - As of January 1, 2013 clinical labs have been utilizing new CPT codes when billing for molecular pathology services. These new codes were originally going to be used in 2012. However CMS, recognizing the need for more time to fully implement them, delayed their use until this year.

It has recently come to my attention that there are serious concerns about how CMS and, more specifically, the regional Medicare administrative contractors (MACs) are implementing and pricing these new codes. Despite the year reprieve, it appears that the MACs have yet to set prices for many of these new codes and, for the codes they have priced, set a rate that is inconsistent with both the historic prices and the tests' actual costs. In either case, there has been a serious lack of transparency in how the MACs are calculating the prices and what, if any, methodology they are using.

The ongoing delay has resulted in clinical labs in New Jersey going without reimbursement for these tests since the beginning of the year, or being reimbursed at rates upwards of 90 percent below the rates used just last year. I am concerned with how the process of implementing and pricing these new CPT codes will impact beneficiaries' ability to receive, physicians' ability to order, and labs' ability to conduct these molecular pathology tests.

What specific steps is CMS taking to address the ongoing concerns with these new molecular pathology codes, including providing oversight and guidance to the MACs, requiring transparency in the pricing methodology, and ensuring a timely and accurate reimbursement for tests that have already been conducted?

Answer: CMS uses CPT codes developed by the AMA in establishing payment rates for Medicare services. The AMA CPT Panel developed 114 new single CPT codes to replace multiple “stacking codes” (based on component steps) that were previously used to bill for molecular pathology tests. The old “stacking codes” were deleted at the end of 2012 and are no longer available.

While the new codes were issued in 2012, CMS decided to delay their use for a year in order to consider whether they should be paid under the physician fee schedule (as pathologists preferred) or the clinical laboratory fee schedule (as preferred by laboratories). After requesting comments as part of the 2013 physician fee schedule rule, we decided to keep them on the lab fee schedule, with an additional payment available for interpretation by a pathologist. New rates for these tests (generally genetic tests) are being established through the “gap-filling” process, which enables the Medicare contractors to collect a wide range of relevant data. While this process is underway, the tests are being paid interim rates set by the contractors, which may reflect invoice amounts, old “stacking code” prices, or case-by-case determinations by the contractor medical directors.

The local gap-fill prices will be submitted to CMS this month and will be open to public comment for 60 days. CMS will post final prices in September, at which point stakeholders may request reconsideration, with supporting evidence. The 2014 fee schedule, including national limitation amounts for the new test codes, will be issued in November.

Questions from Senator Toomey

Question 1

I am concerned by reports of physicians closing their oncology practices due to reimbursement concerns. Is CMS tracking practice closings? Could CMS track National Provider Identifiers to see if those physicians are moving into a hospital system? As sequester begins to take effect, could CMS track the mix of Medicare beneficiaries receiving oncology services in a physician office versus an outpatient department both pre and post sequester?

Answer: We share your concern about the potential adverse impacts of the payment cuts mandated by sequestration, both with regard to Medicare payments, and more broadly across all government programs. That is why the Administration has indicated that we stand ready to work with Congress on balanced approaches to replace sequestration to avoid its adverse impacts. CMS is committed to preserving Medicare beneficiaries’ access to quality health care. We will continue to monitor the impact of provider payment cuts mandated under the Budget Control Act to assess their impact on Medicare beneficiaries and we are happy to share our results.

Question 2

PA is one of the most rural states in the country and health systems have been working towards expanding telemedicine to ensure expanded access to quality health services. How does CMS plan to expand telemedicine efforts?

Answer: I am very supportive of telehealth initiatives as a means to enhance access to needed services for Medicare beneficiaries. The Center for Medicare and Medicaid Innovation is testing several projects related to increased use of telehealth. A project in Hawaii received a Health Care Innovation Award for telehealth-based home monitoring for very high risk patients with complex health care needs in order to prevent hospitalizations. A project in Wyoming received a Health Care Innovation Award to improve care coordination and communication with practitioners in ten rural Iowa counties using telehealth and web-based personal health records. In addition, the Affordable Care Act requires accountable care organizations (ACOs) participating in the Medicare Shared Savings program to coordinate care for beneficiaries, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

Under the fee for service Medicare benefit, although the statute stipulates that Medicare may pay for telehealth services only in rural health professional shortage areas or counties that are not metropolitan statistical areas, CMS has the flexibility to determine the types of services that are paid for. CMS annually evaluates whether to add services to this benefit and last year in the final rule for the CY 2013 Physician Fee Schedule, a variety of new services were added. Some of these new services include: alcohol and substance abuse and intervention services; annual alcohol misuse screening; annual depression screening; intensive behavioral therapy for cardiovascular disease; and intensive behavioral therapy for obesity.

Question 3

The Medicare wage index is an issue of particular importance to hospitals in parts of Pennsylvania as well as in other states. CMS has acknowledged that the Medicare wage index system needs to be fixed. How do you view this issue? How would you suggest addressing this issue and what would be your timeframe?

Answer: Under the current hospital wage index system, hospitals are classified into geographically similar labor market areas. However, because some hospitals view their wage index as not accurately reflecting the labor costs they incur for hospital staff, a number of acute care hospitals seek to “reclassify” into other labor areas.

In April of 2012, CMS submitted a Report to Congress entitled, “Plan to Reform the Medicare Wage Index.” In that report, we discussed a different approach to calculating the wage index that we believe would more accurately reflect the labor costs incurred by each hospital based on the hospital employees’ commuting patterns. This “commuting-based wage index” would allow for the wage index to be calculated at a more granular level, down to the individual hospital. It could also potentially obviate the need for hospital reclassifications to other labor market areas.

In the report, we indicated that more data on hospital employee commuting patterns may be necessary before adopting a commuting-based wage index. Additionally, we stated that certain special adjustments to the wage index under current law may no longer be applicable and should

be reviewed in order to determine if they would still be relevant under the new system. Current law is prescriptive with respect to the wage index; nonetheless, we continue to evaluate whether improvements could be made under existing authority.

Questions from Senator Nelson

Question 1

Regarding Medicaid expansion: There has been a lot of talk not only in my state but other states considering what is now being referred to as the “Arkansas model” for expanding their Medicaid programs through some variation of premium assistance to private insurers.

It’s my understanding that just because a beneficiary receives premium assistance, he or she does not lose the protections of the Medicaid program—they are still considered a Medicaid beneficiary and they still have retain Medicaid’s benefits, protections, and cost-sharing restrictions. Can you discuss CMS’s guidance to states on what their responsibilities are to Medicaid beneficiaries if the insurance plan does not have these protections? How can we be sure that if states are allowed to experiment they will adequately provide for their beneficiaries? How will CMS actively monitor these newer models to be sure that they are working as intended?

Answer: CMS has recently released a set of Frequently Asked Questions (FAQs) regarding state interest in the use of premium assistance. Under all premium assistance arrangements, beneficiaries remain Medicaid beneficiaries and continue to be entitled to all benefits and cost-sharing protections. States must have mechanisms in place to “wrap-around” private coverage to the extent that benefits are less and cost sharing requirements are greater than those in Medicaid.

Some states have expressed interest in section 1115 demonstrations to provide premium assistance. CMS has indicated that we will consider approving a limited number of premium assistance demonstrations and that as part of such demonstration would consider states’ ideas on cost effectiveness that include new factors introduced by the creation of Health Insurance Marketplaces and the expansion of Medicaid. CMS has described the type of proposals that it will consider including only those proposals that provide beneficiaries with a choice of at least two qualified health plans, that make arrangements to provide any necessary wrap around benefits and cost sharing, that are limited to individuals whose benefits are closely aligned with the benefits available on the Marketplace and that end no later than December 31, 2016. As is our practice, CMS will include in any demonstration approval, requirements for the state to closely monitor and report on the demonstration’s progress and has time limited the demonstrations to ensure these demonstrations will inform policy for the State Innovation Waivers that start in 2017.

Question 2

Regarding Price Transparency: Stephen Brill’s TIME magazine article, “The Bitter Pill,” generated a fair level of conversation about the transparency of prices charged by hospitals for various procedures. However, the article did not mention the huge step forward the Affordable Care Act took in this direction. The provision of the ACA that establishes the

Medical Loss Ratio requirements for health insurers also includes an often-forgotten provision that requires hospitals to establish and make public a list of standard charges for items and services, including diagnosis-related groups. What work has been done to implement this provision?

CMS has also run the “Hospital Compare” website for several years now, which allows Medicare beneficiaries to compare the quality of hospitals in their area. Do you have any recommendations to improve “Hospital Compare” to incorporate hospital pricing information so that beneficiaries can search hospitals based on the overall value of services provided?

Answer: We believe that Hospital Compare is an extremely important tool in enhancing quality of care. Not only does it give patients the ability to evaluate the care that hospitals furnish, it give hospitals a direct and clear incentive to seek to improve the quality of care that they provide.

Hospital Compare is now a rich source of data and includes the following measures: mortality rates; readmission rates; clinical process of care measures for heart failure, pneumonia, and acute myocardial infarction; surgical care measures; complications measures; and very importantly, survey measure data from our HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey.

We have recently added measures of healthcare associated infections (HAI) to Hospital Compare, including measures of: Central Line Associated Bloodstream Infections (CLABSI), Catheter Associated Urinary Tract Infections (CAUTI), and Surgical Site infections from colon surgery and abdominal hysterectomy. In the next few years, we plan to add the additional HAI measures of MRSA and C-difficile, which are two measures that have recently been added to the hospital Inpatient Quality Reporting program. As the science of quality measurement rapidly evolves and more measures are added to the Hospital Inpatient Quality Reporting program, the data in the Hospital Compare website will become richer as well.

Additionally, Hospital Compare includes information on Medicare payments to hospitals. We are exploring ways to make more information on hospital pricing publicly available in a manner that is consumer-friendly and helpful to individuals who are making decisions about where to seek care. We welcome your ideas on how we can make our health care system more transparent to consumers.

We will consider your suggestion to incorporate hospital pricing information in Hospital Compare, as we work to continually improve this important tool.

Question 3

Regarding Medicare Fraud in the Mental Health Benefit: Recently, the HHS Office of the Inspector General has highlighted skyrocketing fraud in the mental health benefit in Medicare. A number of the OIG’s fraud recovery activities in the Medicare mental health benefit have focused on providers that are no longer licensed or have had their licenses revoked, but still bill Medicare for millions of dollars each year. My Committee has

undertaken a broader investigation into the types of fraud perpetrated, but I am very concerned already that beneficiaries in need of mental health services do not receive value for the taxpayer dollar.

How does Medicare prevent fraud in mental health service billing? Are there additional challenges with fraud prevention and recovery activities in the mental health benefit as compared to other types of fraud? I know that Medicare requires these community mental health providers to follow state licensing rules- but how does the agency enforce this requirement and, in your opinion, is it adequate? What communication does CMS have with state licensure boards to ensure that the mental health provider billing Medicare for services is still licensed currently in their state?

Answer: As a result of the new authorities and resources provided by the Affordable Care Act and the Small Business Jobs Act of 2010, CMS has new powerful anti-fraud tools to shift the agency beyond a “pay and chase” approach to preventing fraud before it happens. As part of our enhanced program integrity efforts, CMS has implemented a risk-based screening process for newly enrolling and revalidating Medicare providers and suppliers. This screening process requires certain categories of providers and suppliers that have historically posed a higher risk of fraud to undergo greater scrutiny prior to their enrollment or revalidation in Medicare. Community Mental Health Centers (CMHCs) are in the moderate risk category and are subject to unannounced site visits along with licensure verifications. All providers and suppliers are required to meet applicable state licensure and certification requirements in order to enroll or participate in the Medicare program.

In 2012, CMS began the implementation of the Automated Provider Screening System (APS). The APS is designed to verify the data submitted on enrollment applications against independent commercial and health care data, including licensure and certification checks, to establish eligibility for enrollment or revalidation in the Medicare program. Since March 2011, CMS validated or revalidated enrollment information for nearly 410,000 Medicare providers and suppliers under the enhanced screening requirements of the Affordable Care Act. Because of revalidation and other proactive initiatives, CMS has deactivated 136,682 enrollments and revoked 12,447 enrollments.

CMS is also using cutting-edge fraud prevention tools such as predictive modeling on fee-for-service claims. Since June 2011, the Fraud Prevention System has screened over a billion claims for suspicious billing activity, including claims from CMHCs, while using models targeted to the services provided by CMHCs. CMS is also launching a pilot targeting the highest CMHC fraud risk states of Florida, Texas, and Louisiana.

Similar efforts have produced promising results in the past. In 2009 and 2010, CMS conducted a special project, the South Florida High-Risk Provider Enrollment Project, which targeted fraud among especially susceptible provider types, including CMHCs, in South Florida. As part of the project, CMS contracted with the Medicare Administrative Contractor (MAC) and Zone Program Integrity Contractor (ZPIC) in that area to conduct specific actions designed to detect and deter CMHC fraud in Palm Beach, Broward, and Miami-Dade Counties, Florida (i.e., South Florida). For example, the MAC conducted site visits to all South Florida CMHCs in its jurisdiction to

verify their existence and operations. CMS used the results of these site visits, along with other information, to create a fraud-risk score for each of these CMHCs. CMHCs with high fraud-risk scores were subject to ZPIC investigation, which could result in referrals to law enforcement, payment suspensions, or revocations of billing privileges.

As of May 2011, the South Florida High-Risk Provider Enrollment Project had resulted in revocations for 239 providers and suspensions for 8. Use of edits also avoided approximately \$156 million in wasteful or fraudulent claims.

Question 4

Regarding Long-Term Care: As Chairman of the Senate Aging Committee, efficient quality care in the long-term care environment is an area of particular interest for me. However, I am concerned that most of our efforts have focused on acute care payers thus far.

As you may know, 31.5 percent of Medicaid's \$400 billion in shared federal and state spending goes to long-term care for the elderly and the disabled; a full 70 percent of long-term care payments come from Medicaid dollars. Yet, I noticed that none of the current Medicaid demonstrations are in this area, despite the fact that Medicaid is the primary payer of long-term care services. How will CMS do a better job in the future to pilot quality activities in the long-term care environment?

I am aware that there are actions in some of the states that are doing dual-eligible demonstrations surrounding long-term care, but what about the states that are not currently participating in the demonstrations? More broadly, please tell me what CMS' over-arching strategy has been thus far to ensure that equal attention is paid to reforming the post-acute care delivery system?

I have also heard anecdotally from providers in my home state of Florida that CMS has not provided clear guidance to state entities on requirements for Medicaid long-term care proposals; for instance, one provider did not realize the extent of documentation needed showing partnership with the state's Medicaid program. Such confusion delays proactive ideas from the community related to innovation in the post-acute care space.

What steps can the agency take right now to provide guidance to state and local entities that may wish to develop demonstration projects in the Medicaid post-acute care space? Are you soliciting the involvement and perspective of long-term care providers regularly? How has the agency engaged the long-term care community more broadly?

Answer: We continue working with states, beneficiaries and advocates, providers and other stakeholders to provide efficient and quality long-term care. We continue to produce resources and develop technical assistance that will help nursing homes improve care through continuous attention to quality of care and quality of life. In addition, to provide efficient long-term care in the most integrated setting, we continue to work with states to provide home and community-based alternatives to institutional care. The Money Follows the Person Medicaid Demonstration helps states rebalance their long-term care systems to transition Medicaid beneficiaries from

institutions to the community. As part of this demonstration, states must establish procedures to provide quality assurance and improvement of home and community-based services. The Balancing Incentive Program is a Medicaid grant program that helps states transform their long-term care systems by reducing cost through improved systems performance and efficiency, creating tools to assist with care planning and assessment, and improving quality measurement and oversight. The Innovation Center's Initiative to Reduce Avoidable Hospitalizations Among Nursing Home Residents is working to help Medicare and Medicaid beneficiaries avoid disruptive hospital admissions by placing nurse care managers in nursing facilities. Additionally, states have the option to create health homes under the Medicaid state plan for individuals with chronic conditions. Health Homes integrate and coordinate all primary, acute, behavioral health, and long-term services and supports. As always, we encourage states to develop innovative ways to provide long-term care services and we will continue to work with states to implement state-specific Medicaid demonstrations to enhance their long-term care systems.

Question 5

Regarding Care planning/wellness (Alzheimer's): Just last week, the New England Journal of Medicine published a study by the RAND Corporation that the cost of Alzheimer's and dementia on our health care system was somewhere between \$157 and \$215 billion, with Medicare paying a portion of that cost.

Later this month, I will be holding a hearing in the Aging Committee on the first anniversary of the National Plan to Address Alzheimer's Disease. One of the issues we will be examining is the fact that the vast majority of people do not think about or plan for the long-term care they might need. This is particularly critical for people facing Alzheimer's and dementia because far too many people with Alzheimer's are not diagnosed until their symptoms have become severe, making it much more difficult and complex for them and their loved ones to plan for the future.

When confirmed, what will be your role and CMS's role in implementing the National Plan? What is CMS doing to link the public with both diagnostic and care planning tools?

What is the agency is doing to ensure timely access and coverage to new technologies for Alzheimer's disease as they become available, particularly diagnostic tools that can help individuals to get the care they need before it's too late?

What is CMS doing to ensure that seniors know that detection of cognitive impairment as part of the annual wellness visit?

Answer: CMS agrees that tackling Alzheimer's disease is a national priority. We are an active participant in the National Plan to Address Alzheimer's Disease, established by the Department of Health and Human Services (HHS) pursuant to the National Alzheimer's Project Act (NAPA) enacted in January 2011. The National Plan sets forth five goals, including the development of effective prevention and treatment approaches for Alzheimer's disease and related dementias by 2025. A National Alzheimer's Project Advisory Council (including a senior CMS representative) meets quarterly to discuss the efficacy of government programs in this area, and annually evaluates and updates the National Plan.

We are also actively engaged in reviewing new technology to ensure timely access to innovation for our beneficiaries. In October 2012, we opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans, which provided national coverage of PET using only specified radioisotopes for certain indications, and conditional coverage for additional uses under the process known as Coverage with Evidence Development (CED). Reconsideration of this NCD was requested by a stakeholder to consider coverage of PET using a new type of radiopharmaceutical approved by the FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline. To help inform this evidence review, we convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in January 2013. A proposed coverage decision is expected by July 2013, with a final decision (including consideration of public comments) expected by October 2013.

Finally, as you noted, an assessment of cognitive function is a required element of the new Annual Wellness Visit benefit established by the Affordable Care Act at no charge to beneficiaries. While this is still a relatively new benefit (beginning in 2011), over 3 million people with Original Medicare obtained an Annual Wellness Visit in 2012 (as well as additional beneficiaries in Medicare Advantage plans). CMS has undertaken a range of initiatives to educate providers and beneficiaries about the importance of prevention and Medicare coverage of preventive services including the Annual Wellness Visit.

Question 6

Regarding Medicare Part D: In the recent Medicare Call Letter there is an assertion that there is significant waste in part D in the mail order space. Can you please provide more information as to how CMS came to this conclusion?

Answer: The 2014 Call Letter instructs Part D plans sponsors that they should ensure that Medicare beneficiaries only receive new prescriptions and refills that they have requested, for coverage year 2014. To meet this objective, Part D sponsors should require their network retail and mail pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. CMS has received complaints that beneficiaries have had medications delivered that had been previously discontinued or were otherwise unwanted and unnecessary at the time of delivery. Once the prescription is delivered, pharmacies are unable to return the medication to stock and generally do not reverse the claim if the patient does not want the prescription. Consequently, automatic delivery practices are potentially generating significant waste and unnecessary additional costs for beneficiaries and the Part D program overall. We believe unintended waste and costs could be avoided if pharmacies confirmed with the patient that a refill, or new prescription received directly from the physician, should be delivered. Shipment of unwanted medications is not only wasteful, but also a source of significant beneficiary aggravation and a financial imposition that can negatively affect enrollee satisfaction with the plan. Supporting this idea, we received a number of comments that indicate beneficiaries return large quantities of unneeded medications to community pharmacies for take-back programs because they were unable to stop auto-ship refill programs.

Questions from Senator Casey

Question 1

Much of the work CMS does focuses on older citizens and people with disabilities. But there are several million children who receive care through CMS run programs. How do you see your role as Administrator in serving their needs? What innovative initiatives are you looking to undertake that are children focused?

Answer: Medicaid and the Children's Health Insurance Program (CHIP) provide health coverage to more than 43 million children, including half of all low-income children in the United States. One of CMS' most important missions is to ensure that these programs continue to provide high-quality care to children.

We have a number of initiatives and programs that focus on improving the health and healthcare outcomes for pediatric populations, including the Strong Start for Mothers and Newborns initiative. The Strong Start initiative is a project at the Center for Medicare and Medicaid Innovation (Innovation Center) focusing on reducing early elective deliveries and reducing the rate of preterm births among high-risk women in Medicaid and CHIP. Additionally, we have released the Initial Core Set of Child Health Care Quality Indicators for Medicaid and CHIP, established for voluntary use by state Medicaid and CHIP programs, which includes a range of children's quality measures encompassing both physical and mental health, including chronic conditions such as asthma and diabetes. CMS' Pediatric Quality Measures Program and the Pediatric Electronic Health Record Format also represent other initiatives the agency is pursuing to help improve the health and care children enrolled in our programs receive. Additionally, the Innovation Center is testing medical homes for individuals with disabilities and complex health conditions, high-risk chronically ill children, and individuals with breast, lung, or colorectal cancer.

As we do in all areas, we continue to look for opportunities to test promising models in the Medicaid program and understand the importance of delivering better, more efficient care to Medicaid beneficiaries. We are working closely with our colleagues at the Center for Medicare and CHIP services to coordinate our collective efforts to identify new opportunities.

Question 2

CMS does an outstanding job using its Medicare data to support studies on how to improve health care. However, as we all know Medicare is mostly older citizens while Medicaid covers one in three children nationally, making it the largest health care program for children. One of the issues I have heard over the past few years is how challenging the Medicaid data is due to the tremendous variation from state to state. What is CMS doing to try to improve the quality and usability of the Medicaid data to support research to improve children's health care?

Answer: While preparing for the future, CMS also continues to work on maintaining and improving the systems currently used to manage programs and monitor the quality of care provided to children in Medicaid and CHIP. CMS has several strategies focused on these goals. CMS is working to streamline several current Medicaid and CHIP data-collection and reporting

efforts through a unified data model. The two primary components of this model are: (1) the Medicaid and CHIP Program system, which will serve as the single repository for states to submit key programmatic information and the system of record for all state Medicaid and CHIP actions; and (2) the Transformed Medicaid Statistical Information System (T-MSIS), which is an expanded, streamlined MSIS, the claims-based system that serves as the primary data source to manage Medicaid and CHIP programs.

Other data and quality measurement efforts include the Initial Core Set of Child Health Quality Indicators for Children in Medicaid and CHIP. The majority of states are now reporting one or more of these quality measures, which encompass both physical and mental health, including chronic conditions such as asthma and diabetes. CMS continues to make improvements to the CHIP Annual Reporting Template System (CARTS), the vehicle states use to report the children's quality measures to CMS. These changes aim to both facilitate more accurate and complete reporting by states, and also reduce potential burdens associated with this reporting.

CMS has also made improvements to the Form CMS-416, the reporting tool used to assess the effectiveness of Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. CMS developed a set of criteria to flag data that raise concerns about the accuracy of the data submitted on the CMS-416 and has conducted a state-by-state audit of the data and worked with states where concerns were identified.

CMS expects that efforts to streamline, improve, or develop new information systems will help ensure that information is more accurate, complete, and uniform, having the potential to strengthen quality reporting for children, reduce health care costs associated with inefficiencies in the health care delivery system, and ultimately facilitate better health outcomes for children.

Question 3

One of the most challenging patient-care issues facing CMS is Alzheimer's Disease among Medicare and Medicaid beneficiaries. Last Congress, we enacted the National Alzheimer's Project Act (NAPA) and I want to commend the Department for moving quickly to develop a national plan.

Now we need CMS' help to allow beneficiaries and their caregivers to better understand, diagnose and treat Alzheimer's Disease. Can you tell me how your agency will ensure that the new diagnostic and therapeutic innovations, approved by the FDA, will be available to the beneficiaries?

Answer: CMS agrees that tackling Alzheimer's disease is a national priority. We are an active participant in the National Plan to Address Alzheimer's Disease, established by the Department of Health and Human Services (HHS) pursuant to the National Alzheimer's Project Act (NAPA) enacted in January 2011. The National Plan sets forth five goals, including the development of effective prevention and treatment approaches for Alzheimer's disease and related dementias by 2025. A National Alzheimer's Project Advisory Council (including a senior CMS representative) meets quarterly to discuss the efficacy of government programs in this area, and annually evaluates and updates the National Plan.

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Question 4

I have heard concerns from my constituents that some of the documentation requirements for the coverage of prostheses are causing problems for providers and that some beneficiaries are getting denied when auditors cite misunderstood documentation. I also understand that some of these new processes have begun without going through necessary procedures and some of the auditors do not have thorough guidelines to follow. While we all support necessary oversight and fraud prevention, can you please let me know what steps you are taking in conjunction with those processes to ensure beneficiaries are getting the care they need?

Answer: Medicare beneficiaries are receiving high quality prosthetics and orthotics that help them live active and healthy lives, and CMS continues to ensure they have access to appropriate prosthetics and orthotics. In 2011, the HHS Office of the Inspector General (OIG) released a report that found Medicare claims for lower limb prosthetics had a high improper payment rate. CMS is working to educate providers and suppliers on Medicare coverage and documentation requirements for lower limb prosthetics to reduce the improper payment rate. In addition, CMS is developing a clinical template in consultation with prosthetic and orthotic suppliers to assist providers in complying with Medicare coverage policies.

Question 5

The Administration has indicated its strong interest in taking action to repeal the SGR. The President's budget, for example, would replace the current Medicare physician payment system by instituting a period of stable payments for providers and then transitioning into new accountable payment models. What role could the Center for

Medicare and Medicaid Innovation play in the development of these models and how would the agency engage providers and payers in the process?

Answer: We are testing a variety of models that improve care quality, coordinate care, and reduce the total cost of care that may help inform reforms to physician payments.

For example, the Comprehensive Primary Care Initiative is a multi-payer initiative where CMS pays primary care providers monthly care management fees for comprehensive care management on top of their regular Medicare Fee-for Service payment. After two years, CMS offers the providers the chance to share in any savings they generate. Other payers, often including Medicaid, are also providing enhanced payment for primary care services.

Another model is the accountable care organization (ACO). In addition to the Medicare Shared Savings Program, we are testing the Pioneer ACO model and the Advance Payment ACO model. ACOs involve groups of doctors, hospitals, and providers that accept accountability for providing high quality coordinated care to Medicare beneficiaries. ACOs are eligible for shared savings and may be subject to losses.

Finally, the Bundled Payments for Care Improvement initiative is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. We think episode-based payment has the potential to transform the delivery system.

Question 6

Both the GAO and MedPAC have looked at the Medicare in-office ancillary services exception (IOASE), but neither has actually recommended repealing it. Yet, the President’s budget seeks to exclude certain services from the IOASE. The administration’s proposal would exclude “radiation therapy, therapy services, and advanced imaging from the in-office ancillary services exception to the prohibition against physician self-referrals (Stark law), except in cases where a practice meets certain accountability standards, as defined by the Secretary” and results in a savings of \$6.1 billion over 10 years. I have several questions about this proposed policy. First, why did the administration decide to exclude these services from the IOASE? Second, when OMB modeled this proposal, how did they define “accountability standards?” Third, could you please share the analysis and the data used to determine the \$6.1 billion savings?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer quick turnaround services. While there are many appropriate uses for this exception, certain services, such as advanced imaging and outpatient therapy, are rarely performed on the same day as the related physician office visit. For example, according to MedPAC’s 2010 annual report, MRI and CT services were performed on the same day as an office visit less than a quarter of the time, with only 8.4 percent of MRI scans of the brain being performed on the same day as an office visit. Additionally, evidence suggests that this exception may have resulted in overutilization and rapid growth of certain services. In a report released last September, GAO found that in 2010, providers who self-referred likely made 400,000 more referrals for advanced

imaging services than they would have if they were not self-referring. GAO found that these additional referrals cost Medicare about \$109 million.

Effective calendar year 2015, the President's proposal would seek to encourage more appropriate use of select services by excluding radiation therapy, therapy services, and advanced imaging from the in-office ancillary services exception the prohibition against physician self-referrals (Stark law), except in cases where a practice meets certain accountability standards, as defined by the Secretary.

Questions from Senator Grassley

Question 1

Background: You sent a letter to CMS in 2011 asking about its policies on communicating with the political intelligence community. CMS replied a month later saying it did not track meetings with political intelligence firms. However, CMS does have policies in place concerning the dissemination of information to the public.

On April 4, 2013, the WSJ reported that Height Securities successfully predicted CMS's policy decision on MA plans. Height Securities sent out an alert to clients at 3:42 pm successfully predicting CMS's policy decision on MA. This had major consequences on the market.

You sent a letter on April 4, 2013, asking CMS who they told this information to prior to publicly releasing the information. This question follows up on your most recent letter to CMS.

Lead-In: Ms. Tavenner, I have been impressed with you in our meetings. I think you would make a fine Administrator and want to be able to support your confirmation. But we have a problem here.

On Monday, April 1, 2013, at 3:42 p.m., Height Securities sent an advisory that told their clients of the CMS Medicare Advantage policy decision and that they supported related stocks.

The consequence of a political intelligence firm having access to this information 18 minutes before the market closed was astonishing.

In the 18 remaining trading minutes on April 1, the volume of Humana, UnitedHealthGroup, and Aetna's stock was more than a half BILLION dollars! More stock in those companies was traded in those 18 minutes than throughout the rest of the day. When information leaks from the Administration that has the ability to cause significant market movement, it is wrong and quite possibly illegal.

I sent a letter last Thursday formally seeking specific information from you. Ultimately you are responsible here.

What you are doing to hold someone accountable for this leak?

Answer: I share your concern with the news that an outside entity issued an advisory about the 2014 Medicare Advantage rates before CMS announced the rates. Given the seriousness of the issue, the HHS Acting General Counsel has referred the matter to the HHS Office of Inspector General. As you know, the IG has the investigative expertise to request and review relevant agency documents and to conduct any interviews with agency personnel that it deems necessary.

I am committed to ensuring that CMS safeguards confidential and non-public information and intend to use the results of the OIG investigation to improve our processes as appropriate. I appreciate what you have done in this area and look forward to working with you to safeguard sensitive government information.

Question 2

IF TAVENNER SAYS THAT SHE DOES NOT KNOW WHO THE LEAK WAS AND THAT IT WASN'T CMS AND THEY ARE CONDUCTING THEIR OWN INVESTIGATION.

Thank you, Ms. Tavenner. I appreciate that you have started an investigation of your own. For it to be credible, you need to be including the Health and Human Services, Office of Inspector General. I'd be curious what authority your investigation has to compel the production of information within CMS. I'd be even more curious what authority your investigation has to compel the production of information at HHS, OMB or the White House.

But how about his ... why don't we work together?

You can speak softly and I will bring a big stick.

I don't believe you can get to folks at HHS or OMB or the White House without help. The sooner we figure out where the leak is, the sooner we can get you confirmed.

Question 3

Last year, CMS suspended implementation of the Quality Indicator Survey (QIS) for nursing homes. Why did CMS suspend implementation of the QIS? When will CMS resume implementation? How long do you expect it will take CMS to complete QIS training in every state? How do you plan to avoid similar complications or any other problems that would prevent a quick transition to the new survey system?

Answer: CMS temporarily suspended implementation of the QIS based on feedback from states and regions about some hardware and software issues that could impact time on surveys or survey effectiveness. In addition, survey time for the QIS States has tended to exceed the survey time required for the traditional survey. This will require some redesign of the QIS survey before we can enable expansion to additional States within the available survey budget. We determined that addressing and resolving these issues before further implementation would facilitate a more effective computer-assisted survey process.

CMS has already begun to bring on a few additional states through partnerships with states that have already successfully implemented QIS. We are evaluating the ability to bring on each new

state and are also looking at a multi-year strategy for completing the transition to QIS in all states. While we continue to address issues related to hardware, software, and survey time required for the QIS survey are resolved, CMS will continue to take a very deliberate approach to expanding QIS to additional states.

We anticipate that completing QIS training in all states will take several years, especially in the largest states. CMS is also exploring new training strategies such as regional and state-based training models with reduced time to competency.

Question 4

Last year, CMS promoted an initiative to address overutilization of antipsychotics in nursing homes. The stated goal of the initiative was to reduce antipsychotic use 15 percent by the end of 2012. Early projections indicate the initiative yielded an underwhelming four percent decrease. What caused the initiative to fall so short of its goal? Do you plan to continue the initiative this year? If yes, what are the goals for 2013 and what will CMS do to meet those goals?

Answer: The Partnership to Improve Dementia Care is a national partnership to improve dementia care and optimize behavioral health for nursing home patients. By improving dementia care and person-centered interventions for behavioral health in nursing homes, this collaboration between federal and state partners, providers, advocacy groups, and caregivers set an ambitious goal; to reduce the national prevalence rate of antipsychotic medication use in nursing home residents by 15 percent by the end of 2012.

Partners used strategies such as enhanced training, increased transparency, and alternatives to antipsychotic medication to work toward this goal. In addition, to address this challenge in the long-term CMS is conducting research to better understand the decision to use antipsychotic drugs in residents with dementia. Findings will be used to target and implement approaches to improve the overall management of residents with dementia, including reducing the use of antipsychotic drugs in this population.

Early indications suggest that we are nearly halfway to our initial, ambitious goal. Additionally, partner reported data indicates that three states have met or exceeded the 15 percent goal. Given the short amount of time the Partnership has been working, we consider this reduction a modest success. We also have data that suggests this rate of reduction may be increasing; more states and regions have become partners and are implementing changes. CMS believes that this initiative is facilitating changes that will be sustainable over time, and we will continue efforts to reduce the use of unnecessary antipsychotic medication in nursing homes. We intend to continue the National Partnership and believe that we will reach the goal of 15 percent reduction in the national prevalence rate in 2013.

Question 5

Accurate information about staffing levels is one of the most important quality indicators to measure nursing home quality. The current collection method allows nursing homes to self-report staffing data which has proven to be terribly unreliable. The Affordable Care Act required CMS to start collecting staffing data from payroll records, agency contracts,

and cost reports. The deadline to implement this requirement was March 2012. Why has CMS still failed to implement this important reform? What has CMS done to move toward this new data collection method and when will it be fully implemented?

Answer: As part of a long-term plan to increase the accuracy and comprehensiveness of staffing data, CMS has been evaluating the use of payroll data as a basis for the information on Nursing Home Compare. Payroll data can be used to calculate measures of staff turnover and staff retention in addition to supporting more accurate calculation of the staffing measures currently posted. A two phase field study of the feasibility of collecting payroll data was completed. The first phase involved interviewing nursing homes, nursing home corporations, and payroll vendors. The second phase included providing data specifications to a sample of facilities to determine their capacity to generate and submit data. This second phase was achieved through a payroll-based staffing reporting pilot program in approximately 100 nursing homes in June 2012. This pilot program ended in December 2012 and yielded a great amount of complex data. As we analyze the results of the pilot project, we will work to determine the amount of resources needed to continue implementing this provision of the Affordable Care Act.

Questions from Senator Crapo

Question 1

Regarding Ambulatory Surgical Centers - In a recent article in TIME Magazine called “A Bitter Pill: Why Medical Bills Are Killing Us.” One of the conclusions of the increase in Medicare payments is the lack of competition and too much consolidate among hospitals in the nation. I have historically been an advocate of choices and competition in the healthcare marketplace. Unfortunately, there is a growing trend of physician practices, Ambulatory Surgical Centers, oncology centers and other providers being purchased by hospitals. In April, I requested data, with several of my colleagues on the impact that these purchases/conversions had on ASCs. I received a final answer in September. Is there something that Congress needs to do to provide CMS with greater statutory authority to measure how these changes are impacting costs in the Medicare program?

Answer: We are aware that hospital acquisitions of other health care entities such as physician practices have been commonplace in the last few years. One of the ways that we are encouraging competition in hospital markets is through the operation of the Medicare accountable care organizations (ACOs). We 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.

CMS is providing aggregate claims data to the antitrust agencies to assist them in their monitoring efforts to ensure ACO formation and implementation does not have a detrimental effect upon competition. The antitrust agencies have existing enforcement processes for evaluating concerns raised about an ACO’s formation or conduct. In addition, we believe the testing of the Advance Payment ACO model had led to increased participation by smaller

organizations in the Medicare Shared Savings Program, thus increasing competition. I would be happy to work with you and your staff on how we can improve on these efforts.

We also understand the published fiscal year 2012 Work Plan for the Department of Health and Human Services Office of Inspector General (OIG) includes work related to ASCs. Specifically, they plan to do an ASC payment analysis and also relayed an interest in looking into hospital acquisitions of ASCs. We look forward to the OIG findings and recommendations.

Question 2

Medicare Part D - In its 2014 Call Letter, CMS identified potential issues with preferred networks in the Part D program. Specifically, CMS expressed concern that preferred networks may be costing the Medicare program more than open networks, and beneficiary access to care may be threatened especially in rural areas. This is worrisome to me because the Part D program was made to drive down costs to the system and ensure more choice and access to beneficiaries and has been delivering on this goal so far.

Can you tell me what potential issues CMS has identified with preferred networks and what CMS plans to do to make sure that preferred networks in Medicare Part D plans are not hindering beneficiary access to their prescriptions and are following their current goal of decreasing costs in the Part D program?

Answer: Part D regulations that permit lower cost sharing at some “preferred” network pharmacies also require that such cost sharing reductions must not increase CMS payments. In order to ensure that Part D sponsors with preferred pharmacy networks are meeting this requirement, we have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks. Our initial results suggest that for some plans, aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks. Combined with lower cost sharing, we are concerned that these higher unit costs may violate the requirement not to increase payments to such plans. We have contacted the plan sponsors identified in our analysis to initiate the validation of our findings.

As we indicated in the 2014 Call Letter issued April 1, we strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to ensure that such networks promote price competition and lower costs in the Part D program. Opening preferred pharmacy networks to any pharmacy that can meet the network’s terms and conditions would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas. Extending this policy to all Part D sponsors would require rulemaking by CMS. We welcome your ideas to ensure that the Part D program remains strong.

Question 3

Regarding Patient Protections- Non-Discrimination Rule - In Round 1 of CBP, suppliers limited the range of products offered to Medicare beneficiaries. CMS anticipated this problem in the CBP and established a rule that requires, “The items furnished by a

contract supplier...must be the same items that the contract supplier makes available to other customers.” CMS reasoned, One of the main objectives of the Medicare DMEPOS Competitive Bidding Program is to ensure that beneficiaries have access to quality DMEPOS. Therefore, we have built safeguards into the competitive bidding program to ensure there is continued access to quality medical equipment and supplies. We believe the nondiscrimination clause will ensure that Medicare beneficiaries have access to the same items as other as individuals.

CMS wanted to ensure that Medicare beneficiaries receive the same items that the contract supplier would furnish to other customers.

Given that Congress extended the CBP single payment amount to retail settings, retailers will now have the same financial incentives to limit the range of diabetes testing supplies available. A group of stakeholders recently asked CMS to extend these patient protections to the retail channel, and CMS responded that it would monitor implementation to see if these protections prove to be necessary. If CMS felt that these protections were necessary to protect beneficiaries in anticipation of the CBP in mail order contexts, why does the agency not think that these same protections will be necessary in retail settings? Why wait and monitor?

Answer: Retail pharmacies do not have the same incentives to provide certain items as mail-order contract suppliers. We note that retail pharmacies do not have to bill Medicare on an assignment-related basis, while mail-order contract suppliers do, and therefore can charge customers more than the Medicare-approved amount for diabetic test strips (which is commonly referred to as balance billing). Notice and comment rulemaking was required to include the non-discrimination requirement as a term of the contract for suppliers under the national mail-order program for diabetic testing supplies. CMS will be closely monitoring access to necessary diabetic supplies following implementation of the new payment amounts, but we do not believe it is necessary to initiate rulemaking for the retail setting at this time.

Questions from Senator Isakson

Question 1

The Patient Protection and Affordable Care Act reduces Medicare spending by \$750 billion over the next 10 years to pay for new health care programs. One of the largest of the law’s Medicare cuts is a “productivity adjustment” that reduces the annual inflation updates to provider reimbursements. These productivity adjustments will have a compounding effect over time, and when the law was passed, the CMS Office of the Actuary projected that they would cause about 15 percent of hospitals, skilled nursing facilities, hospices, and other Part A providers to become unprofitable within the next 10 years. I am concerned that this may have an especially severe impact on rural areas, where providers are less able to shift costs to patients with private insurance. Already this year, two rural hospitals in my state have been forced to close their doors and have cited reimbursement cuts as a major factor. Do you believe your actuaries’ projection is accurate? What are you doing to monitor the impact of these cuts and how will you act to prevent Medicare beneficiaries from losing access to care when their local providers close down?

Answer: The Affordable Care Act includes a number of important delivery system reforms that will enable Americans to get better care at lower costs and will help the health care system operate more efficiently. We continue to carefully monitor access to services, and to date, access to services remains strong. Hospitals will also benefit from the insurance coverage expansions in the Affordable Care Act, adding new sources of revenues for most health care providers. Furthermore, a number of provisions in the Affordable Care Act designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and providers in underserved areas and investments in health professional training programs to increase supply. We will continue to carefully monitor access to ensure our policies continue to lower costs while maintaining access to quality services.

Question 2

I appreciate the work you and CMS have been doing to move the Medicare payment system away from silos and toward rewarding high-value care. One area where I've been concerned that current payment policies do not support the provision of the right care in the right setting is the lack of coverage for infusion therapies that can be provided in the home setting. In many cases, receiving infusion treatment at home is clinically appropriate and has the potential to reduce costs as well as preventing hospital acquired infections. Many private payers provide coverage for home infusion and have achieved positive results, but Medicare still lacks coverage for many of the services and supplies associated with home infusion. Would you agree that we ought to explore Medicare coverage for home infusion therapy to ensure that seniors and people with disabilities have access to this life-preserving treatment in whatever setting is most clinically appropriate and convenient for them?

Answer: We agree that it is important that seniors and people with disabilities have access to life-preserving treatment in the most clinically appropriate setting. Medicare covers certain items and services for home infusion therapy. Generally, infusion pumps, as well as drugs and other supplies necessary for the effective use of the infusion pumps, are covered under the durable medical equipment (DME) benefit under Medicare Part B for treatment of certain conditions. In addition, the services of a home health nurse required to administer the medications safely and effectively may be covered under the home health benefit for those who qualify for home health services, provided the services are reasonable and necessary to the treatment of the illness or injury. Home infusion supplies are covered under the home health benefit, only when related to "gravity" infusion. Beneficiaries who do not qualify for home health services have access to these services and supplies in hospitals, outpatient departments, and physician offices. Infusion drugs are also covered for those enrolled in the Part D benefit. The Part D plan is responsible for ensuring that beneficiaries have the necessary services and supplies for home infusion therapy before dispensing the infusion drugs.

Medicare does not have a distinct home infusion benefit. Adding a home infusion benefit to the Medicare program would require a statutory change. In the recently enacted, "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayer Act of 2012," CMS is required to establish and implement a demonstration project under Medicare Part B to evaluate the benefits of providing payment for items and services needed for the in-home administration of

intravenous immune globin. This demonstration project may provide insight into the benefits of a Medicare home infusion therapy benefit.

Question 3

Children with complex medical conditions represent approximately five percent of the children enrolled in Medicaid, but account for about 45 percent of Medicaid spending on children. Medicaid is critical to this population, but often our current system leaves them with fragmented care that does not work for them. How do you envision CMS will approach improving care coordination for children with complex medical needs and how will CMS partner with stakeholders as it addresses the needs of this population in Medicaid?

Answer: CMS is working with state Medicaid programs to test medical homes for individuals with disabilities and complex health conditions, including high-risk chronically ill children. These Health Homes will operate under a “whole-person” philosophy to integrate and coordinate all primary, acute, behavioral health, and long-term services and supports to treat the whole person. Some of the Innovation Challenge Awards are also testing new ways to better care for such children, such as extending the skills available at a children’s hospital to communities to care for children with chronic illness like asthma.

Additionally, CMS has released the Initial Core Set of Child Health Care Quality Indicators for Medicaid and CHIP, established for voluntary use by state Medicaid and CHIP programs, which includes a range of children’s quality measures encompassing both physical and mental health, including chronic conditions such as asthma and diabetes. CMS’ Pediatric Quality Measures Program and the Pediatric Electronic Health Record Format also represent other initiatives the agency is pursuing to help improve the health and care children enrolled in our programs receive.

Question 4

At a February 14 hearing before the Senate Finance Committee, I asked CCIIO Director Gary Cohen about the Administration’s preparations for transitioning enrollees in the Pre-existing Condition Insurance Plan (PCIP) to coverage through the exchanges. Public health officials in my state have been concerned about the lack of a clear plan for ensuring continuous care for these vulnerable patients. I was somewhat disturbed that while Mr. Cohen did not answer my question about whether the Administration expected to cut off enrollment in federally-run PCIPs, CMS announced the following day that new enrollment would be cut off effective immediately. In a subsequent conversation with my staff, CMS staff acknowledged that they will need to issue additional guidance regarding the “handoff” of enrollees from PCIP to federal exchanges, but could not provide any information about when this guidance might be issued. When will CMS issue detailed guidance on how you plan to transition enrollees from PCIPs to federally facilitated exchange coverage? Also, what is CMS’s contingency plan in the event that PCIP funding runs out before exchanges are ready for enrollment?

Answer: Open enrollment for plans in the new Marketplaces begins October 1, 2013, for coverage beginning January 1, 2014, which generally coincides with the statutory end of the PCIP program. To help effectively transition PCIP members who wish to enroll in a qualified

health plan offered through the new Marketplaces, we are working with our PCIP contractors to ensure enrollees in both state-based PCIPs and the federally-administered program receive information about the new Marketplace. Specifically, we are developing three notices that will be sent to enrollees in federally-administered PCIP over the next several months explaining that PCIP coverage ends after December 31, 2013, describing the Marketplaces, how to enroll in coverage, and where enrollees can get assistance with enrolling in coverage. Additionally, we have directed our contractors to update their PCIP websites with transition content, train customer service representatives, and provide adequate staffing at their call centers during the last quarter of calendar year 2013 and the first quarter of calendar year 2014 to handle anticipated calls from transitioning enrollees. CMS is aggressively managing costs in the federal PCIP program and has taken a variety of steps to ensure that the limited funds provided by the Affordable Care Act are applied efficiently in funding patient care and program administration. These include a change in provider networks used by the federally-administered PCIP, reducing both its negotiated and out-of-network payment rate for providers; negotiation of additional discounts on reimbursement rates with targeted hospitals that were treating a disproportionate number of PCIP enrollees; limiting the specialty drug benefit to provide coverage only if the specialty drug is dispensed by an in-network pharmacy, and; consolidation of three benefit plan options into one, increasing the maximum out-of-pocket limit from \$4,000 to \$6,250 for in-network services.

Question 5

Over 5 million people in the United States have Alzheimer’s disease. Getting a clear and early diagnosis is an important part of addressing this disease. Leading experts, including HHS’s own Alzheimer’s website, stress the value of a timely and accurate diagnosis of Alzheimer’s disease. Early diagnosis allows families to better plan for the course of the disease and caregiving needs, and it allows patients and medical experts to explore various treatments that may be able to help delay or mitigate symptoms associated with Alzheimer’s. Diagnosing Alzheimer’s has long been a challenge for the medical community, but new technologies are emerging that can help determine whether memory problems are resulting from Alzheimer’s or another condition. What will you do to ensure that Medicare beneficiaries have appropriate and timely access to these diagnostic tools and other new innovations as they are approved by FDA?

Answer: CMS agrees that tackling Alzheimer’s disease is a national priority. We are an active participant in the National Plan to Address Alzheimer’s Disease, established by the Department of Health and Human Services (HHS) pursuant to the National Alzheimer’s Project Act (NAPA) enacted in January 2011. The National Plan sets forth five goals, including the development of effective prevention and treatment approaches for Alzheimer’s disease and related dementias by 2025. A National Alzheimer’s Project Advisory Council (including a senior CMS representative) meets quarterly to discuss the efficacy of government programs in this area, and annually evaluates and updates the National Plan.

We are also actively engaged in reviewing new technology to ensure timely access to innovation for our beneficiaries. In October 2012, we opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans, which provided national coverage of PET using

only specified radioisotopes for certain indications, and conditional coverage for additional uses under the process known as Coverage with Evidence Development (CED). Reconsideration of this NCD was requested by a stakeholder to consider coverage of PET using a new type of radiopharmaceutical approved by the FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline. To help inform this evidence review, we convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in January 2013. A proposed coverage decision is expected by July 2013, with a final decision (including consideration of public comments) expected by October 2013.

Question 6

Hospitals in my state have raised a number of concerns about Medicare's Recovery Audit Contractor (RAC) program, arguing that compliance with RAC audits is a severe burden on both their finances and time, and that the vast majority of RAC denials are overturned on appeal. The RACs maintain that they are working to safeguard the Medicare Trust Fund by correcting improper payments, and that only a small percentage of their recoveries are overturned. Given your background as a hospital administrator, I would be interested to hear your personal views on how this program is working. What, if any, steps is CMS taking to ensure that there is an adequate balance between protecting the Trust Fund and avoiding an undue burden on health care providers who are trying in good faith to comply with the law? To the extent that a significant number of RAC denials are being overturned, especially at the Administrative Law Judge level, are there structural changes that could be made to the program to improve consistency and sharpen the focus on truly improper payments?

Answer: Recovery Audit Contractors are an important tool in reducing improper payments and recovering overpayments. CMS is sensitive to the concerns of hospitals and suppliers, and continues to work with these communities to reduce the burden of the Recovery Audit review process. CMS has undertaken several efforts to help reduce provider burden. These include imposing additional limits on the number of medical records a Recovery Auditor may request, ensuring claims are not being reviewed by multiple Medicare entities, and allowing providers to send medical documentation electronically to Recovery Auditors. CMS understands that additional staffing is often required to address Recovery Auditor documentation request and we are constantly working to ensure providers can respond to requests without compromising beneficiary care.

CMS also strives to reduce the appeal rate to decrease provider burden and administrative costs. Recovery Auditors are required to return any contingency fee if an improper payment is overturned on appeal, which creates an incentive to make accurate improper payment determinations. In FY 2011, 2.9 percent of all Recovery Auditor determinations were overturned on appeal. In addition, Recovery Auditors are subject to performance evaluations that hold them accountable for activities such as timely reviews of audits.

Question 7

The Patient Protection and Affordable Care Act included several incentive programs for primary care physicians. While I agree that we need to increase the primary care

workforce, I have heard concerns from some physician groups that these incentive programs do not adequately account for the need for cognitive care specialists, such as neurologists and rheumatologists. These specialists primarily bill Medicare under evaluation and management (E&M) codes, rather than procedural codes, and are not as highly compensated as the procedural specialties. However, they are ineligible for incentive programs that are specifically targeted to primary care. The March 2013 report of the National Commission on Physician Payment Reform, chaired by former Senate Majority Leader Bill Frist, recommended that physician payment reform should differentiate between E&M codes and procedural codes, rather than between primary care physicians and specialists. Would you agree that efforts to strengthen the primary care workforce should also include cognitive specialties that are similarly facing workforce shortages?

Answer: Ensuring that beneficiaries of our programs have access to providers to furnish the care they need is important. We support efforts to strengthen the health care workforce that provide the full range of services that a beneficiary needs including the services of cognitive specialties. We recognize that a range of responses is needed to address workforce shortages in various geographic areas and among different specialists. I look forward to working with you to continue to develop and implement measures to address this issue.

Question 8

Round 2 of the durable medical equipment competitive bidding program is set to take effect on July 1 in 91 metropolitan areas across the country, including Atlanta and Augusta. Suppliers in my state are very concerned about the sustainability of this program in its current form. I have heard anecdotal accounts of companies winning bids despite having no presence in the local region and no demonstrated ability to supply the type of medical equipment for which they were bidding. Some winning bidders appear to be desperately trying to find existing suppliers to subcontract, or even sell their business. Also, due to the “median price” structure employed by CMS, some suppliers report being offered contracts at prices significantly below their bids. If these suppliers determine they cannot accept the offered price, it is unclear to me how Medicare plans to ensure that there is adequate capacity to supply beneficiaries in these markets. What specific mechanisms are you putting in place to ensure that any access issues arising in Round 2 regions are promptly identified, and how will identified problems be corrected? What steps are you taking to monitor and verify the quality of DME supplies under competitive bidding?

Answer: CMS is confident that the Round 2 and national mail-order program single payment amounts provide appropriate payment for the equipment, supplies and related services. All bidders are evaluated to ensure that they meet all applicable state licensure requirements, financial standards, quality standards and accreditation requirements, and other program requirements. All bids submitted under the program are screened and evaluated to ensure that they are bona fide. CMS selects more than enough qualified suppliers to meet beneficiary demand for each product category in each area.

In addition, CMS has implemented a robust monitoring program to track and resolve any issues that might occur with program implementation. To date, the program has maintained beneficiary access to quality products from accredited suppliers in the Round 1 Rebid areas. Extensive real-

time monitoring data have shown successful implementation with very few beneficiary complaints and no negative impact on beneficiary health status based on measures such as hospitalizations, length of hospital stay, and number of emergency room visits compared to non-competitive bidding areas. In addition to our real-time claims monitoring, CMS also requested feedback from beneficiaries through consumer satisfaction surveys conducted before and after the rollout of the program. CMS provides a local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen, who closely monitor implementation of the program. There is also a formal complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues. In addition, contract suppliers are responsible for submitting quarterly reports identifying the brands of products they furnish, which is used to inform beneficiaries, caregivers, and referral agents. Finally, CMS has appointed a Competitive Acquisition Ombudsman who responds to complaints and inquiries from beneficiaries and suppliers about the application of the program and issues an annual Report to Congress. CMS will employ the same aggressive monitoring program for the competitive bidding areas added in Round 2.

And to the extent an issue arises, CMS will act promptly to address it. If a supplier does not meet its contractual obligation, CMS may take one or more of the following actions: require the contract supplier to submit a corrective action plan; suspend the contract supplier's contract; terminate the contract; preclude the contract supplier from participating in the competitive bidding program; revoke the supplier's billing privileges; or impose other remedies allowed by law.

With regard to the quality of supplies, Medicare requires that all suppliers in the program meet applicable state licensure requirements, meet strict quality and business standards, and be accredited by a national accreditation organization. Quality product-specific service standards include intake, delivery and setup, training and instruction of the beneficiary and/or their caregiver, and follow-up service. Business standards focus on administration, financial management, human resource management, consumer services, performance management, product safety, and information management. The quality standards ensure that Medicare beneficiaries only receive products as ordered by their physician. Products must meet applicable quality standards and be provided by qualified professionals.

The program includes an anti-discrimination policy, meaning that suppliers have to offer their Medicare beneficiaries the same products they offer their other customers. This applies to all product categories.

All items furnished under the competitive bidding program must meet applicable Food and Drug Administration requirements, including regulation and medical device effectiveness and safety standards. CMS believes beneficiaries are receiving quality items under the competitive bidding program because the agency has received few inquiries and complaints about the program and because the real-time monitoring shows that there have been no changes in beneficiary health status outcomes resulting from the competitive bidding program.

Question 9

CMS recently responded to a letter that I sent along with Senator Chambliss regarding CY 2013 changes in Medicare reimbursement for proton beam therapy. Emory University is currently developing the Georgia Proton Therapy Center, a state-of-the-art facility that will bring this life-saving treatment to residents of Georgia. In the response to our letter, CMS stated that “we did not exclude the purportedly aberrant data in setting the final CY 2013 payment rates for these services.” I continue to have serious concerns with CMS’s action because it is my understanding that only three hospitals submitted cost report data with respect to this therapy, and one of them subsequently identified an error in the initial data submission and provided corrected data. Does CMS have any process for addressing errors of this nature, particularly in cases like this where one entity’s cost report can have a significant impact on the aggregate data? Will you commit to working with us to ensure that this erroneous data is not perpetuated in future rate setting processes?

Answer: We understand your concern that payment for these proton beam therapy services be accurate in order to provide these services to Medicare beneficiaries. Because few hospitals bill Medicare for proton beam therapy, and because we rely on the data submitted to us by hospitals in setting annual hospital outpatient prospective payment system (OPPS) rates based on our standard OPPS rate setting methodology, the payments for these services may vary over time.

Each year, CMS updates payment rates using claims and cost report data reported by hospitals that pass edits and are paid through our claims processing system. An integral part of this process is our reliance on hospitals to code claims accurately and to submit accurate cost report information on a timely basis. CMS will update the OPPS payment rates this year for the CY 2014 rates, once again using the most recently available claims and cost report data submitted by hospitals and relying on hospitals to ensure accuracy of the data submitted.

Question 10

Section 644 of the American Taxpayer Relief Act of 2012 rescinded most unobligated funds for the Consumer Operated and Oriented Plan (CO-OP) Program. It also created a reserve fund of approximately \$190 million to provide “assistance and oversight” to health insurance issuers who had already received loans or grants under the program. I was recently contacted by an organization in my state that had applied for CO-OP funding. Since they did not receive an award prior to the end of 2012, they understand that they will not be eligible to receive start-up funding. However, they noted that CMS’s original funding announcement stated that applicants could receive up to \$100,000 to cover the cost of preparing a feasibility study and business plan. Since they had already incurred this cost prior to the rescission, they are trying to determine whether they can still obtain reimbursement for these expenses and have not been able to get an answer from CMS on this question. Could you look into this issue and determine whether CMS has the authority to provide this limited reimbursement for already-incurred expenses from the CO-OP contingency fund?

Answer: The CO-OP Funding Opportunity Announcement noted that costs up to a total amount of \$100,000 for preparing the feasibility study and business plan required with the application was considered an eligible cost for the Start-Up Loans. Loans for these costs were only provided to successful applicants who were awarded Start-Up Loans.

As you know, the American Taxpayer Relief Act of 2012 (Pub. L. 112-240) transfers 10 percent of the unobligated balance of funds appropriated by section 1322(g) of the Affordable Care Act to a new CO-OP contingency fund and rescinds the remaining 90 percent of the unobligated funds. Due to this change in statute, CMS no longer has the authority to make loan awards to new borrowers or enter into loan agreements with new borrowers. As a result, CMS denied all applicants who did not have loan agreements in place by December 31, 2012 deadline.

Questions from Senator Enzi

Question 1

The Medicare Trustees concluded in their 2012 report that the Medicare Advantage cuts included in the health care reform law would result in a 10 percentage point drop in enrollment in the program due to the increased premiums and reductions in benefits that would result. What is the updated estimated impact on Medicare Advantage premiums and benefits by the CMS Office of the Actuary on the combined impact of the Medicare cuts in the health reform law on Medicare Advantage and the health insurance tax?

Answer: The Medicare Advantage (MA) program remains a strong and viable option for Medicare beneficiaries. MA premiums for 2013 are stable, increasing less than a \$1.50 from last year and as of February 2013; total MA enrollment is 14.5 million, up from 13.1 million in 2012, an increase of 11 percent. Beneficiary access to the MA program also remains strong, with 99.6 percent of beneficiaries having access to a MA plan.

The number of non-employer MA plans for 2013 is 2,704, up from 2,532 in 2012, a 7 percent increase. The average number of MA plans available in a county increased to 28 plans in 2013 compared to 26 plans in 2012.

The 2013 Trustees Report will provide updated enrollment and other information regarding the Medicare Advantage program.

Question 2

In the recently released Call Letter for the 2014 plan year CMS identified concerns it had with the use of preferred pharmacy networks in the Medicare Part D program, particularly the potential for beneficiary disruption and travel costs, especially in rural areas. CMS also indicated it was concerned that the structure of some preferred networks may actually be increasing costs for the Medicare program.

As the use of these networks has become more widespread in recent years and is expected to continue to grow, what actions has CMS taken, or does CMS plan to take, to ensure that the use of preferred pharmacy networks in the Medicare Part D program does not affect beneficiary access and health, lessen quality of care or increase costs to the Medicare program?

Answer: Part D regulations that permit lower cost sharing at some “preferred” network pharmacies also require that such cost sharing reductions must not increase CMS payments. In order to ensure that Part D sponsors with preferred pharmacy networks are meeting this requirement, we have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks. Our initial results suggest that for some plans, aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks. Combined with lower cost sharing, we are concerned that these higher unit costs may violate the requirement not to increase payments to such plans. We have contacted the plan sponsors identified in our analysis to initiate the validation of our findings.

As we indicated in the 2014 Call Letter issued April 1, we strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to ensure that such networks promote price competition and lower costs in the Part D program. Opening preferred pharmacy networks to any pharmacy that can meet the network’s terms and conditions would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas. Mandating this policy for all Part D sponsors would require rulemaking by CMS. We welcome your ideas to ensure that the Part D program remains strong.

Question 3

The OIG recently released a report stating that gaps exist in CMS’s oversight of the Medicare Plan Finder reporting requirements. How is CMS ensuring that beneficiaries have access to all of the information they need about specific plan benefits, including whether or not a plan uses a preferred pharmacy network and which pharmacies are included in those networks?

Answer: The Medicare Plan Finder continues to be refined to make sure that it provides the most accurate information possible. As of April 2012, a beneficiary is now able to see drug price estimates that reflect if the pharmacy selected is preferred or non-preferred for a given plan. If a pharmacy is not in the selected plan’s network, the full price of the drug is shown. Concerns about the Medicare Plan Finder being time-consuming may be a reflection of the increased number of inputs needed to generate an accurate cost estimate. Having the Medicare Plan Finder prompt the user for exact drug names, quantity and dosing regimen, Part D plan, subsidy eligibility, and choice of pharmacy provides beneficiaries access to highly valuable information, to help select the best coverage option and to anticipate medical expenses for the coming year.

Question 4

We have heard significant concerns from the kidney care community that patient access to dialysis care could be disrupted if Medicare payments for End-Stage-Renal-Disease (ESRD) are not properly designed and implemented. I share these concerns, especially as they relate to patients in rural or underserved areas, and would appreciate your attention to this issue. Will you commit to working with me and my staff to ensure that the comprehensive ESRD bundled rate is adjusted fairly without harming patient access and quality of care?

Answer: We agree with the importance of appropriate payments to ensure access to dialysis treatment for ESRD beneficiaries. Section 632 of the American Taxpayers Relief Act of 2012 requires that the ESRD prospective payment system (PPS) rate be reduced beginning in 2014 to reflect the change in utilization of drugs and biological from 2007 with 2012. Before we make any changes to the ESRD PPS rate, we will carefully analyze the data on utilization and include the proposed payment change based on the data in a proposed rule for public comment. We will review comments taking into consideration issues raised by stakeholders to ensure that beneficiaries continue to have access to the medications they need before we make a final decision on the payment change. I welcome your input to help us ensure that payments are adequate and appropriate in the Medicare ESRD program.

Question 5

The 2006 IOM report on the Quality Improvement Organization (QIO) program stated that the QIOs should remain state-based and that if CMS did not have such a local field force to work on quality improvement, it would have to create it. Do you believe that any efforts to regionalize the QIO program directly contradict those findings by IOM?

Answer: As we make plans to determine how to structure the QIO program in the 11th SOW, we are keenly aware of the recommendations made in the 2006 IOM report on Medicare's Quality Improvement Organization Program. This was a comprehensive and extensive study with multiple recommendations, among them that the QIO program should be updated and focus more on technical assistance for performance measurements and improvement. Many of the recommendations have already been incorporated into the structure of the program in recent years, and the added flexibility of the Trade Adjustment Assistance Extension act of 2011 provides an opportunity to incorporate enhancements that will allow us to achieve large scale improvements in health care quality.

CMS is committed to the continued involvement of local physicians working in a community with their peers. We agree that improvements in health care occur at the local level and that this involvement is essential in many of the QIO improvement projects. While local access will be maintained, some quality improvement activities may be carried out more effectively under a modified structure that takes advantage of the most highly experienced and expert quality improvement entities in a region.

Question 6

The federal government has invested considerable resources over the last three decades in the QIO program so that relationships could be built, so that we could continue to learn from past successes in an incremental way, and so that we could have a local field force achieving maximum results. Do you feel that a massive switch toward regional QIOs would undermine the current program by cutting those relationships and eroding institutional knowledge after we've made such a giant investment in the program?

Answer: CMS is currently in the process of evaluating how to structure the QIO contracts in the 11th Statement of Work (SOW) using the flexibility and new authority provided in the Trade

Adjustment Assistance Extension Act of 2011. We plan to capitalize on the strengths and institutional knowledge of the QIO program that have been built throughout the years.

Under the 11th SOW that we are developing, we will ensure that no locality will lose access to a Medicare QIO. While CMS is still determining the number of QIO contracts to be awarded, the agency will require that every QIO—regardless of the size of its jurisdiction—reach providers and beneficiaries at the local level. We also understand the importance of involvement of physicians in the peer review process and understand that the best way improve health care is to drive quality improvement at the local level.

Question 7

In your testimony, you state that “more than 6.3 million people with Medicare have saved more than \$6.1 billion on prescription drugs.” Please provide more details on how these savings have been achieved. I am concerned that the incentives in the coverage gap of the Part D program encourage people to remain with brand-name drugs, rather than switch to cheaper generic products. What steps has CMS taken to incentivize the use of generic drugs in the Part D program? What can Congress do to improve these incentives?

Answer: These savings resulted from the one-time rebate provided in 2010 to Medicare beneficiaries who hit the Part D coverage gap, as well as the manufacturer discounts on brand name drugs provided in the coverage gap. In addition to these savings, beneficiaries are saving from increasing coverage for generic medicines in the coverage gap.

In 2010, Medicare beneficiaries who hit the coverage gap or “donut hole” in the Medicare prescription drug benefit received a one-time \$250 rebate, under the Affordable Care Act. In 2011, as a result of the Affordable Care Act, Medicare beneficiaries began receiving a 50 percent discount on covered brand name drugs and coverage for 7 percent of the cost of generic drugs in the coverage gap. In 2012, Part D covered 14 percent of the cost of generic drugs in the coverage gap. Coverage for both brand name and generic drugs in the gap will continue to increase over time until 2020, when the coverage gap will be closed.

The competitive Part D structure implemented through CMS regulation allows Part D sponsors the flexibility to implement benefit designs, such \$0 or low copays for drugs on the generic tier, that incentivize beneficiaries to use lower cost generics. These incentives have been a key factor in restraining the growth in per-capita Part D costs. In fact, the Office of the Actuary’s most recent estimates of trends in per capita Part D costs is resulting in a decrease in the standard deductible and out-of-pocket limit for 2014.

In terms of Congressional action to improve incentives for generic utilization in Part D, the President’s FY2014 budget includes proposals to lower the generic copayment for beneficiaries receiving the Part D Low Income Subsidy while raising copays for brand name drugs in therapeutic classes where a generic is available and therapeutic substitution is appropriate. The budget also includes proposals that would speed the entry of generic biologics onto the market and prohibit brand and generic drug manufacturers from entering into agreements that delay availability of new generic drugs and biologics.

Questions from Senator Wyden

Question 1

Medicare Secondary Payer reimbursements have been an area of concern for me. At the close of last Congress, the SMART Act (P.L. 112-242), which streamlined the Medicare Secondary Payer system, became law. When do you expect to begin the process of implementing the law?

I understand that CMS issued an Advanced Notice on Proposed Rulemaking on the issue of payment of future medicals costs in reference to Medicare as a secondary payer last year. In light of this Advance Notice, I want to be sure that changes will not impact the ability to maintain and improve access to services and supports for those individuals who have acquired a disability or chronic condition in relation to an unfortunate event resulting in a liability settlement. What are you doing to ensure that this rule is fair and won't result in consumers losing access to health care? What are your plans, if any, for next steps regarding this proposal?

Answer: Since the enactment of the SMART Act, we have reviewed the legislation and expect to implement the law through notice and comment rulemaking so that stakeholders may provide feedback on our planned implementation.

We received over 100 comments on the Advance Notice of Proposed Rulemaking (ANPRM) we published on June 15, 2012. The ANPRM solicited public input on CMS' proposed options to address Medicare Secondary Payer (MSP) future medicals obligations, and it invited stakeholders to propose additional options for resolving MSP future medicals obligations. As we stated in the ANPRM, we intend to respond to comments received in response to the ANPRM in future rulemaking, consistent with the SMART Act.

Question 2

Regarding Analysis of Possible Market Consolidation - Given the growing trend of consolidation in the health care delivery system, what tools does CMS have at its disposal to monitor the impact integration and consolidation may be having on the health system? Similarly, what analysis – if any – is being done to identify the impact consolidation might be having on Medicare spending? Finally, given the incentives for providers to come together in integrated systems, how is CMS evaluating the impact that payment disparities between sites might have in incentivizing consolidation of providers?

Answer: Our efforts to encourage competition in hospital markets include the operation of the Medicare accountable care organizations (ACOs). We believe that competition among ACOs will foster improvements in quality, innovation, and choice for Medicare beneficiaries. We intend to ensure that appropriate monitoring of the competitive effects of ACOs is underway by coordinating closely with the antitrust agencies (Department of Justice and Federal Trade Commission) throughout both ACO application process and the Medicare ACO's participation in the Medicare Shared Savings Program. These agencies issued guidance for providers seeking to

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

CMS is providing aggregate claims data to the antitrust agencies to assist them in their monitoring efforts to ensure ACO formation and operation do not have a detrimental effect upon competition. In addition, the antitrust agencies have existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct.

In addition, we believe 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.

I would be happy to work with you and your staff on how we can improve on these efforts.

Question 3

Regarding Appropriateness Criteria for Advanced Diagnostic Imaging Services - The Medicare Improvements for Patients and Providers Act of 2008, or "MIPPA," required that CMS establish a two-year demonstration project beginning January 1, 2010, that would examine and collect data regarding physician compliance with clinical appropriateness criteria for advanced diagnostic imaging services. MIPPA also required CMS to submit a report to Congress on the demonstration, including legislative recommendations, within a year after completion of the demonstration. Incentivizing appropriateness criteria may prove to be a far more effective way to prevent misuse and over utilization than prior authorization and other arbitrary cuts to medical imaging. At what point in 2013 will Congress receive the report from CMS on the results of this imaging appropriateness demonstration?

Answer: The Medicare Improvements for Patients and Providers Act of 2008 required the demonstration to be conducted for a 2-year period. The demonstration started on October 1, 2011 and is expected to conclude on September 30, 2013. The statute also requires the Secretary to submit a report to Congress containing the results of the evaluation of the demonstration along with recommendations for legislative and administrative action. This report is required to be submitted not later than one year after the completion of the demonstration.

Question 4

Regarding Oregon's 1915(k) Waiver - My state has been a longstanding leader in home and community based services. Last September Oregon submitted a request for a Community First Choice waiver, and they feel they have worked diligently with your workgroups on this but it seems like there has been some conflicting information on the status of the request. Oregon has been hopeful that this waiver can be approved by July 1. What actions are necessary for Oregon to gain approval to implement the Community First Choice provisions by July 1, 2013? Will you commit to review Oregon's application and ensure it receives full and fair consideration?

Answer: We applaud Oregon’s work in providing home and community-based alternatives to institutional care. Our work with Oregon on its proposal is well underway and we are committed to continuing our work with the state mindful of the state’s anticipated July 1 implementation.

Questions from Senator Portman

Question 1

I continue to have concerns regarding the Centers for Medicare & Medicaid’s (CMS) competitive bidding program for durable medical equipment (DME). As we discussed during the hearing, two of the nine bidding areas are located in Ohio. This summer those nine bidding areas will expand to 91 areas, six of which will be in Ohio.

CMS has provided assurance that it is strengthening the bid review process to ensure that low bids are sustainable for the suppliers. Can you describe the measures you have already taken to strengthen the review process and what you will do before moving forward with expansion of the program this summer?

If you find that the existing measures are not adequate to ensure winning bidders are capable of supplying this equipment, would CMS be willing to delay the expansion planned for round two?

Answer: We made numerous successful improvements to the program since the program started and are continually looking at ways we can improve the process. For the Round 2 and National Mail Order competitions, we increased our scrutiny of bids and enhanced our successful bidder education program.

We already had a rigorous, comprehensive process in the Round 1 Rebid to check for low-ball bids, which included the following steps: screening the bidders to verify that they meet all requirements (i.e., that they are enrolled and accredited and meet financial standards, applicable licensing requirements, and other bidding requirements); screening the bids from qualified bidders using statistical measures to identify any bids that are very low in comparison to other bids; asking bidders that submitted bids that fell below the statistical screening thresholds to submit a rationale and documentation to prove that their bids are sustainable; and rejecting bids that are not proven feasible (and are not used to set prices).

Even though we didn’t see any problems with low-ball bids in the Round 1 Rebid, we made the following process enhancements for Round 2:

- We improved our bidder education so that it more strongly emphasizes the need to submit bids that include the cost for the supplier to buy the item, overhead, and profit.
- We targeted our screening to focus more on the highest cost, highest volume items that have the greatest impact on a supplier’s composite bid. We applied tougher screens to these high cost, high volume items.
- We had stricter rules about the information bidders could submit to prove that their bid prices are realistic.

The competitive bidding program includes many safeguards beyond the enhanced bona fide bid evaluation process to ensure that there are a sufficient number of qualified suppliers to meet beneficiary demand. We are confident that the single payment amounts for Round 2 and the National Mail-order program provide appropriate payment for the equipment and supplies and related services. Our comprehensive monitoring program has shown that the program has preserved beneficiary health status and access to medically necessary items while saving money for taxpayers and beneficiaries in the first nine areas. We will continue to aggressively monitor the program in all 91 Round 2 areas to ensure that there are no negative effects on either access or beneficiary health status.

Question 2

I have heard from a number of Ohio business owners and their employees regarding the definition of a “full time employee” as someone who works 30 hours per week. There is significant concern that this will cause a shift of many full time employees to part time status. It also appears that the effects of this provision are hampering the ability of employers to hire even part time employees. The University of Akron recently announced that it is planning to limit not only the number of part time employees, but also the number of hours part time employees can work. The University Provost cited concerns stemming from the Affordable Care Act (ACA) in the University’s decision-making. Several other colleges and Universities in Ohio have already made similar changes to their hiring of part time employees. This is just the latest example of the damaging effect the ACA is having on hiring in Ohio and throughout the country. The March 2013 report from the U.S. Department of Labor revealed the lowest labor force participation since 1979, so this is hardly the time to disrupt hiring practices and discourage full time employment.

Would you be willing to work with members of Congress who want to change the ACA’s definition of full-time employee to be consistent with the generally accepted 40 hours per week? Would you be willing to work with other agencies involved to re-evaluate the policy?

Answer: The employer responsibility provision only applies to firms with 50 or more full-time equivalent employees. A 2009 Kaiser Health News study found that 95 percent of employers with at least 50 workers already offer their employees health insurance. The Affordable Care Act creates the Marketplace designed specifically to make it easier to provide health insurance to employees of small businesses, including through a tax credit for eligible participating employers. We have and will continue to work with the Department of Treasury as it implements the rules for these policies.

Question 3

HHS recently announced that key components of the Small Business Health Options Program will be delayed until 2015. It is my understanding that this program is an essential part of the administration’s vision for the Health Insurance Exchanges (“Exchanges”). The provision in question was designed to let employers give workers a set amount of money to purchase insurance coverage in an online marketplace. The U.S. Department of Health & Human Services (HHS) cited “operational challenges” in their decision to delay this part of the Small Business Health Options Program.

Does the delay in the Small Business Health Options Program indicate a broader issue with the implementation timeline? Do you anticipate there being further delays?

Answer: Both the Marketplaces and the SHOP will be ready for open enrollment beginning October 1, 2013. Small employers will then have access to a variety of plans offered through SHOPs in all states. The Federal SHOP will provide qualified small employers with detailed information on the qualified health plans (QHPs) that offer coverage in their area and will provide the tools employers need to compare different QHPs and choose the QHP that best meets their needs.

We have proposed a one-year transition in implementing “employee choice” function of the federal SHOP: “Employee choice” means that qualified employers would be able to offer each employee their own choice of health plans at the same level (“metal level”) of coverage. Under the current proposal, the federally facilitated SHOP would enable employee choice for plan years beginning on or after January 1, 2015. State-based SHOPs could choose to offer these functions on or after January 1, 2014, and would be required to do starting January 1, 2015.

We proposed the transition after reviewing public comments. CMS concluded that continuing the status quo of employers offering their employees a single QHP for the first year of SHOP would provide employers with price transparency, stability, and an online comparison of benefits and rates, maximize issuer participation in the SHOP in 2014, and build toward successful implementation of the employee choice model in 2015.

Question 4

At last count, 26 states, including Ohio, will have federally-run Exchanges. An additional seven states will run partnership Exchanges with the federal government. These Exchanges are supposed to begin open enrollment on October 1st, 2013.

Given that the October 1st deadline for open enrollment is quickly approaching, will the necessary Information Technology (IT) systems be ready to process the large amount of data and information on day one? Is CMS planning to test these IT systems prior to open enrollment to ensure that they will be able to handle such a large data volume?

Answer: Yes, CMS is engaged in a variety of tests, both internally and with external partners, to ensure that IT systems are ready to handle the expected volume of data once open enrollment begins. CMS is undertaking ‘Secure Communications’ and the ‘FEPS and Partner’ functional testing with the IRS, beginning in October 2012. These tests have been successful in testing the services between IRS and CMS.

The following federal agencies will begin similar testing in Spring 2013:

- Department of Homeland Security (DHS)
- Internal Revenue Service (IRS)
- Office of Personnel Management (OPM)
- Peace Corps

- Social Security Administration (SSA)
- TRICARE Management Activity (TMA)
- Veterans Health Administration (VHA)

Several State Based Marketplaces and Federally Facilitated Marketplace states will begin ‘Secure Communications’ and ‘FEPS and Partner’ in the spring of 2013. All states will participate in the ‘Regression and End to End’ Testing in August 2013. Plan issuers are scheduled to begin testing plan management templates in the spring of 2013.

Together, internal and external testing will validate system functionality. Performance Stress Testing will examine infrastructure capacity and scalability with the most active trading partners. Security Testing will take place in the same manner as with all CMS systems. We have dedicated significant resources and personnel to work with stakeholders in developing a robust testing infrastructure that will allow for testing to occur once the system is operational.

Question 5

Providers are facing multiple compliance deadlines that are converging at once: meaningful use, billing code changes, value based modifier, and HIPAA privacy provisions. Many of these programs involve financial penalties for noncompliance. Providers are being asked to undertake these efforts at the same time they are trying to move into new payment and delivery models.

What concrete steps is CMS taking to educate and assist providers in meeting these deadlines and complying with these programs?

Answer: We have worked to align the requirements of various programs to minimize implementation and reporting burdens for providers. For example, we are better aligning the Physician Quality Reporting System, the Electronic Health Records Incentive program and the Physician Value-based Modifier with that goal that a physician will only have to report measures once for all three programs. While I understand that addressing the requirements of each of these programs can be time and resource intensive, I also believe that initiatives such as the ones you have named are important to improving quality and efficiency in the health care delivery system. We continue to think about how to minimize provider reporting burden and have been actively engaged with the provider community on these issues.

Questions from Senator Brown

Question 1

Regarding Medicaid Expansion: CMS has been negotiating with individual states about the details of coverage expansion. I know the Kasich Administration is in active discussions with CMS and is working toward expansion that works for Ohio.

I understand some Governors are interested in using Medicaid expansion funds to purchase private insurance. I am concerned that state flexibility in this area - while an admirable goal - risks undermining the traditional benefits and protections afforded to

Medicaid beneficiaries. What sort of flexibility is CMS allowing for states interested in this alternative model and what is the Agency doing to ensure beneficiaries retain their rights under the Medicaid program?

**Are you confident CMS can work with states like Ohio?
If Medicaid is expanded in Ohio, how many people will be helped and what will be the cost for the state's if Medicaid expansion occurs?**

Answer: CMS has recently released a set of Frequently Asked Questions (FAQs) regarding state interest in the use of premium assistance. Under all premium assistance arrangements, beneficiaries remain Medicaid beneficiaries and continue to be entitled to all benefits and cost-sharing protections. States must have mechanisms in place to “wrap-around” private coverage to the extent that benefits are less and cost sharing requirements are greater than those in Medicaid.

Some states have expressed interest in section 1115 demonstrations to provide premium assistance. CMS has indicated that we will consider approving a limited number of premium assistance demonstrations and would also consider states’ ideas on cost effectiveness related to the Health Insurance Marketplaces and the expansion of Medicaid. CMS will consider only those proposals that provide beneficiaries with a choice of at least two qualified health plans, that make arrangements to provide any necessary wrap around benefits and cost sharing, that are limited to individuals whose benefits are closely aligned with the benefits available on the Marketplace and that end no later than December 31, 2016. As is our practice, CMS will include in any demonstration approval, requirements for the state to closely monitor and report on the demonstration’s progress. We have time limited the demonstrations to ensure they can inform policy for the State Innovation Waivers that begin in 2017.

Additionally, CMS remains committed to addressing questions from and working with states, like Ohio, as they consider the low-income adult Medicaid eligibility expansion. We continue to believe that adopting the Medicaid expansion is beneficial for states. As you know, for the first three years, the expansion is fully paid for by the federal government and will lead to expanded coverage, improved health and lower rates of uncompensated care.

Question 2

Regarding Part D Preferred Provider Networks: I am concerned with the growing use of preferred pharmacy networks in the Medicare Part D program, and have heard concerns from small and medium-sized pharmacies in Ohio about being excluded from the networks. It seems the insurance companies are inviting only a few big box and other large pharmacies to participate. In the recently released Call Letter for the 2014 plan year, CMS itself identified concerns with the use of preferred pharmacy networks in the Medicare Part D program, particularly the potential for beneficiary disruption and travel costs, especially in rural areas. CMS also indicated concern that the structure of some preferred networks may actually be increasing costs for the Medicare program.

As the use of these networks has become more widespread, what actions does CMS plan to take to ensure that the use of preferred pharmacy networks in the Medicare Part D

program does not affect beneficiary access, lessen quality of care, or increase costs to the Medicare program?

Additionally, the Office of the Inspector General (IOG) recently reported that gaps exist in CMS’s oversight of the Medicare Plan Finder reporting requirements. How is CMS ensuring that beneficiaries have access to all of the information they need about specific plan benefits, including whether a plan uses a preferred pharmacy network and which pharmacies are included in those networks?

Answer: Part D regulations that permit lower cost sharing at some “preferred” network pharmacies also require that such cost sharing reductions must not increase CMS payments. In order to ensure that Part D sponsors with preferred pharmacy networks are meeting this requirement, we have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks. Our initial results suggest that for some plans, aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks. Combined with lower cost sharing, we are concerned that these higher unit costs may violate the requirement not to increase payments to such plans. We have contacted the plan sponsors identified in our analysis to initiate the validation of our findings.

As we indicated in the 2014 Call Letter issued April 1, we strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to ensure that such networks promote price competition and lower costs in the Part D program. Opening preferred pharmacy networks to any pharmacy that can meet the network’s terms and conditions would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas. Mandating this policy for all Part D sponsors would require rulemaking by CMS.

We are continuing to refine the Medicare Plan Finder to ensure that it provides the most accurate information possible. As of April 2012, a beneficiary is now able to see drug price estimates that reflect if the pharmacy selected is preferred or non-preferred for a given plan. If a pharmacy is not in the selected plan’s network, the full price of the drug is shown. Concerns about the Medicare Plan Finder being time-consuming may be a reflection of the increased number of inputs needed to generate an accurate cost estimate. Having the Medicare Plan Finder prompt the user for exact drug names, quantity and dosing regimen, Part D plan, subsidy eligibility, and choice of pharmacy provides beneficiaries access to highly valuable information, to help select the best coverage option and to anticipate medical expenses for the coming year. We welcome your ideas to ensure that the Part D program remains strong.

Question 3

Investment in Pediatric Innovations

The Center for Medicare and Medicaid Innovation was created to support the development and spread of delivery and payment reforms in Medicaid and Medicare that improve quality of care and reduce health care costs. The Innovation Center has supported a number of projects intended to innovate care for adults, but there has not been a similar

investment in innovations for children. In fact, some of the funding opportunities offered by the Innovation Center have excluded children.

How will you ensure CMS invests in delivery system and payment reforms that can improve care for our nation's children, especially those with complex medical needs?

Answer: We have a number of initiatives and programs that focus on improving the health and healthcare outcomes for pediatric populations, including the Strong Start for Mothers and Newborns initiative. The Strong Start initiative is an Innovation Center project focusing on reducing early elective deliveries and reducing the rate of preterm births among high-risk women in Medicaid and CHIP. Additionally, we have released the Initial Core Set of Child Health Care Quality Indicators for Medicaid and CHIP, established for voluntary use by state Medicaid and CHIP programs, which includes a range of children's quality measures encompassing both physical and mental health, including chronic conditions such as asthma and diabetes. CMS' Pediatric Quality Measures Program and the Pediatric Electronic Health Record Format also represent other initiatives the agency is pursuing to help improve the health and care children enrolled in our programs receive. Additionally, the Innovation Center is testing medical homes for individuals with disabilities and complex health conditions and high-risk chronically ill children.

As we do in all areas, we continue to look for opportunities to test promising models in the Medicaid program and understand the importance of delivering better, more efficient care to Medicaid beneficiaries. We are working closely with our colleagues at the Center for Medicaid and CHIP services to coordinate our collective efforts to identify new opportunities.

Question 4

Regarding Primary Care Workforce: In many ways, the success of the ACA will depend on an adequate supply of physicians, nurse practitioners, and nurses, especially primary care providers who provide a usual source of care for most seniors.

How well do you think CMS is doing to ensure an adequate pipeline of primary care providers?

Answer: We recognize the need to invest in the workforce to improve the health care system. New payment reforms, like Accountable Care Organizations and other models to promote coordination can play a role in addressing a shortage of physicians by encouraging a team approach to medicine. By using the skills of other providers, like nurse practitioners and pharmacists, this approach allows physician to more efficiently use their time. In addition, CMS has implemented the Affordable Care Act's 10 percent payment increase to primary care physicians. And the Innovation Challenge Awards are testing ideas to strengthen the primary care workforce.

In 2012, CMS revised the hospital conditions of participation to broaden the concept of the medical staff and allow hospitals the flexibility to include other practitioners as eligible candidates for the medical staff in accordance with state law. Non-physician practitioners are capable of handling many common patient complaints, initial patient work-up and follow-up,

patient education and counseling, and other specific aspects of patient care. Physicians, as leaders of these teams due to their more extensive training and expertise, are then able to more fully turn their attention to more complicated patient problems. In this way, non-physician medical staff members allow physicians to more efficiently and effectively manage their time so that these physician leaders can focus on more medically complex patients.

CMS has also implemented the Affordable Care Act's Graduate Nurse Education Demonstration to support hospitals for the cost of providing clinical training to advanced practice registered nurse students. Five hospitals were selected, including the Hospital of the University of Pennsylvania, Duke University Hospital, and Memorial-Hermann Texas Medical Center Hospital.

Finally, CMS is working closely with our partner agencies across HHS, including the Health Resources and Services Administration (HRSA), to ensure an adequate pipeline of primary care providers is supported.

What are you doing to enhance training opportunities in community outpatient settings?

Answer: CMS is undertaking a number of initiatives to enhance community outpatient care and, as a result, the training opportunities in those settings. The Affordable Care Act amended the Social Security Act to allow any time spent by residents training in a nonprovider setting to count toward direct graduate medical education (GME) and indirect medical education (IME) costs if the hospital incurs the costs of residents' salaries and fringe benefits. This change was effective for cost reporting periods beginning on or after July 1, 2010, for direct GME, and for discharges occurring on or after July 1, 2010, for IME and was finalized in the Calendar Year 2011 Hospital Outpatient Prospective Payment System final rule. This change was expected to lead to an increased number of residents training in nonprovider sites such as community-based settings.

The Health Care Innovation Awards are funding new models of payment and service delivery. The Innovation Awards recognized the need for an appropriate trained workforce to support new models of payment and service delivery. Applicants were encouraged to propose models that included a significant opportunity to develop and deploy health care workers in innovative ways, which can include community outpatient care. For example, in Michigan, the Michigan Public Health Institute received an award to integrate community health workers into primary care teams in order to coach patients on self-management and encourage regular primary care visits. Additional efforts to enhance training opportunities in community outpatient settings are supported by our sister agency, HRSA.

Question 5

Regarding Pediatric Dental Care: I am concerned about the affordability of the pediatric oral health benefit. As you know, it is specifically listed as an essential health benefit and a part of the comprehensive set of pediatric services promised to families entering any exchange. However, the Center for Consumer Information and Insurance Oversight (CCIIO) has interpreted the "allow-ability" of stand-alone dental plans inside the exchange

to mean that families that opt for or are forced to choose a stand-alone dental plan will be faced with out of pocket limits above and beyond those established in the underlying law.

Can you explain how you will ensure that pediatric dental care is reasonably affordable for average Americans?

Answer: CMS has taken steps to implement the provisions regarding the pediatric dental essential health benefit in a manner that is consistent with the statute and provides as many consumer protections as possible. Essential health benefit requirements mandate that certain issuers offer certain benefits, but do not require individuals or families to obtain coverage for a particular benefit. As you note, the statute is different with respect to issuers inside Marketplaces. While the Affordable Care Act requires issuers offering non-grandfathered coverage in the individual and small group markets to offer the essential health benefits. Section 1302 of the Affordable Care Act also allowed issuers in an Marketplace to opt not to offer pediatric dental coverage if there is a stand-alone dental plan offering the pediatric dental essential benefit operating in that Marketplace.

There are several ways that the Affordable Care Act and the implementing regulations help with the affordability of pediatric dental essential health benefits. Specifically with respect to stand-alone dental plans, individuals may use premium tax credits to purchase a stand-alone dental plan. Our rules provide that if a family is enrolled in a QHP and a stand-alone dental plan, the premium tax credit is first applied to the portion of the premium for the QHP related to the essential health benefits, and any remaining amount is then applied to the portion of the premium for the dental plan related to essential health benefits.

In addition, the final essential health benefits rule requires dental plan issuers to offer plans at either a low (70%) or high (85%) actuarial value. Actuarial value is a measure of expected plan spending across a standard population. This means that every stand-alone dental plan purchased in an Exchange will cover, on average, 70% or 85% of costs that individuals could be expected to incur in a year for pediatric essential dental benefits.

Finally, as you note, the final essential health benefits rule established a separate annual limitation on cost-sharing for stand-alone dental plans provided that such limitation was reasonable, as defined by a Marketplace. For coverage year 2014, CMS has interpreted a reasonable limit to be \$700 for a plan with one child enrollee or \$1,400 for a plan with two or more child enrollees. It is important to remember that these annual limits on cost-sharing are catastrophic limits beyond which all pediatric essential health benefits would be covered in full.

Question 6

Regarding Small Business: I have heard from Ohio business owners concern about their responsibilities under the Affordable Care Act. Some are looking at ways around providing insurance, such as cutting workforce hours or their number of employees. Businesses are also overwhelmed with trying to determine whether their health insurance plans are both affordable (cannot exceed 9.8% of employee's income) and provide minimum value. I have also heard that the tax incentives for small business are being under-utilized.

What are CMS and the IRS doing to help business owners make good decisions about employment and health insurance that will fit with the spirit of the ACA?

Answer: The Small Business Health Options Program (SHOP) Marketplaces will help small businesses provide affordable, quality coverage for their employees. Eligible small businesses will be able to access tax credits and obtain access to information about coverage options through the SHOP. By pooling employers together, reducing transaction costs, and increasing transparency and competition, the Health Insurance Marketplace for individuals and small employer groups will be more efficient and competitive.

The Affordable Care Act creates a Marketplace designed specifically to make it easier to provide health insurance to their employees, including through a tax credit for eligible participating employers who obtain coverage through the Marketplace.

CMS has been developing SHOP-focused training and materials to help small businesses understand the Affordable Care Act and the opportunities it presents to them. And we have a strong partner in the Small Business Administration, which has created its own education sessions for small businesses that they will start offering this spring. We also expect agents and brokers to play a significant role in working with the small business community.

To what degree do you think CMS is meeting goals for including small business into the process of working toward insuring workers?

Answer: CMS has worked with our regional offices and the Small Business Administration to provide updates to small businesses on recent policies and regulations. Starting in 2014, small businesses will be able to purchase private health insurance for their employees through the Marketplace. CMS has also already released the draft single streamlined application for small businesses and has begun engaging small business to hear their input and communicate how the Marketplace will work and when it will be ready. These discussions, which are led by CMS regional offices, are the start of ongoing conversations with all stakeholders including the small business community.

What in particular is CMS doing to help small businesses make necessary adjustments and make full use of tax incentives?

Answer: CMS has been developing SHOP-focused training and materials to help small businesses understand the Affordable Care Act and the opportunities it presents to them. We also have a strong partner in the Small Business Administration, which has created its own education sessions for small businesses that they will start offering this spring. We also expect agents and brokers to play a large role in working with the small business community.

Question 7

Regarding Health Care Spending and Medicare Solvency: Earlier this year, report after report found that national health spending had slowed and created a smaller difference between the rate of health care growth and the rate of growth in the whole economy. Some

of the slowdown could be attributed to events before the Affordable Care Act (ACA) was in place and some to the transformation the ACA is having on delivery system reforms and attitudes.

What effect is this slowdown having on Medicare's long-term solvency? Is CMS working to predict whether – at least for Medicare and Medicaid – the slowdown is a recession driven event or if this new trajectory will remain, at least for a time?

Answer: Thanks partly to reforms in the Affordable Care Act—including anti-fraud measures and new incentives for doctors to eliminate duplication and waste—Medicare spending per beneficiary grew at a historically low rate of 0.4 percent in 2012. This slowdown reflects, in part, the successful implementation of the Affordable Care Act's provisions that strengthen the Medicare program. These statistics show that the Affordable Care Act has helped in part to set Medicare on a more sustainable path to keep its commitment to seniors and persons with disabilities today and well into the future. The President's 2014 Budget request would add 4 years to the solvency of the Medicare Trust Fund. The success in reducing the rate of spending growth has been achieved without any reduction in guaranteed benefits for beneficiaries. To the contrary, Medicare beneficiaries have gained access to additional benefits, such as increased coverage of preventive services and lower cost-sharing for prescription drugs.

The economic recession may have contributed to the 2010 to 2012 decrease in per beneficiary spending growth as consumers used less care due to its cost. However, as almost all Medicare beneficiaries have supplemental coverage and thus face relatively low out-of-pocket costs, it seems unlikely that consumer behavior alone is responsible for the slow growth in Medicare spending.

Question 8

Regarding Observation Status: Senator Schumer mentioned my legislation, the Improving Access to Medicare Coverage Act, during the hearing and I would like your thoughts on addressing this problem. Too many Ohio seniors have written to me about high out-of-pocket costs they are enduring because, while they required skilled nursing facility (SNF) care after a hospitalization, Medicare will not pay for it.

Aside from legislation, what authority does CMS have to work with seniors to get these services covered? Additionally, has CMS been looking into why hospitals are increasingly leaving people in medical limbo for several hours and even days?

Answer: We are also concerned about the recent increases in the length of time that Medicare beneficiaries spend as an outpatient receiving observation services. This can affect beneficiaries' financial liability during the hospital stay and their ability to meet the 3-day qualifying inpatient hospital stay requirement for coverage of skilled nursing facility services. We solicited comments from stakeholders on a rule last year that would address this issue.

We heard from stakeholders that hospitals appear to be responding to the financial risk associated with admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting beneficiaries as inpatients. In

addition, hospitals could only rebill under Part B for a limited set of services they furnished during these inpatient stays. As a step to address this concern, we recently released a Ruling and proposed rule that would allow hospitals to bill for additional services under Medicare Part B when a Part A inpatient claim is denied by our contractors.

We also received comments on the 3-day qualifying inpatient stay requirement. Many commenters indicated that the statutory 3-day qualifying inpatient stay requirement is obsolete, given the advances in medical care, the trend towards reduced length of stay, and the migration of services from the inpatient to outpatient setting. Some of these commenters recommended that the 3-day inpatient stay requirement be replaced with clinically meaningful criteria that are not time based or based on patient status. Other commenters expressed their support for legislation that would allow time in observation to be counted as inpatient time for purposes of SNF qualification. In addition, some commenters recommended waiving the 3-day rule for certain diagnoses that benefit from short inpatient stays and speedy access to post-acute rehabilitative services. We will consider these comments for possible future rulemaking.

However, we cannot change the statutory requirements for Medicare coverage of skilled nursing facility services. Section 1861(i) of the Social Security Act defines post-hospital skilled nursing facility services as services furnished to a beneficiary after transfer from a hospital in which the beneficiary was an inpatient for not less than 3 consecutive days before discharge from the hospital. The Social Security Act is explicit on the requirements for coverage of skilled nursing facility services that the beneficiary be an inpatient prior to transfer from a hospital. By contrast, observation stay services are furnished on an outpatient basis and, therefore, do not meet the statutory criteria for the 3-day qualifying hospital stay requirement for coverage of skilled nursing facility services.

Question 9

Informing Seniors of Their New Benefits: Since 2010, seniors have been able to have annual wellness check-ups and preventive screenings. Over a million seniors have taken advantage of at least one screening, but fewer have had their annual check-up. We all know an ounce of prevention is worth a pound of cure. Encouraging prevention will improve the health of seniors and save Medicare money.

How is CMS ensuring that seniors understand and take advantage of the new benefits? Additionally, do you have a demographic breakdown of who is and who is not utilizing the screenings? Have you been able to calculate the amount of cost savings provided by these preventive screenings?

Answer: Medicare covers a wide range of screening and preventive benefits, including services that have been covered by statute for many years (for example, influenza and pneumococcal vaccinations, Pap tests, and screening mammography), and services added through evidence-based National Coverage Determinations under authority granted by the Medicare Improvements for Patients and Providers Act of 2008 (for example, tobacco cessation counseling, and intensive behavioral therapy for cardiovascular disease). In addition, the Affordable Care Act established

coverage of an Annual Wellness Visit beginning in 2011 (building on the one-time “Welcome to Medicare Visit” for new beneficiaries).

Prior to 2011, people with Medicare had to pay cost-sharing for many preventive services. However, under the Affordable Care Act, many preventive services are now offered free of charge to beneficiaries, with no deductible or co-pay, so that cost is no longer a barrier for seniors who want to stay healthy and treat problems early.

During 2012, an estimated 34.1 million people with Original Medicare or Medicare Advantage received one or more preventive benefits free of charge. Over 3 million people with Original Medicare took advantage of the new Annual Wellness Visit in 2012. In February 2013, CMS issued a report on use of Medicare’s preventive services in 2011 and 2012, including a state-by-state breakdown on 2012 utilization in Original Medicare.

CMS has undertaken a range of initiatives to educate providers and beneficiaries about the importance of prevention and Medicare coverage of preventive services, including the Annual Wellness Visit, and will continue to work toward increasing awareness and use of these important benefits.

Questions from Senator Cornyn

Question 1

CMS has had three years to implement the SHOP program that would allow employees of small businesses to shop for insurance plans. Why is this one-year delay necessary? How long has CMS known that it would not be prepared to implement the SHOP program on time? Can we expect other PPACA implementation delays?

Answer: The SHOP will be ready for open enrollment in October, 2013. The Federal SHOP will provide small qualified employers with detailed information on the qualified health plans (QHPs) that offer coverage in their area and will provide the tools employers need to compare different QHPs and choose the QHP that best meets their needs.

We have proposed a one-year transition in implementing the “employee choice” function of the federal SHOP.” “Employee choice” means that qualified employers would be able to offer each employee their own choice of health plans at the same level (“metal level”) of coverage. Under the current proposal, the federally facilitated SHOP would enable employee choice for plan years beginning on or after January 1, 2015. State-based SHOPS could choose to offer these functions on or after January 1, 2015, and would be required to do starting January 1, 2015.

We proposed the transition after reviewing public comments. CMS concluded that continuing allowing employers to continue offering their employees a single QHP for the first year of SHOP would provide employers with price transparency, stability, and an online comparison of benefits and rates, maximize issuer participation in the SHOP in 2014, and build toward successful implementation of the employee choice model in the 2015 small group market.

Question 2

A recent article published in Contingencies, a magazine of the American Academy of Actuaries, found that premiums for individuals in the nongroup market aged 21 to 29 who are not eligible for premium assistance will increase by 42 percent. For those aged 30 to 39, premiums are expected to increase by 31 percent. Administration officials have noted that the PPACA allows individuals under 30 to purchase a catastrophic plan option. However, the actuaries are predicting large increases for those over 30 and not eligible to purchase catastrophic plan options. In addition, Administration officials often point to the fact that the premium tax credits will offset these premium increases. However, actuaries note that adults up to 44 with incomes above 300 percent of the FPL (approximately \$33,510) will see premium increases, even taking into account premium assistance. For those below 30, individuals at about 225 percent of FPL (approximately \$25,000) can expect to see premium increases, even after taking into account premium assistance. Do you believe that premiums will rise as a result of the PPACA? Are you concerned about these premium increases?

Answer:

The individual and small group markets – the markets that much of the Affordable Care Act is designed to improve in particular -- are broken. People are currently locked out of these markets because of their pre-existing conditions, or if they are able to buy insurance, they may find out their coverage will not extend to the care they need when they get sick. Young women who currently pay for their own insurance plan may discover that, simply on account of their gender, they are charged 50 percent more than young men are for the same plan. This fall, people are going to be able to buy comprehensive insurance without discrimination based on gender or pre-existing conditions. Also, low- and middle-income people may qualify for premium tax credits to help them buy insurance.

Starting in 2014, people will be able to choose their health plans based on the actuarial value they think fits their needs and their budget. Actuarial value means the percentage paid by a health plan of the total allowed costs of benefits. For example, if a plan has an actuarial value of 70 percent, the average consumer would be responsible for 30 percent of the costs of the essential health benefits the plan covers. Plans will range from 60 to 90 percent of actuarial value.

Additionally, the Marketplace will increase competition between issuers on the individual market. With transparent prices and standard tier benefits, CBO projects a 7 percent to 10 percent decrease in premiums.

Also, young adults and certain other people for whom coverage would otherwise be unaffordable may enroll in catastrophic plans, which have lower premiums, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing. Young people under the age of 26 are also generally allowed to stay on their parents' insurance, helping make insurance more affordable for that group.

There are also many provisions in the law to slow health care cost growth and create competition in the insurance marketplace. For example, the reinsurance and risk adjustment programs will help stabilize premiums.

Question 3

Will the Pre-Existing Condition Insurance Program (PCIP) program run out of its \$5 billion appropriation before 2014? What is CMS doing to ensure that funds remain available for individuals enrolled in this program? How is CMS planning to communicate information to these individuals about their transition out of the PCIP program?

Answer: CMS is doing everything it can to ensure that the limited amount of funding appropriated to the program by Congress is available to continue providing covered services to enrollees until 2014. CMS is aggressively managing costs in the federal PCIP program and has taken a variety of steps to ensure that the funds provided by the Affordable Care Act are applied efficiently in funding patient care and program administration. These include a change in provider networks used by the federally-administered PCIP, reducing both its negotiated and out-of-network payment rate for providers; negotiation of additional discounts on reimbursement rates with targeted hospitals that were treating a disproportionate number of PCIP enrollees; limiting the specialty drug benefit to provide coverage only if the specialty drug is dispensed by an in-network pharmacy and providers that were most cost effective, and; consolidation of three benefit plan options into one, increasing the maximum out-of-pocket limit from \$4,000 to \$6,250 for in-network services.

Open enrollment for plans in the new Marketplace begins October 1, 2013, for coverage beginning January 1, 2014, which generally coincides with the statutory end of the PCIP program. To help effectively transition PCIP members who wish to enroll in a qualified health plan offered through the new Marketplaces, we are working with our PCIP contractors to ensure enrollees in both state-based PCIPs and the federally-administered program receive information about the new Marketplaces. Specifically, we are developing three notices that will be sent to enrollees in federally-administered PCIP over the next several months explaining that PCIP coverage ends after December 31, 2013, describing the Marketplaces, how to enroll beginning in October, and where enrollees can get assistance with enrolling in coverage. Additionally, we have directed our contractors to update their PCIP websites with transition content, train customer service representatives, and provide adequate staffing at their call centers during the last quarter of calendar year 2013 and the first quarter of calendar year 2014 to handle anticipated calls from transitioning enrollees.

Question 4

The health reform law specifically states that the Independent Payment Advisory Board's (IPAB's) recommendations may not:

- **Raise revenues;**
- **Raise Medicare beneficiary premiums;**
- **Increase beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or;**
- **Modify eligibility criteria.**

What types of proposals do you believe the IPAB could propose? The health reform law also specifically prohibits the IPAB from making recommendations that would “ration health care” or “otherwise restrict benefits.” Would you agree that provider payment rates can be cut so low that this ultimately leads to rationing of care?

Answer: The Independent Payment Advisory Board (IPAB) builds on the commitment we have made to our seniors’ health. The Affordable Care Act provides for consultation between the President and Congressional leadership in appointing members of the Board, and appointments are subject to the advice and consent of the Senate. The Board’s primary responsibility will be to recommend certain improvements to Medicare. Recommendations of the IPAB will focus on ways to improve health care while lowering the growth in Medicare spending. For example, the Board could recommend approaches that would build on and strengthen the initiatives mentioned above, from reducing medical errors, to strengthening prevention and improving care coordination, or targeting waste and fraud.

At the same time, the law contains important limitations on what the Board can recommend. The statute is very clear: the IPAB cannot make recommendations that ration care, raise beneficiary premiums or cost-sharing, reduce benefits, or change eligibility for Medicare. The IPAB cannot eliminate benefits or decide what care Medicare beneficiaries are entitled to receive. Considering the requirements and limitations on recommendations from the Board, we expect it will focus on ways to find efficiencies in the payment systems and align provider incentives to drive down costs without affecting our seniors’ access to the care and treatment they need. The Board’s recommendations are will not take effect unless Congress fails to act to keep Medicare cost growth in check.

Question 5

In January 2012, the CBO released an issue brief on Medicare demonstration projects that finds:

The evaluations show that most programs have not reduced Medicare spending: In nearly every program involving disease management and care coordination, spending was either unchanged or increased relative to the spending that would have occurred in the absence of the program, when the fees paid to the participating organizations were considered.

Of the ten major demonstrations reviewed, CBO stated: “CBO finds that most programs tested in those demonstrations have not reduced federal spending on Medicare.”

Given CBO’s findings regarding the lack of cost savings produced by demonstrations, what is different about the demonstrations conducted at CMMI? How can members of Congress be assured that the \$10 billion appropriated to the CMMI in the PPACA is not wasted? Is CMS prepared to expand successful demonstrations quickly?

Answer: The United States has one of the best and most innovative health care systems in the world. We are a global leader in developing new treatments, drugs and procedures to help heal patients. At the same time, we know that we need to do more to help ensure every patient gets the very best care – and that we are spending our health care dollars wisely. This CBO report outlined how difficult this challenge is. The same report recommended that future efforts focus

on collecting better data, targeting resources at the patients who need it most, and encouraging care providers to work together. The Innovation Center is charged with engaging doctors, hospitals, and other providers that want to try new approaches to keeping their patients healthy and out of the hospital. Even before the CBO was released, the Innovation Center was putting some of these lessons and recommendations into practice.

Some examples of how the Innovation Center has already adopted some of CBO's recommendations:

- CBO Recommendation: Gather timely data on the use of care, especially hospital admissions.
 - Innovation Center action: Health systems participating in the Pioneer ACO and ACO Shared Savings models will receive updates on care received by their patients within a few weeks of when it occurred, down from 6 months or more in previous demonstrations.
- CBO Recommendation: Focus on transitions in care settings.
 - Innovation Center action: The Community-Based Care Transitions Program will invest in organizations such as Area Agencies on Aging that help seniors as they leave the hospital, including through home visits. In addition, the Demonstration to Reduce Hospitalizations of Nursing Facility Residents will invest \$134 million in providing additional care and supports to help reduce preventable hospitalizations among nursing home residents.
- CBO Recommendation: Use team-based care.
 - Innovation Center action: The Comprehensive Primary Care Initiative provides new supports from both Medicare and private health insurers to make sure that participating primary care practices have robust care teams – which could include nurses, pharmacists, and dieticians – available 7 days a week to coordinate care and avert visits to the emergency room.
- CBO Recommendation: Target interventions toward high-risk enrollees.
 - Innovation Center action: Along with the Medicare-Medicaid Coordination Office, the Innovation Center is empowering states to invest in new models targeted toward beneficiaries that are eligible for both Medicare and Medicaid, a group of beneficiaries at particularly high risk for having multiple chronic health conditions and high health care costs.
- CBO Recommendation: Limit the costs of intervention.
 - Innovation Center action: The Innovation Center is testing several new payment models, such as the Pioneer ACO Model and the Bundled Payments for Care Improvement, with no upfront payments to participating doctors and hospitals. Rather, these groups will be rewarded once their innovative approach is proven to have reduced costs and kept patients healthier.

The Innovation Center is committed to rapid cycle evaluation. Instead of the usual process of waiting until the testing and evaluation are completed, the Innovation Center is monitoring the

outcomes of the initiative as it is ongoing. We are hopeful to identify early indicators of success or failure and make any necessary modifications to the model as may be necessary. Once testing has begun, the Affordable Care Act requires the Innovation Center to terminate or modify the model, unless the Secretary determines that the model is expected to improve the quality of care without increasing spending; reduce spending without reducing the quality of care; or improve the quality of care and reduce spending. The statute is clear that a model must reduce spending without reducing the quality of care, or improve quality of care without increasing spending (among other requirements) in order to be expanded by the Secretary through rulemaking.

Question 6

Members of this Committee have heard significant concern from the kidney care community that patient access to quality dialysis care could be disrupted if the payment adjustment to the Medicare ESRD bundle contained in the fiscal cliff bill is not properly designed and implemented. As you know, these patients are some of the most vulnerable—approximately 87 percent of patients are Medicare beneficiaries and nearly half are dual eligibles. Do I have your commitment that you will implement the bundle adjustment fairly to ensure that reimbursement remains adequate to maintain patient access to high quality care?

Answer: We agree with the importance of appropriate payments to ensure access to dialysis treatment for ESRD beneficiaries. Section 632 of the American Taxpayers Relief Act of 2012 requires that the ESRD prospective payment system (PPS) rate be reduced beginning in 2014 to reflect the change in utilization of drugs and biologicals from 2007 with 2012. Before we make any changes to the ESRD PPS rate, we will carefully analyze the data on utilization and include the proposed payment change based on the data in a proposed rule for public comment. We will review comments taking into consideration issues raised by stakeholders to ensure that beneficiaries continue to have access to the medications they need before we make a final decision on the payment change. To date, the bundled payment system has not comprised access or availability of care. Any further changes will continue strong access and improved quality of care.

Question 7

Recent changes to the statute governing Medicare quality improvement organizations (QIOs) give CMS broad authority to modify aspects of the program, including the geographic scope of the QIO jurisdictions? What are the agency's plans for the future of the QIOs with regard to the geographic scope of the program?

Answer: CMS is currently in the process of evaluating how to structure the QIO contracts in the 11th Statement of Work (SOW) using the flexibility and new authority provided in the Trade Adjustment Assistance Extension Act of 2011. We plan to capitalize on the strengths and institutional knowledge of the QIO program that have been built throughout the years.

Under the 11th SOW that we are developing, we will ensure that no locality will lose access to a Medicare QIO. CMS is still determining precisely how many QIO contracts will be awarded; however, CMS will require that every QIO—regardless of the size of its jurisdiction—reach providers and beneficiaries at the local level. We also understand the importance of involvement

of physicians in the peer review process. CMS' best success in transforming health care is to drive quality improvement at the local level.

Question 8

Last year, former Administrators of CMS met with the Senate Finance Committee to discuss alternatives to the sustainable growth rate (SGR). According to testimony from these former Administrators (from both parties), all agreed that CMS consider moving the physician rate setting function within CMS or create an independent physician Advisory Board that would assign the relative value for physician services. What is your opinion on this?

Answer: The rate-setting process for the Physician Fee Schedule (PFS) is complex. Each year, through notice and comment rulemaking, we develop and propose appropriate adjustments to relative value units (RVUs). We consider and respond to all timely public comments, including those from medical specialty societies, as well as from a committee comprised of physicians representing various specialties that was formed to review codes and estimate the resources involved with furnishing a service (such as clinical staff time, supplies, and equipment used in the provision of these services). We consider recommendations made by this committee as well as from MedPAC and other stakeholders in establishing the final relative values each year. In recent years, CMS has focused its work on identifying misvalued codes in order to eliminate mispricing in the fee schedule. We plan to continue that work and welcome input regarding how to improve the process.

Question 9

Recent press articles have raised concern that oncology clinics may have to close their doors or sell their practices to hospitals given concerns about inadequate Medicare reimbursements for cancer drugs due to sequestration. Have you met with stakeholders on this issue, and is CMS monitoring the potential consolidation and closures that are predicted?

Answer: We share your concern about the potential adverse impacts of the payment cuts mandated by sequestration, both with regard to Medicare payments, and more broadly across all government programs. That is why the Administration has indicated that we stand ready to work with Congress on balanced approaches to replace sequestration to avoid its adverse impacts. CMS is committed to preserving Medicare beneficiaries' access to quality health care. We will continue to monitor the impact of provider payment cuts mandated under the Budget Control Act to assess their impact on Medicare beneficiaries and we are happy to share our results.

Question 10

While you have been Acting Administrator, what work has CMS engaged in to advance SGR reform? Will you commit to making SGR reform a priority if you are confirmed as Administrator?

Answer: The current SGR system creates a level of uncertainty for the physician community, for our beneficiaries, and for the health plan payment systems that are tied to the physician

payment system. It can be challenging to manage the programs with an ever-present risk of significant cuts. I am committed to working with Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. The Administration supports replacing the SGR with a period of payment stability lasting several years to allow time for the continued development of scalable accountable payment models. Such models would encourage care coordination, reward practitioners who provide high quality, efficient care, and hold practitioners accountable through the application of financial risk for consistently providing low quality care at excessive costs.

To help inform future reforms to physician payment systems, CMS is testing a variety of models through the Innovation Center that improve care quality, coordinate care, and reduce the total cost of care. For example, the Comprehensive Primary Care Initiative is a multi-payer initiative where CMS pays primary care providers monthly care management fees for comprehensive care management on top of their regular Medicare Fee-for-Service payment. After two years, CMS offers the providers the chance to share in any savings they generate. Other payers, often including Medicaid, are also providing enhanced payment for primary care services.

Another model is the accountable care organization (ACO). In addition to the Medicare Shared Savings Program, we are testing the Pioneer ACO model and the Advance Payment ACO model. ACOs involve groups of doctors, hospitals, and providers that accept accountability for providing high quality coordinated care to Medicare beneficiaries. ACOs are eligible for shared savings and may be subject to losses.

Finally, the Bundled Payments for Care Improvement initiative is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. We think episode-based payment has a lot of potential to transform the health care delivery system.

Question 11

You have expressed your commitment to addressing behavioral health issues as Administrator of CMS. The number of tragic incidences involving people with serious mental illness – both as victims as well as perpetrators - seems to be escalating in number and magnitude over the last several years. What efforts are underway to ensure that Medicare and Medicaid beneficiaries with mental illness are receiving appropriate care and have access to adequate treatment options?

Answer: CMS agrees that behavioral health issues are a serious concern, particularly in light of the number of tragic incidences involving people with serious mental illness. CMS programs help to ensure that people on Medicare and Medicaid have access to needed mental health services and other treatment options. Under the Medicaid program, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit ensures that the health care needs of children and youth are addressed to maximize their growth and development, including prevention and early identification of mental health and substance use conditions. And for Medicare beneficiaries, Part B covered preventive and screening services cover depression screenings. These are just some of the ways the Medicare and Medicaid programs work to ensure beneficiaries' access to preventive care to more effectively identify and manage mental illness.

Question 12

In Texas, 9.7 percent of adults have been diagnosed with diabetes. (The U.S. average is 9.3 percent.) For minority communities in Texas, the numbers are even worse. Eleven percent of Hispanics and 16.5 percent of African Americans have been diagnosed with diabetes. In what ways is CMS working to address this health crisis and do you believe CMS has a role to play in ensuring thorough, yet timely review of new technologies and treatment options that could improve the quality of care for diabetes patients?

Answer: CMS 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. For beneficiaries' ongoing care, accountable care organizations (ACOs) are a CMS initiative to better coordinate care, which is particularly important for patients with multiple chronic conditions. ACOs are designed to promote accountability for a patient population, coordinate items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. ACOs have the ability to redesign care to address their unique circumstances, patient populations and local community needs. Many ACOs have indicated that they plan to focus on chronic disease, patients transitioning care and high risk patient populations.

This is also addressed through the Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) model, which is testing the effectiveness of providing incentives directly to Medicaid beneficiaries of all ages who participate in MIPCD prevention programs, and change their health risks and outcomes by adopting healthy behaviors. A total of ten states are participating in this model.

Question 13

You have indicated that CMS is now moving into a third phase of anti-fraud measures (i.e., use of moratorium authority). This authority would allow you to impose temporary moratoria on problem providers applying for Medicare participation numbers. Thus far, this authority has not been exercised. For instance, in 2010, 65 new provider numbers were established for new home health agencies in Miami-Dade county alone. Can you (1) explain how and why this happened; and (2) explain how, as Administrator of CMS, you would exercise your moratorium authority and when you will begin using it.

Answer: Currently all providers, including home health agencies, can enroll in Medicare so long as they meet our current eligibility application processes and enrollment standards.

The use of an enrollment moratorium is a significant and powerful tool Congress provided us to fight fraud in Medicare and Medicaid under the Affordable Care Act. I take the authority to impose the use of this tool very seriously. We are closely evaluating the use of the enrollment moratorium authority in areas at high risk of fraud.

Since passage of the Affordable Care Act, CMS has implemented a comprehensive anti-fraud strategy that is using increased and enhanced provider enrollment checks, the ability to stop payments during an investigation of fraud, new requirements on ordering and referring high risk services, and a new predictive analytic claims screening system (using additional resources provided in the Small Business Jobs Act of 2010).

While CMS has yet to impose a moratorium, I have directed the agency to take implementing steps to impose one if warranted. In February 2011, CMS issued final regulations setting out the criteria to be used when imposing a temporary enrollment moratorium on providers and/or suppliers under the Affordable Care Act. (See 75 Fed. Reg. 5862, Feb. 2, 2011). Because the moratoria authority extends beyond Medicare to also Medicaid, the agency is currently evaluating the impact moratoria would have on access to providers and suppliers in both programs. While high utilization and costs may be a factor in determining if there is a “significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type or particular geographic area,” it is not the deciding factor in whether a moratorium is warranted. We want to carefully strike a balance between combatting fraud in high-risk areas and making sure beneficiaries will not be adversely impacted by a moratoria. As detailed in our regulations we would announce any moratorium in the Federal Register explaining our underlying rationale for taking such action in the areas in which it would apply.

Question 14

The Food & Drug Administration reported this year that there are 200 fewer mammography facilities and nearly 1,000 fewer mammography scanners available to American women than in 2007, when several major Medicare imaging payment reductions were implemented. Centers for Disease Control and Prevention data also indicates that mammography screening rates have fallen slightly over the 2003 through 2010 period. In light of the critical role that early detection can play in improving clinical outcomes, is CMS monitoring the impact that Medicare payment rate cuts may be having on beneficiary access to important diagnostic imaging services, like mammography?

Answer: Medicare covers screening mammograms to check for breast cancer once every 12 months for all women with Medicare 40 and older. Beneficiaries pay nothing for the test if the doctor or other qualified health care provider accepts assignment.

We believe access to these preventive services are important and are monitoring access to care.

Question 15

Is CMS monitoring potential health care consolidation that may result from policies set forward in the PPACA, such as accountable care organizations? Can you share this information with Congress?

Answer: We are aware that hospital acquisitions of other health care entities, such as physician practices, by hospitals have been commonplace in the last few years. One of the ways that we are encouraging competition in hospital markets is through the operation of the Medicare accountable care organizations (ACOs). We 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.

CMS is providing aggregate claims data to the antitrust agencies to assist them in ensuring ACO formation and implementation does not have a detrimental effect upon competition. The antitrust agencies have existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct. In addition, we believe 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. I would be happy to work with you and your staff on how we can improve on these efforts.

Questions from Senator Carper

Question 1

I think we can all agree that on the importance of curbing waste and fraud in Medicare and Medicaid. The GAO estimates that for fiscal year 2012, improper payments for both programs totaled \$63.5 billion. In addition, the Attorney General also notes billions more in fraud.

The good news is that this figure is down slightly from the previous two years, even as overall spending on the two programs has increased. The bad news is that we still have a long way to go. However, I think it is also important to recognize that the Centers for Medicare and Medicaid Services, under your leadership, has continued to put strengthened controls and procedures, including the use of advanced cutting edge data analysis, as a high priority. The Centers for Medicare and Medicaid Services has adopted the philosophy of preventing waste and fraud, as opposed to simply pursuing "pay and chase" where the agency would make bad payments and then try to chase them down for recovery.

Ms. Tavenner, during last congressional session, I joined with a bipartisan list of 37 Senate colleagues in legislation to take a number of important steps to fight waste and fraud in Medicare and Medicaid. Many of these ideas were even adopted by your agency, even without the bill becoming law. I also very much appreciate the fact that your staff reviewed the "Medicare and Medicaid "FAST" Act, giving a lot of important technical advice. We plan on reintroducing a new and improved version of the bill this spring.

Do you see some ongoing opportunities for continued improvement in the fight against Medicare and Medicaid waste and fraud? Do you believe that this progress represents significant savings for both programs?

Answer: I appreciate your interest in improving the Medicare and Medicaid programs and combating the fraud, waste and abuse that could put these important programs at risk. As you know this administration considers fraud prevention a top priority and we appreciate the opportunity to work together to combat fraud in the Medicare, Medicaid, and CHIP programs. I

challenge my management team each and every day to improve the way we do business and I have made it clear that combatting fraud, waste and abuse in all of our programs is a top priority. We are continually looking at ways our Center for Program Integrity can leverage the expertise of other CMS components, our contractors and other partners, such as the States, OIG, FBI and the Department of Justice.

I know you have been following the results of the FFS Recovery Audit program closely and to date the RACs have recovered more than \$4 billion dollars. CMS is using new cutting-edge fraud prevention tools such as automated provider screening and predictive modeling on fee-for-service claims to help the agency stay one step ahead of fraudsters. We are also collaborating with new partners on fraud prevention in unprecedented ways through our joint HHS-DOJ HEAT Task Force, our Health Care Fraud Prevention Partnership (HFPP) and our Fraud Prevention System (FPS).

Pursuant to new authority and resources provided under the Small Business Jobs Act of 2010 CMS began screening all fee-for-service Medicare claims through a predictive analytic modeling system similar to that used by financial sector companies to identify fraud. To build the system CMS contracted with leading private sector companies that bring significant experience in the field of predictive analytics to the Medicare program. Since June 2011 the FPS has screened over a billion claims for suspicious billing activity. In its first year of implementation the FPS identified or prevented \$115.4 million in inappropriate payments, generated leads for 536 investigations, and augmented information for 511 pre-existing investigations.

As you know CMS was provided several new tools under the Affordable Care Act to strengthen our fraud prevention efforts and stop improper payments particularly with respect to high risk providers such as home health agencies and DME suppliers. For example, the Affordable Care Act gave CMS the ability to use enhanced screening measures on all providers before letting them bill the Medicare program. Under our new screening rules, new DME suppliers and home health agencies will be subject to higher levels of screening. We are also improving the enrollment standards for DME suppliers. Over the last four years, the Administration's enforcement efforts have recovered \$14.9 billion, up from \$6.7 billion over the prior four-year period. Since 1997, the HCFAC Program has returned more than \$23 billion to the Medicare Trust Funds.

Question 2

I recently went to visit the Mayo Clinic and UnitedHealth and found that both health care providers and private insurers understand the pressing need to move away from fee-for-service payments in Medicare as quickly as possible. Many doctors and hospitals have recommended bundled payments as a promising way to pay for improved health outcomes and higher quality care.

What does CMS need to expand bundled payments throughout Medicare more rapidly?

Answer: The Bundled Payments for Care Improvement initiative is testing whether a single bundled payment for an episode of care can improve coordination between health providers. We are testing this idea against four separate model designs. In January 2013, the Innovation Center announced the participants in Model 1, which tests bundled payments for acute care hospital stays, as well as the participants in Phase One of Models 2 through 4 of the Bundled Payments for Care Improvement Initiative. Phase One is the initial period of the initiative where the participants and CMS prepare for implementation and assumption of financial risk by sharing data and information. Phase Two will begin this summer. Because we began testing in January, I do not have results to report yet. We are happy to work with you to provide updates on results as they become available.

Question 3

I see Medicare Advantage (MA) as a promising solution to move us away from fee-for-service Medicare more quickly. However, we have to ensure that we don't spend more on these private plans than we do in traditional Medicare and we also need to make sure that Medicare Advantage plans are fully available as a competitive option to all Medicare beneficiaries. I'm particularly concerned about states like Delaware and as many as nine other states that have 10 percent or less of our populations in Medicare Advantage plans, partially because there are often few MA plans to choose from.

What could we do to expand Medicare Advantage and ensure that seniors in all of our states have a meaningful choice between high quality Medicare Advantage plans and traditional Medicare? At the same time, how could we ensure that traditional Medicare is able to compete with Medicare Advantage plans more effectively?

Answer: Many beneficiaries have several high quality Medicare Advantage plan choices. People with Medicare will have access to 127 four and five-star Medicare Advantage plans, 21 more top-performing plans than the previous year. Additionally, 30 percent of stand-alone prescription drug plans available to beneficiaries received a star rating of 4 or higher. More than 37 percent of Medicare Advantage enrollees are now enrolled in a four- or five-star plan.

To help provide beneficiaries with high quality care, CMS is working to make FFS care as strong as possible, with ACOs and other models, to better coordinate FFS care. At the same time, we want to make sure that our managed care program is as strong as possible and that we are incentivizing plans to improve their quality. CMS is focused on making sure both programs are as strong as possible so even if beneficiaries don't select managed care, or do not have all the choices that other parts of the country have, they still receive the same care coordination and that high-quality managed care offers.

Question 4

The federal government and states have paid out over twelve billion dollars to providers, doctors and hospitals for the electronic health record implementation incentive program. There is concern that this program has not delivered on the significant improvement in care that is given to U.S. citizens through expanded and improved data sharing across providers.

Can you explain what CMS is doing to adjust the program so that these monies are invested more effectively to enable patient's data to "electronically" follow the patient better as they move through the healthcare system? This would improve the coordination and quality of care delivery while reducing cost by eliminating duplicative services.

Answer: Health IT that enables the secure exchange of information across providers is crucial to reforming the system, and must be a routine part of care delivery.

I assure you that electronic health record technology will be significantly improved when Stage 2 begins in 2014. This is due to the efforts of nearly 1,000 participants representing more than 500 organizations from the health information technology standards community working with us over the past two years.

In Stage 2, providers will have to demonstrate that they can exchange structured clinical summaries with other providers, regardless of the providers' EHR vendor, and vendors will have to demonstrate that they can support this interoperability. The Stage 2 final rules define common content, format, and structured data for these summaries and include basic clinical information regarding the care provided, such as medications, upcoming appointments, or other instructions.

CMS will also increase its emphasis on ensuring electronic exchange across providers through many of its policies and programs. We, along with the Office of the National Coordinator, have issued a request for information (RFI) seeking public input on what policies we believe will strengthen the business case for electronic exchange across providers to ensure patients' health information will follow them seamlessly and securely wherever they access care.

Question 5

My understanding is that there has been some significant delay, over a year since it was approved by the FDA, of making a new innovative imaging technique that contributes to the diagnosis of Alzheimer's disease available to Medicare and Medicaid beneficiaries. This delay continues despite the joint development and endorsement by both the Alzheimer's Association and the Society for Nuclear Medicine of Appropriate Use Criteria that provides physicians with a best practices diagnostic pathway for their patients with cognitive impairments.

Could you explain how this new technology is outside the "reasonable and necessary" for the "diagnosis or treatment" standard which governs what the CMS should be making available to Medicare and Medicaid beneficiaries?

Answer: CMS is actively engaged in reviewing new technology to ensure timely access to innovation for our beneficiaries. In October 2012, we opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans, which provided national coverage of PET using only specified radioisotopes for certain indications, and conditional coverage for additional uses under the process known as Coverage with Evidence Development (CED). Reconsideration of this NCD was requested by a stakeholder to consider coverage of PET using a new type of radiopharmaceutical approved by the FDA in 2012 to image beta-amyloid plaques

in certain patients being evaluated for Alzheimer’s disease and other causes of cognitive decline. To help inform this evidence review, we convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in January 2013. A proposed coverage decision is expected by July 2013, with a final decision (including consideration of public comments) expected by October 2013.

Question 6

Given that Congress extended the CBP single payment amount to retail settings, retailers will now have the same financial incentives to limit the range of diabetes testing supplies available. A group of stakeholders recently asked CMS to extend these patient protections to the retail channel, and CMS responded that it would monitor implementation to see if these protections prove to be necessary.

If CMS felt that these protections were necessary to protect beneficiaries in anticipation of the CBP in mail order contexts, why does the agency not think that these same protections will be necessary in retail settings?

Answer: Retail pharmacies do not have all of the same incentives as mail-order contract suppliers in terms of providing certain items. We note that retail pharmacies do not have to bill Medicare on an assignment-related basis, while mail-order contract suppliers do, and therefore can charge customers more than the Medicare-approved amount for diabetic test strips (which is commonly referred to as balance billing). Notice and comment rulemaking was required to include the non-discrimination requirement as a term of the contract for suppliers under the national mail-order program for diabetic testing supplies. CMS will be closely monitoring access to necessary diabetic supplies following implementation of the new payment amounts, but we do not believe it is necessary to initiate rulemaking for the retail setting at this time.

Question 7

Accountable Care Organizations and bundling payment programs present opportunities to lower costs and achieve higher quality care by changing payment incentive structures to encourage greater cooperation and coordination among providers. At the same time, these programs create incentives that could have the inadvertent effect of denying patients access to the most appropriate treatment for their condition as providers are now focused on shared savings and quality metrics.

How is CMS assessing the impact of the ACO and bundling arrangements on patient access to medical specialists and advances in medical treatments and technologies? What safeguards are in place to ensure clinically superior procedures/technology are not sacrificed purely for ACO participants to reduce costs and increase financial gain through “shared savings?”

Answer: CMS’ first and most important responsibility is to ensure that its beneficiaries receive appropriate, high-quality care. The fee-for-service payment structure does not always incentivize quality or efficiency, since it pays for the quantity of care instead of the quality of care. Medicare is trying to transform the care delivery system by implementing effective practices that deliver higher quality care.

ACOs are working to encourage providers to work together to provide more coordinated care to their patients. ACOs agree to take responsibility for the cost and quality of their patients' care, to improve care coordination and safety, and to promote appropriate use of preventive health services. In return, if they meet quality standards, they may receive a portion of any savings gained. ACOs must meet performance measure standards on quality of care and patient satisfaction in order to receive any shared savings monetary rewards. Those measures include patient surveys about their doctors, shared decision-making, access to specialists, and health status, as well as patient safety measures such as hospital readmissions, medication reconciliation, and avoidable admissions. These quality and patient satisfaction measures provide an important incentive to ensure that providers use effective care that results in positive outcomes, even if the treatments required to achieve these outcomes are more costly in the short run.

Questions from Senator Roberts

Question 1

The ACA depends on an adequate supply of physicians, especially primary care physicians. This is not a new issue. Many reports state that in fact we should expect access issues because there will not be enough physicians to meet the expanded demand. Yet, I've heard feedback that CMS objects to innovation in GME programs that provide support for primary care that would allow the money to follow the resident, and other novel proposals. What approaches does CMS support and would CMS propose to address this issue?

Answer: CMS agrees that ensuring an adequate supply of physicians is crucial to the success of the Affordable Care Act. The Affordable Care Act amended the Social Security Act to allow any time spent by residents training in a nonprovider setting to count toward direct graduate medical education (GME) and indirect medical education (IME) costs if the hospital incurs the costs of residents' salaries and fringe benefits. This change was effective for cost reporting periods beginning on or after July 1, 2010, for direct GME, and for discharges occurring on or after July 1, 2010, for IME and was finalized in the Calendar Year 2011 Hospital Outpatient Prospective Payment System final rule. This change was expected to lead to an increased number of residents training in nonprovider sites such as community-based settings. Because funding for Graduate Medical Education is awarded based on a statutory formula, CMS may not have flexibility to consider all innovative approaches. The President's budget includes a proposal that would give the Secretary the authority to set standards for teaching hospitals receiving Graduate Medical Education payments to encourage training of primary care residents and emphasize skills that promote high-quality and high-value health care delivery. I look forward to working with you on this and other ideas to improve Graduate Medical Education.

Question 2

ATRA directed the agency to reduce the ESRD PPS base rate in light of the significant reduction of drug utilization, which has coincided with an increase in the rate of non-bundled services (e.g., blood transfusions). How does the agency plan to ensure that:

- a. **The new PPS rate is adequate so dialysis providers aren't incentivized to inappropriately reduce necessary care in order to reduce costs, and**
- b. **in the face of incentives to reduce costs, that treatment decisions will not be detrimental to patient health and quality care and that the penalties for failing quality metrics be of sufficient consequence (financial or otherwise) to incentivize provider achievement and maintenance of quality guidelines.**

Answer: Before we make any changes to the ESRD PPS rate as required by section 632 of American Taxpayers Relief Act of 2012, we will carefully analyze the data on utilization and include the proposed payment change based on the data in a proposed rule for public comment. We will review comments taking into consideration issues raised by all interested parties to ensure that beneficiaries continue to have access to the medications they need before we make a final decision on the payment change.

Since the implementation of the ESRD PPS in January 2011, CMS has monitored real-time health outcomes and usage rates of ESRD-related drugs, biologicals, and related procedures for Medicare beneficiaries receiving outpatient maintenance dialysis. We will continue monitoring outcomes and access of ESRD beneficiaries as we implement the payment change required under section 632 of the American Taxpayers Relief Act of 2012.

Question 3

The recent crisis with the New England Compounding Centers and the meningitis outbreak has generated renewed interest in compounding and compounded products. Can you clarify CMS policy as it relates to compounded products? There is some confusion in this area. I have heard that CMS has a broad policy not to reimburse for compounded products. However we also believe that there have been LCDs that contradict this NCD. In addition I am under the impression that CMS has codes for compounded products. Clarity on CMS policy in this area would be appreciated.

Answer: We share your concern for the safety of drugs used by Medicare and Medicaid beneficiaries. While we believe that most patients' needs can be met with Food and Drug Administration (FDA)-approved drug products, we also believe it is medically appropriate for some patients to receive compounded drugs in certain situations, including when patients are allergic to inactive ingredients in FDA-approved drug products, or when dosage forms or strengths of drugs that are needed by the patient are not available in FDA-approved drug products. In such cases, we think it is appropriate for Medicare to pay for compounded drugs (when they meet other criteria for coverage and payment) to ensure beneficiaries and recipients have access to clinically appropriate drug therapies.

Compounded drugs may be covered under Medicare Part B when the compounded drugs are created by a pharmacist in accordance with the Federal Food, Drug, and Cosmetic Act and when their use meets all other criteria for services incident to a physician's service. Medicare Part D plans may cover multi-ingredient compounds that contain at least one ingredient that is a Part D drug (i.e., it contains an ingredient that is an FDA-approved drug product). Additionally, Medicare Part D plans may pay for only those ingredients within the compound that

independently meet the definition of a Part D drug. Consequently, Medicare Part D plans may not cover compounds made entirely from bulk active pharmaceutical ingredients.

Question 4

The number of tragic incidences involving people with serious mental illness and substance use disorders seems to be escalating in number and magnitude over the last several years. At the same time innovative treatments are being approved by the FDA that patients don't have access to. What are the most prominent barriers to access, for the Medicare and Medicaid populations, for all FDA-approved products that have been shown to be safe and effective to treat people with serious mental illness and substance use disorders? What are your suggestions for making these treatments more accessible to the Medicare and Medicaid populations?

Answer: Medicare and Medicaid beneficiaries have access to FDA approved products (for Medicaid beneficiaries, subject state supplemental rebate policies). CMS takes seriously issues of access to care for the Medicare and Medicaid populations and will be happy to work with you and your staff on specific issues related to access to benefits.

Questions from Senator Bennet

Question 1

In Colorado, we have a number of CMS activities, including the Comprehensive Primary Care effort, Medicaid Accountable Care Organizations, Bundled Payment pilots, the Care Transitions program and the state innovation model. But while Coloradans have embraced transformation and innovation, they will need leadership from CMS to help navigate how all of these programs fit together. How is CMS planning to eventually integrate the results of all these various programs state-by-state to transform the delivery system?

Answer: We are testing a number of ideas -- both at the local and national level and within different geographical settings -- that address the best way to change the incentive structure, reward integrated care, and explore payment alternatives to the fee-for-service system. There is no one solution to lowering costs while improving care across all populations, providers, and care settings.

One of our first considerations when deciding whether to test a model is whether a model will be able to be expanded if it succeeds. Finding those types of successful models that can affect the Medicare or Medicaid on a large scale is the purpose of our Center for Medicare and Medicaid Innovation, and that is why we are testing a broad range of models.

Since Medicare and Medicaid serve diverse populations in different settings, we know that every model may not be able to be expanded universally because it may not be applicable for every beneficiary or community. But, every model we test could potentially be expanded in some way. For example, a model that is tested in part of a frontier state could be scaled to serve beneficiaries in other frontier states. A model that succeeds in a rural area might not be appropriate for a large urban center, but we believe it is important to test models that may hold

answers for rural communities, or for certain populations, even if they may not be expanded to every community nationwide.

Question 2

For years, Congress has been looking for bipartisan ways to replace the Medicare fee-for-service system with a new payment reform that pays for quality—not quantity of service. While we wait for the results of various demonstrations and pilot projects, can CMS give any immediate options to Congress on ways to replace the Medicare fee-for-service system?

Answer: As you mentioned, CMS is testing a variety of payment models that seek to better integrate care and better incentivize quality. We are also eager for results from these new payment models. For example, the Comprehensive Primary Care Initiative is a multi-payer initiative where CMS pays primary care providers monthly care management fees for comprehensive care management on top of their regular Medicare Fee-for Service payment. After two years, CMS offers the providers the chance to share in any savings they generate. Other payers, often including Medicaid, are also providing enhanced payment for primary care services.

Another model is the accountable care organization (ACO). In addition to the Medicare Shared Savings Program, we are testing the Pioneer ACO model and the Advance Payment ACO model. ACOs involve groups of doctors, hospitals, and providers that accept accountability for providing high quality coordinated care to Medicare beneficiaries. ACOs are eligible for shared savings and may be subject to losses. Finally, the Bundled Payments for Care Improvement initiative is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. We think episode-based payment has the potential to transform the delivery system.

Question 3

We recently held a roundtable on mental health issues with Colorado mental health stakeholders. The participants highlighted issues regarding the rules and regulations around mental health treatment in both Medicare and Medicaid. Providers in Colorado tell me that Medicaid and Medicare have different rules on who can provide certain kinds of treatment, where they can be provided, and what services are covered. These different rules lead to an extraordinary amount of extra paperwork and billing time, all time that could be spent with patients. As we hope to see more alignment of mental health services with primary care, as Administrator, would you prioritize aligning the rules and regulations of mental health services between Medicare and Medicaid?

Answer: I've been on the other side of regulations, and know we need to reduce the regulatory burden on hospitals and health care providers, so they can focus on the important work of serving their patients. CMS is aware that different rules between Medicare and Medicaid can cause confusion for both providers and beneficiaries. To help address these differences, the Medicare-Medicaid Coordination Office has launched the Alignment Initiative, with the goal to more effectively integrate the Medicare and Medicaid programs. Partnering with States, health care providers, caregivers and beneficiaries, CMS is working to improve quality, reduce costs and improve the Medicare-Medicaid enrollee experience. Through the Alignment Initiative, the

Medicare-Medicaid Coordination Office seeks to transcend boundaries, facilitating a national conversation with stakeholders from around the country to identify opportunities for alignments and to improve the two programs.

CMS is streamlining regulations that have been identified as unnecessary, obsolete, or excessively burdensome on health care providers. Under the President's Executive Order on Improving Regulation and Regulatory Rules, we have already finalized two regulations that will reduce this burden-. The first rule revises the Medicare Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). CMS estimates that annual savings to hospitals and CAHs will be approximately \$940 million per year. The second, the Medicare Regulatory Reform rule, will produce savings of \$200 million in the first year by promoting efficiency. This rule eliminates duplicative, overlapping, and outdated regulatory requirements for health care providers.

Question 4

Alzheimer's disease is estimated to cost the nation \$200 billion this year alone, and about 70 percent of that - \$140 billion – is shouldered by taxpayers in Medicare and Medicaid costs. If the current trajectory holds, this number will exceed \$1 trillion annually in the coming decades. Leading experts and the government have stressed the value of an early and accurate diagnosis in treating Alzheimer's to prevent costly and time-consuming misdiagnoses, and the need to begin proper care planning earlier. At the same time, companies have been working to create diagnostic tests that could lead to an earlier finding of Alzheimer's. As diagnostic technologies for Alzheimer's and other diseases continue to be developed and gain approval by the FDA, what measures can CMS take to prioritize coverage of diagnostic tools, particularly when early diagnosis of diseases like Alzheimer's and others can lead to dramatically lower costs?

Answer: CMS agrees that tackling Alzheimer's disease is a national priority. We are an active participant in the National Plan to Address Alzheimer's Disease, established by the Department of Health and Human Services (HHS) pursuant to the National Alzheimer's Project Act (NAPA) enacted in January 2011. The National Plan sets forth five goals, including the development of effective prevention and treatment approaches for Alzheimer's disease and related dementias by 2025. A National Alzheimer's Project Advisory Council (including a senior CMS representative) meets quarterly to discuss the efficacy of government programs in this area, and annually evaluates and updates the National Plan.

We are also actively engaged in reviewing new technology to ensure timely access to innovation for our beneficiaries. In October 2012, we opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans, which provided national coverage of PET using only specified radioisotopes for certain indications, and conditional coverage for additional uses under the process known as Coverage with Evidence Development (CED). Reconsideration of this NCD was requested by a stakeholder to consider coverage of PET using a new type of radiopharmaceutical approved by the FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline. To help inform this evidence review, we convened a meeting of the Medicare Evidence Development and

Coverage Advisory Committee (MEDCAC) in January 2013. A proposed coverage decision is expected by July 2013, with a final decision (including consideration of public comments) expected by October 2013.

Question 5

CMS recently announced that they will postpone rulemaking on Stage 3 meaningful use requirements until early next year. Timely implementation of Stage 3 meaningful use requirements as well as provider and hospital adoption of electronic health records are critical to improving patient outcomes and facilitating health care savings. As the Food and Drug Administration releases their Unique Device Identifier (UDI) System final rule in the coming year, can you comment on ways that CMS could link UDI to improvement in health outcomes?

Answer: CMS and the Office of the National Coordinator are working together to accelerate health information exchange (HIE) and build a seamless and secure flow of information essential to transforming the health care system. We do not expect a delay in Stage 3 implementation. In 2013, CMS is focusing on successful implementation of MU2, program integrity, advancing interoperability, achieving alignment across programs, and hitting clear adoption targets by year's end. We think it is important to have an opportunity to learn from stakeholders during meaningful use implementation, and use this feedback to inform Stage 3.

We continue to coordinate with a wide range of stakeholders, including our federal partners, to inform the electronic health records system and our quality measures. CMS and FDA work in a partnership that is facilitated by a formal Memo of Understanding (MOU). The partnership between the agencies enhances information sharing efforts, promotes efficient utilization of tools and expertise for product analysis, validation and risk identification, and build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics and medical devices.

Question 6

What steps do you plan to take to improve CMS' ability to measure the quality of care provided in ACOs? I see many providers in my state of Colorado willing to implement innovative technologies that are clinically appropriate, but they are concerned that quality measures do not always keep up. What steps can CMS take to ensure that the use of such clinically appropriate technology and implementation of new innovations will not result in the provider being penalized on their quality score? Is there a mechanism to adjust the quality scores where quality measures may not have caught up to advanced care delivery?

Answer: In the Medicare Shared Savings Program, accountable care organizations (ACOs) are accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. ACOs have significant flexibility to invest in redesigned care processes for high quality and efficient service delivery, including implementing innovative technologies.

The quality metrics proposed for ACOs and finalized after consideration of public comments were a careful balance between ensuring that quality of care is maintained while decreasing the reporting burden on ACOs. CMS is committed to developing and adopting a mix of process,

outcome, and patient experience of care measures, including measures of safety, care transitions, and changes in patient functional status. As the science of quality measurement evolves, we will be able to make determinations on which measures are the most meaningful to providers and health care professionals and will most effectively drive progress and improvement. In future rulemaking for the Medicare Shared Savings Program, we anticipate reviewing the selected quality measures and seeking public comment on other measures that could be used by ACOs.

Question 7

Section 1341 of the Affordable Care Act establishes a transitional reinsurance program intended to stabilize premiums for coverage in the health care marketplace from 2014 to 2016. The Act requires \$25 billion to be collected from health insurance issuers and group health plans, including self-insured employers, over the three-year period. Additionally, the HHS Notice of Benefit and Payment Parameters for 2014 (CMS-9964-P): Application of Transitional Reinsurance Program to Self-funded Health Plans proposes a national per capita fee in 2014 of \$63 per covered life, including employees, dependents, early retirees, and COBRA-eligible individuals. I want to ensure that my constituents still have access to robust, affordable, employer-sponsored health insurance. Has CMS performed an impact analysis of the effects of the transitional reinsurance fee on employer-sponsored coverage? In particular, how might it affect the cost to and coverage of dependents, early retirees, and participants?

Answer: The Affordable Care Act directs that a transitional reinsurance program be established to help stabilize premiums for coverage in the individual market from 2014 through 2016. The reinsurance program is designed to alleviate the need for issuers to build into premiums the risk of enrolling individuals with significant unmet medical needs. The program is expected to reduce premiums in the individual market by between 10 and 15 percent in 2014.

To assist with the development of the payment parameters used for reinsurance, HHS developed a model with reference to existing national models such as those used by the Congressional Budget Office and Office of the Actuary. The policy resulting from the model maximizes the range of health insurance issuers and self-insured group health plans contributing to the reinsurance pool, lowering the cost per enrollee to the extent possible permitted by the law. Both reinsurance and market reforms such as guaranteed issue should lead to fewer unreimbursed health costs, lowering the costs for issuers and group health plans.

Question 8

The American Taxpayer Relief Act included a payment adjustment to the End Stage Renal Disease bundled payment. The rebasing of dialysis care payment was estimated by CBO to be a cut of at least 4%. I have been hearing concerns from my constituents in Colorado that this could adversely impact patient access, particularly in underserved areas. Dialysis providers have expressed concerns that facilities could close. As CMS implements this payment adjustment, what measures will you take to monitor and protect access for patients?

Answer: We agree with the importance of appropriate payments to ensure access to dialysis treatment for ESRD beneficiaries. Since the implementation of the ESRD PPS in January 2011,

CMS has monitored real-time health outcomes and usage rates of ESRD-related drugs, biologicals, and related procedures for Medicare beneficiaries receiving outpatient maintenance dialysis. We will continue monitoring outcomes and access of ESRD beneficiaries as we implement the payment change required under section 632 of the American Taxpayers Relief Act of 2012.

In addition, before we make any changes to the ESRD PPS rate, we will carefully analyze the data on utilization and include the proposed payment change based on the data in a proposed rule for public comment. We will review comments taking into consideration issues raised by stakeholders to ensure that beneficiaries continue to have access to the medications they need before we make a final decision on the payment change.

Question 9

As you know, the pediatric dental benefit is an essential health benefit that may be provided as part of a comprehensive package or a standalone dental plan. Nevertheless, recent pronouncements from CCIIO regarding the offer and purchase of the pediatric dental EHB have resulted in confusion in the marketplace. Specifically, on the Colorado exchange, the pediatric benefit must be offered but its purchase is not required. Outside the exchange, the purchase is mandated (even for childless adults) and responsibility for the reasonable assurance that an individual has purchased the pediatric dental benefit of purchase rests with the major medical carrier. This lack of equitable treatment of the pediatric dental benefit inside and outside of the exchanges may preclude children from receiving access to important oral services from their current stand alone dental plan, which is required by the ACA. Has CMS considered how this differing treatment in the Exchange will impact coverage of and access to dental care for kids? Can you ensure that CMS will provide equitable treatment for the pediatric dental benefit?

Answer: CMS has taken steps to implement the provisions regarding the pediatric dental essential health benefit in a manner that is consistent with the statute and provides as many consumer protections as possible. Essential health benefit requirements mandate that certain issuers offer certain benefits, but do not require individuals or families to obtain coverage for a particular benefit. The Affordable Care Act requires issuers offering non-grandfathered coverage in the individual and small group markets to offer the essential health benefits. Section 1302 of the Affordable Care Act also allowed issuers in an Marketplace to not offer pediatric dental coverage if there is a stand-alone dental plan offering the pediatric dental essential benefit operating in that exchange. Outside the Marketplace, issuers are required to offer all essential health benefits, including the pediatric dental essential health benefit; however, the essential health benefit final rule provided a clarification regarding situations in which issuers outside of Exchanges would not be found to be non-compliant with the requirement to offer essential health benefits. In situations in which an issuer is reasonably assured that an individual has purchased a Marketplace-certified stand-alone dental plan, that issuer, as a matter of compliance with section 2707(a) of the Affordable Care Act, would not be found non-compliant.

Questions from Senator Cardin

Question 1

In the Affordable Care Act, the Finance Committee and then the Congress clearly instructed your agency to establish an essential health benefits package that included a pediatric dental benefit. Congress did not intend to create a market advantage for stand-alone dental plans over an affordable pediatric dental benefit embedded in a comprehensive plan.

In addition to the clear language of the ACA, you have also heard about this issue from several members of this Committee, urging you to follow the law and to not permit stand-alone dental plans to require an additional out-of-pocket limit for stand-alone plans in addition to the limit already established by the law. Your own Director of Medicare, Jon Blum, said to this Committee that it is a mistake to “silo” oral health care and treat it separately, as we once did with mental health care.

In your final rule for state exchanges, you allow each state to determine its own separate pediatric dental out-of-pocket limit, creating a patchwork of unequal benefits across the nation. Congress did not permit states to set their own out-of-pocket limits for the comprehensive health plans—why are you discriminating against oral health? Then in the federally funded exchange rule, you proposed a separate out of pocket limit for pediatric dental plans of \$1000. When asked whether the limit was \$1000 per family or per child, the staff who wrote the proposed rule said they didn’t know which. Later, we were told that the high out-of-pocket limit was to ensure that plans’ premiums would be affordable. But the health plans’ own analysis says differently.

You also said that it would be too complex for dental insurance companies to coordinate benefits and determine when the out of pocket maximum had been met in the medical plan. But in CHIP, there is a limit on out-of-pocket expenses on both the medical and dental side. Those out of pocket expenses need to be coordinated between medical and dental plans. It is not the families’ burden.

I have reviewed the Stabenow-Lincoln Amendment that “allow(s) stand-alone dental plans to offer the required pediatric dental services and allows them to be offered in the individual and small group markets including within the insurance exchanges.” I have also reviewed the transcript of Committee’s deliberations on the ACA. It is the view of the Finance Committee that nothing in the Stabenow-Lincoln amendment, the final law, or the committee’s deliberations was intended to remove the ACA’s consumer protections from, or impose additional cost-sharing requirements upon, enrollees in stand-alone pediatric dental policies. This was not based on Congressional intent and is in fact, contrary to the ACA as written.

In what part of the law was CMS given the authority to eviscerate consumer protections for children enrolled in stand-alone dental plans? What in the law gave CCHIO the authority to permit stand-alone plans to require an additional out-of-pocket limit above and beyond what is in the law?

Answer: CMS has taken steps to implement the provisions regarding the pediatric dental essential health benefit in a manner that is consistent with the statute and provides as many

consumer protections as possible. It is important to remember that when provided under a separate policy, certificate, or contract of insurance, or when they are otherwise not an integral part of the plan, limited scope dental benefits are excepted benefits, as defined by PHS Act section 2791 (and its implementing regulations at 45 C.F.R. § 146.145(c)), and thus not subject to the requirements of Parts A and B of Title XXVII of the PHS Act. This means that stand-alone dental plans are not subject to the insurance market reform provisions of the Affordable Care Act that amend the PHS Act and generally apply to non-grandfathered health plans in the individual and group markets inside and outside the Marketplace, such as guaranteed availability and renewability of coverage.

In light of this, CMS sought, through the regulatory process, to apply as many consumer protections as possible. These protections include prohibition on annual and lifetime limits (45 CFR 155.1065(a)(2)), as well as a modified standard for the annual limitations on cost-sharing (45 CFR 155.150(a)).

In addition, the final essential health benefits rule requires dental plan issuers to offer plans at either a low (70%) or high (85%) actuarial value. Actuarial value is a measure of expected plan spending across a standard population. This means that every stand-alone dental plan purchased in an Exchange will cover, on average, 70% or 85% of costs that individuals could be expected to incur in a year for pediatric essential dental benefits.

Finally, with respect to the annual limitation on cost sharing, the essential health benefits final rule provided that stand-alone dental plans covering the pediatric essential dental benefit must demonstrate that they have a reasonable annual limitation on cost-sharing, as defined by an Exchange. For coverage year 2014, CMS has interpreted a reasonable limit to be \$700 for a plan with one child enrollee or \$1,400 for a plan with two or more child enrollees. It is important to remember that these annual limits on cost-sharing are catastrophic limits beyond which all pediatric essential health benefits would be covered in full.

Question 2

In the ACA, CMS had ample opportunity to encourage the coordination of medical and dental plans. A number of states have been interested in requiring qualified health plans to embed dental in the medical plan under one premium. Why has CMS determined that states cannot require the embedding of dental benefits in medical plans?

Answer: CMS has interpreted section 1302 (b)(4)(F) of the Affordable Care Act to allow issuers in an Exchange to not offer coverage of the pediatric dental essential health benefit if an exchange-certified pediatric dental plan is offered in that Exchange.

Question 3

Is CCIIO policy consistent with the terms of the statute? The statute's limitations on payment of cost sharing reduction assistance for pediatric oral health coverage appear to be designed to ensure simply that QHPs that do not offer pediatric oral health benefits also do not receive cost-sharing reductions that instead are properly allocable to pediatric oral health services. Nothing in the provision of law cited by CCIIO appears to limit the entitlement itself, only the manner in which the entitlement is operationalized. Yet the

CCIIO policy appears to suggest that in cases in which children must be enrolled in two different plans, their cost-sharing entitlement will be reduced.

Answer: Yes. Section 1402(c)(5) of the Affordable Care Act states if an individual enrolls in both a QHP and a stand-alone dental plan, the provisions on cost-sharing reductions under sections 1402(a) and(c) of the Affordable Care Act do not apply to that portion of the cost-sharing reductions properly allocable to pediatric dental EHB. Thus, if an individual enrolls in both a QHP and a stand-alone dental plan offered on a Marketplace, cost-sharing reductions are not payable with respect to pediatric dental benefits offered by the standalone dental plan.

Question 4

What organizational options (such as linked offerings) can states – and the FFE – use to overcome the potential issues that arise when one EHB package is offered through two separate plans? CCIIO’s policy does not address the strategies that states might utilize – or that the FFE will use – in order to assure that proper QHP/stand-alone dental packaging occurs so that children receive the full benefits to which they are entitled and premium credits and cost-sharing reduction assistance to which families are entitled are allocated properly across both plans. Having the Exchange play this role is parallel to the one played by employer plans that offer their participants and their families a menu of both medical and dental benefit plan choices. The only difference is that Exchanges automatically would enroll the children in such families in the dental plan as well as in the QHP, while adult dental plan enrollment would remain purely optional and without financial assistance. CCIIO has not yet indicated what flexibility SBEs, SPEs, or the FFE will have to package offerings and coordinate enrollment in order to ensure that children secure full EHB-level coverage, while their families receive the full premium assistance and cost-sharing subsidy protection to which they are entitled.

Answer: Section 1311(d)(2)(ii) of the Affordable Care Act, codified at 45 CFR 155.1065 allows limited scope dental plans meeting the requirements of the pediatric dental essential benefit to be offered in a Marketplace either separately as a stand-alone plan or in conjunction with a qualified health plan. Thus, Marketplaces must allow for the offering of stand-alone pediatric dental plans as well as dental plans that are offered in conjunction with a QHP.

Question 5

Where in the law are you authorized to state that coverage for pediatric dental services is not required coverage?

Answer: Sections 1302 of the Affordable Care Act and 2707(a) of the Public Health Service Act are requirements on health insurance issuers in the individual and small group markets to offer essential health benefits; they are not requirements on individuals or families to obtain coverage for a particular benefit. Section 1302(b)(4)(F) of the Affordable Care Act allows issuers in an Marketplace to not offer pediatric dental coverage if there is a stand-alone dental plan offering the pediatric dental essential benefit operating in that Marketplace. Because of this specific statutory exception, qualified health plans in a Marketplace, which are either individual or small

group market plans, do not fail to be qualified health plans solely because they do not offer coverage of the pediatric dental essential health benefit.

Section 1501 of the Affordable Care Act added section 5000A to the Internal Revenue Code and requires that nonexempt individuals either maintain minimum essential coverage or make a shared responsibility payment. Some types of minimum essential coverage, such as Medicare, do not include coverage of the essential health benefits.

Question 6

I have also been engaged in ongoing discussions with you about protections for Medicare beneficiaries in private health plans, and I have mentioned one particularly troubling situation to you in recent months. It involves a private Medicare HMO plan in Maryland that terminated its agreement with a very popular provider group based at an FQHC with one week to go in the open enrollment period. The Medicare law only requires 60 days notice when a plan and provider terminate their contractual relationship without cause, and as it turned out, the plan chose to end its relationship with this provider group at the end of December.

Physicians tried to contact all beneficiaries but were unable to reach all of them. We later learned that when beneficiaries called the health plan in mid-December to ask if their doctor would be on the plan's panel in 2013, they were told "Yes, your doctor is still in our plan." What they weren't told was that a little more than 60 days later, that would no longer be the case. Despite my written request to you, and that of Maryland's health secretary, to provide these seniors with additional options, to extend their open season, CMS did nothing to help them.

On February 28, they lost their primary care physician. They are locked into this health plan until 2014, but they have lost their primary care physician. These are very vulnerable seniors who live in an area of Baltimore that is not affluent. Their doctors were based at a Community Health Center that was convenient to their homes. The nearest participating provider who is accepting new Medicare beneficiaries is now a long bus or cab ride away from their homes. In fact, the plan is in the process of terminating agreements with other providers who are based in Baltimore City and is moving to operate primarily in wealthier suburban areas. I'd like to hear from you that you are truly committed to the people CMS was created to protect, Medicare, Medicaid and CHIP beneficiaries. However, when viewed along with other recent decisions by this agency, it appears that you may be acting with greater concern for health insurance companies than you are for patients.

What will you do now to help these beneficiaries? What are you planning to do to protect other seniors from this type of abuse in the future? Will you support legislation that restricts plans from terminating contracts close to or during the open enrollment process? If not, why not?

Answer: The law establishes specific election periods during which beneficiaries can change MA plans. As a result, there is an ongoing special enrollment period for individuals that have the Low Income Subsidy. The existing special enrollment period would allow affected enrollees to

change, at any time. In addition, CMS has processes in place for assisting individuals on a case-by-case basis regarding their enrollment issues. Affected individuals who believe they enrolled in a plan based on misrepresented information about the plan can contact 1-800-MEDICARE to see if they can enroll in another plan.

We also become concerned when a network-based MA plan experiences a significant network change during the contract year. When this occurs, CMS reviews the situation to assure that the plan maintains an adequate network, follows our guidelines for member notification and mitigates possible disruption of care for the impacted enrollees.

When an individual enrolls in a MA plan, they are agreeing to receive Medicare benefits through the plan and its network of providers. An MA plan's provider network can change during the year and this possibility is conveyed to members through the plan's Evidence of Coverage, which is provided prior to the Annual Election Period for current members and upon enrollment for new members, and through CMS' educational materials, such as Medicare & You. To protect beneficiaries, CMS has requirements related to plan network changes. If an MA plan's provider network changes during the plan year, it must give its members at least 30-calendar days advance notice of the network change, and demonstrate that its network is still adequate to serve its members.

Question 7

According to 2 USC 906, which clarifies the application of the sequestration cuts to Medicare, it appears that sequestration should only apply to "services furnished during the one-year period beginning on the first day of the first month beginning after the date the order is issued." Stated another way, it appears that Medicare sequestration only should apply to services furnished on or after April 1, 2013 (i.e. the first day of the first month after the March 1, 2013 sequestration order).

However, CMS issued a guidance to health care providers which states that, "In general, Medicare FFS claims with dates-of-service or dates-of-discharge on or after April 1, 2013, will incur a 2 percent reduction in Medicare payment."

I am concerned that, by applying to home health claims submitted for an episode of care that ends after April 1, 2013, the guidance you have issued may be interpreted as affecting payment for services of that episode that were furnished before April 1, 2013. For example, it is unclear if payment for a claim submitted for an episode that began on March 25, but ends on April 15, 2013 will be reduced under sequestration for all of the services furnished under the episode, including services that were provided before April 1.

Does this mean that CMS would subject an entire home health episode of care that began on March 25 but ended on April 2 to the 2 percent reduction? If so, I believe such an interpretation is inconsistent with the statute and would ask that you issue further guidance clarifying that any home health services provided prior to April 1, 2013 will not be reduced.

Answer: Under the Budget Control Act, the sequester applies to Medicare outlays. Home health episode claim payment rates are based on the final day of the episode (the “through date”), rather than the first day of the episode. In addition, the final payment for an episode is made at the end of the episode. Accordingly, the 2% reduction applies to all episodes that have end dates on or after April 1, 2013, regardless of their start date, including episodes that began prior to April 1, 2013. For example, because the final payment for an episode ending on or after April 1, 2013 would be made on or after April 1, 2013, and the funds, or Medicare outlays, for such payment would leave the Trust Funds on or after April 1, 2013, the entire episode is subject to sequestration.

Question 8

In the recently released Call Letter for the 2014 plan year CMS identified concerns it had with the use of preferred pharmacy networks in the Medicare Part D program, particularly the potential for beneficiary disruption and travel costs, especially in rural areas. CMS also indicated it was concerned that the structure of some preferred networks may actually be increasing costs for the Medicare program. As the use of these networks has become more widespread in recent years and is expected to continue to grow, what actions has CMS taken, or does CMS plan to take, to ensure that the use of preferred pharmacy networks in the Medicare Part D program does not affect beneficiary access and health, lessen quality of care or increase costs to the Medicare program?

Additionally, the OIG recently released a report stating that gaps exist in CMS’s oversight of the Medicare Plan Finder reporting requirements. How is CMS ensuring that beneficiaries have access to all of the information they need about specific plan benefits, including whether or not a plan uses a preferred pharmacy network and which pharmacies are included in those networks?

Answer: Part D regulations that permit lower cost sharing at some “preferred” network pharmacies also require that such cost sharing reductions must not increase CMS payments. In order to ensure that Part D sponsors with preferred pharmacy networks are meeting this requirement, we have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks. Our initial results suggest that for some plans, aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks. Combined with lower cost sharing, we are concerned that these higher unit costs may violate the requirement not to increase payments to such plans. We have contacted the plan sponsors identified in our analysis to initiate the validation of our findings.

As we indicated in the 2014 Call Letter issued April 1, we strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to ensure that such networks promote price competition and lower costs in the Part D program. Opening preferred pharmacy networks to any pharmacy that can meet the network’s terms and conditions would also likely mitigate some beneficiary

disruption and travel costs, especially in rural areas. Mandating this policy for all Part D sponsors would require rulemaking by CMS.

Regarding the Medicare Plan Finder, the Medicare Plan Finder continues to be refined to make sure that it provides the most accurate information possible. As of April 2012, a beneficiary is now able to see drug price estimates that reflect if the pharmacy selected is preferred or non-preferred for a given plan. If a pharmacy is not in the selected plan's network, the full price of the drug is shown. Concerns about the Medicare Plan Finder being time-consuming may be a reflection of the increased number of inputs needed to generate an accurate cost estimate. Having the Medicare Plan Finder prompt the user for exact drug names, quantity and dosing regimen, Part D plan, subsidy eligibility, and choice of pharmacy provides beneficiaries access to highly valuable information, to help select the best coverage option and to anticipate medical expenses for the coming year.