Questions for the Record "Hearing to Consider the Nomination of Seema Verma to be Administrator of the Centers for Medicare & Medicaid Services" Before Senate Finance Committee

February 16, 2017

Questions for the record from Senator Chuck Grassley

1. Thirty million Americans suffer from a rare disease and many of these patients have no therapeutic option to address their condition. Timely access to innovative therapies for these patients with no other viable therapeutic options is critical. How can we ensure that Medicaid drug coverage processes include reviews by clinicians with expert knowledge and experience with the particular rare disease and its patient population?

Answer: If confirmed, I commit to working with you and your colleagues in Congress as well as the FDA and other federal agencies to prioritize access to innovative therapies for patients, especially our most vulnerable citizens who have unmet medical needs. I look forward to working with clinical experts and relevant federal entities to ensure patients' needs are at the center of decision making.

2. CMS invests heavily in the training expenses of psychiatry residents serving in both institutions for mental disease (IMD) and general medical inpatient psychiatric units. But IMDs rules either prohibit the small number of IMD teaching hospitals from serving adults with Medicaid, or restrict IMDs from caring for the most severely ill who need care for slightly longer lengths of stay (15-20) days.

This rule exacerbates the severe national shortage of treatment for people with severe mental illness. Resolving this issue would help with the shortage and would also provide psychiatrists in training with invaluable experience.

How can CMS maximize its psychiatry training investments in IMD teaching hospital settings?

Answer: As you know, the nationwide shortage of physicians and the more general health care workforce policy questions are central to the health care challenges our country faces. If confirmed, I look forward to implementing policies to address our nation's opioid epidemic and improving Americans' access to psychiatric care. As such, I will carefully review and evaluate IMD rules. I should also note that in accordance with my Ethics Agreement, which was previously provided to the Senate, because of my husband's practice as a psychiatrist with the Indiana Health Group, Indianapolis, Indiana, and his financial interest in the Indiana Health Group, I have agreed not to participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the Indiana Health Group, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). Under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required

to recuse myself from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group, or the discrete and identifiable class of persons or entities that includes Indiana Health Group. To the extent that I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

Questions for the record from Senator Pat Roberts

1. Health providers continue to ask for relief from the sheer amount of regulations that they must comply with, but also raise the issue of inconsistency in the application of rules and penalties that they are assessed. This is particularly true for our nursing homes. Ensuring program integrity and protecting our scarce taxpayers dollars are extremely important priorities for the agency. How do we balance those priorities so that we are striving toward quality improvements as opposed to our current enforcement system that is focused more on penalties? How would you work to provide more consistency in how regulations are applied?

Answer: I agree that program integrity and the safeguarding of our scarce taxpayer dollars must be a top priority for CMS. Additionally, the enforcement of rules that health care providers follow must be done consistently and fairly. In order to better treat and deliver high quality care to patients, health care providers are better served spending more of their time on health care, and less of it trying to guess which laws and regulations will be enforced at the discretion of a federal agency. The fair and consistent application and enforcement of the law will not only protect taxpayer dollars, but it will help enable health care providers to do what they do best.

2. Critical access hospitals are required to provide acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient. This Condition of Participation was long established and well understood by these key rural safety net providers. However, in the FY2014 hospitals IPPS final rule, CMS clarified they will also begin enforcing the condition of payment requiring physician certification that each patient will stay for 96 hours or less. Will you commit to reviewing this condition of payment and the effect it has had on our hospitals and beneficiaries in rural areas?

Answer: If confirmed, I look forward to working with you and your colleagues in Congress to ensure that critical access hospitals are best enabled to serve rural populations with the highest possible quality of care. I commit to working with you to review the impact of regulation on hospitals and beneficiaries, especially in rural and frontier areas. Rural providers and their beneficiaries face unique challenges, and CMS should prioritize communication and collaboration with rural providers and stakeholders early on in the regulatory process.

Questions for the record from Senator John Cornyn

1. Many states are using Section 1115 Medicaid waivers to provide flexibility and modernize their Medicaid program. It can take an average of 323 days from submission to approval, and have a lack of transparency during negotiations which leaves states and stakeholders in limbo.

- a. What do you think can be done to shorten this timeframe for approval?
- **b.** What can be done to make the approval/renewal process more transparent between CMS and states?
- c. What, if anything, should be done to improve oversight of Section 1115 waivers?

Answer: The uncertainty around the waiver approval process must change. The flexibility and incentives for states to innovate must be a top priority if we are to better care for our most needy citizens. If I am confirmed, I look forward to working with you to shorten and streamline the waiver approval process. Unfortunately, with the way the system is set up, states must report back to and receive permission from the federal government for even routine changes to their Medicaid programs. As a small business owner involved in the waiver process, I can attest that the uncertainty and lack of transparency you describe deters further innovations. As states are forced to spend a great deal of time and resources to receive approval for routine changes or updates to their program, far too often they decide that they don't have the resources or time to pursue more innovative approaches. This is especially important in a state like Texas, which is home to some of the most innovative health care thinkers and actors in the country. Allowing those health care organizations the flexibility to innovate, while being accountable to taxpayers and the citizens they serve, will reward reforms that work for patients. I look forward to working with you to improve the waiver process for Texas and other states seeking greater flexibility and consistency in waiver decisions.

- 2. Many states have been using waivers or demonstrations to operate portions of their Medicaid programs for years, sometimes decades. HHS estimates that a third of all federal Medicaid spending is made under demonstrations. Please outline your thoughts:
 - a. on the importance of evaluating the extent to which demonstrations are achieving the objectives of the Medicaid program; and,
 - b. whether continued review and approval of long-standing demonstration projects are necessary.

Answer: If I am confirmed, I will be committed to improving the waiver process and incentivizing innovation over redundant paper-pushing. We will review the extent and role of evaluations as well as the need for waivers for long-standing demonstration waivers that are performing well. States are best equipped to design and understand the unique needs of their own populations, so it is crucial to ensure the successful innovations continue and that even more innovations that prioritize patients' access to quality care are encouraged and tried without duplicative or unnecessary paperwork.

Questions for the record from Senator Richard Burr

1. Last October, the Centers for Medicare and Medicaid Service (CMS) issued a final rule titled, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities". The rule was designed to ensure protections are in place for seniors receiving care through these facilities. However, CMS' analysis shows that the cost of implementing these regulations will exceed \$800 million in the first year of

implementation alone, which could create access issues for patients currently receiving this care.

- a. As Administrator, how do you plan to balance the need for seniors to have access to safe high quality care, while ensuring that health care providers, including nursing homes and skilled nursing facilities, are able to continue to provide this care to beneficiaries?
- **b.** What solutions, if any, do you see to decrease compliance costs and ensure access to care and needed protections for seniors?

Answer: I have fought throughout my career for access to quality care and I appreciate that an insurance card does not equal health care by itself. If confirmed as CMS Administrator, I look forward to working with you to ensure that seniors have access to safe, quality care while also considering the impact of government actions on health care providers and their ability to serve their patients. It is essential that all CMS actions carefully consider the impact they have on health care providers and their ability to deliver quality care. I look forward to working with you to implement laws that allow health care providers to do what they do best: treat their patients. I will work with all parties and stakeholders to protect the doctor-patient relationship and root out inefficiencies so that greater care for patients and innovation may occur.

2. As you may know, the Patient Access and Medicare Protection Act of 2015 included a provision requiring the Secretary of Health and Human Services (HHS) to submit a report to Congress on the development of an alternative payment model (APM) for certain radiation therapy services this year. As Administrator of the Centers for Medicare and Medicaid Services (CMS), how will you ensure that the agency is engaging with the provider and patient community as it works on this report, and during the development of options for this APM and other APMs for specialty care?

Answer: Communication with providers on the development of the report is paramount to ensuring that the report is successfully completed, and, if confirmed, I will ensure that CMS engages with the stakeholder community.

Questions for the record from Senator Johnny Isakson

1. For Senators Isakson and Warner together- As part of 21st Century Cures, Senator Warner and I worked to include a provision that would provide a home infusion services payment for drugs administered through Durable Medical Equipment (DME) covered under Part B. CMS played a critical role in this success by providing thorough technical expertise to assist in the construction of this benefit. This was an enormous first step in allowing patients to receive care in their home at a lower cost than the hospital. I have seen the benefits of home infusion first hand and it is my hope that we will work together this year to expand this policy to antibiotics. I look forward to working with you and your staff to get the data needed to inform the inclusion of infused antibiotic drugs so as to further benefit patients that require home infusion therapy.

Answer: Thank you Senator Isakson and Senator Warner. If confirmed, I also look forward to working with you both on this priority.

- 2. There has been a lot of discussion around value-based pricing as a possible approach to addressing some cost barriers to drugs some patients are experiencing. As you know, currently any drug manufacturers must offer state Medicaid programs the lowest price it offers any other payer, except for Medicare Part D which is exempt from best price.
 - Do you think value-based drug pricing in Medicaid and other programs should also be made exempt from Medicaid Best Price?

Answer: If confirmed, I look forward to implementing payment reforms enacted by Congress to increase patients' access to medical therapies. I understand the importance of patients having access to life-saving and life- improving innovations. CMS should serve as a faithful steward of taxpayer dollars as it fulfills its role in ensuring Medicaid beneficiaries' access to care.

- 3. We are entering a new era where precision medicine can tailor treatments based on an individual's unique genetic makeup and target diseases that impact less than 1,000 patients per year, saving and lengthening lives while reducing unnecessary utilization. This type of innovation especially is critical for patients with rare diseases because in some instances a few extra weeks or months can mean so much to those patients and their families. A concern is that the Medicare prospective payment systems, which have been the underlying Medicare payment structure since the early 1980's, is ill equipped to support our beneficiaries in this new era. My Congressional colleagues previously have recognized this shortcoming, and now Medicare has some tools, including New Technology Add-On Payments and Pass-Through Payments for outpatient drugs. However, these programs are temporary fixes lasting only two or three years.
 - How can Medicare better incentivize the utilization and remove patient access barriers of innovative treatments currently on the market for rare and ultrarare diseases?
 - Does Medicare's current under-reimbursement of innovative therapies for rare diseases send a signal to the patient and provider community that Medicare does not prioritize access and treatment of rare diseases?

Answer: If confirmed, I will work closely with Congress, the FDA and other entities to ensure that the Medicare program has clear pathways for innovations that benefit patients including the millions of Americans suffering from rare diseases. I appreciate that Medicare should be a partner when it comes to ensuring that beneficiaries have access to cutting-edge therapies. Making sure that Medicare provides access to innovative treatments will be a top priority for CMS if I am confirmed.

4. I have heard from rehabilitation hospital facilities in Georgia that are concerned about the impact that the implementation of ICD-10 coding is having on a regulation applicable to them called the 60 percent rule. CMS has said there is monitoring of the issue, however there have been no changes made. I would appreciate if once confirmed, CMS review this more closely.

Answer: If confirmed I will review this policy closely and look forward to working with you and your staff to better understand how this impacts health care providers in Georgia and around the country.

Questions for the record from Senator Patrick J. Toomey

- 1. Since 2005, the Centers for Medicare and Medicaid Services have sought to restrict long-term care hospitals, known as LTCHs, from receiving more than 25 percent of their patients from a single acute care hospital. Worried that this arbitrary threshold would undermine access for very sick seniors to specialty hospitals, especially in non-urban communities, Congress has repeatedly intervened to block this proposal. Most recently, as part of the 21st Century Cures Act, Congress enacted legislation that I authored with Senator Bennet and Nelson to block the 25 percent rule through September.
- 2. Beginning later this year, LTCHs will be paid on the basis of a patient's physical condition. This new patient-specific criteria obviates any need to restrict payment on the basis of where the patient came from.
- 3. Will you commit to working with my office and other interested lawmakers to make sure that the implementation of the new payment criteria does not include a return to arbitrary thresholds like the 25 percent rule?

Answer: If I am confirmed, I look forward to working with you and your office as well as other members of Congress to develop and implement sound payment policies in accordance with the law. Patient access to quality care in the most appropriate setting for the patient and doctor must be a top priority for CMS.

Questions for the record from Senator Dean Heller

Medicaid Block Grants and Per Capita Allotment:

- **1.** Do you understand why states like Nevada are so concerned with the block grant approach?
- 2. How would you design a block grant that would still protect access to care for the Medicaid expansion population?
- **3.** What is your opinion on reforming Medicaid, so funding is based a per beneficiary allotment?
- 4. Would you take into consideration population growth?
- 5. Would you take into consideration the cost of care in rural areas?

Answer: If confirmed, I look forward to working with your office to implement any reform, whether it involves Medicaid block grants, per beneficiary allotments or other innovative ideas, which empowers our most needy citizens with access to quality health care, while supporting innovation efforts at the state level. At the same time, states must be held accountable to standards that result in better health care quality and access. Ultimately, Congress will decide on any proposals to strengthen the safety net for our most vulnerable citizens, and I look forward to providing any technical assistance that your office or other Members of Congress seek in the development of legislative reforms to the Medicaid program.

Medicaid Waivers:

- 6. What types of reforms have you worked on through the waiver process that you believe has increased coverage for those respective states?
- 7. How would you make it easier for states, like Nevada, that did not originally seek a waiver to go through that process and approve the types of reforms needed to protect the 600,000 Nevadans on Medicaid including 200,000 Nevadans that were eligible through the expansion?

Answer: Innovation starts locally, so if confirmed my job will be to work with Nevada and other states to tailor their Medicaid programs to the unique needs of their citizens. Working through the waiver process at the state level has provided me with the experience to know what works best and what doesn't work as well. I've also been able to learn what the federal government asks for and how they ask for it can slow or stop innovation. My experience at the state level reminds me that Washington often doesn't know best; in fact, Nevadans know better how to structure their programs and deliver care to their most needy citizens. I will make it a priority to ensure that Nevada is able to understand the process from beginning to end. Communication and collaboration with your office, other members of your delegation and stakeholders from around the state is crucial. I commit to working closely with you as early and often as needed.

Questions from State Legislature:

- 8. What steps do you plan to take to ensure that the more than 88,000 Nevadans who have purchased health insurance through the Silver State Health Exchange continue to have the ability to purchase health insurance with adequate coverage in a transparent marketplace?
- 9. What steps do you plan to take to ensure that the more than 77,000 Nevadans who are eligible for federal tax credits under the Affordable Care Act to help purchase private insurance will continue to have access to affordable health insurance options with adequate coverage?
- 10. What steps do you plan to take to ensure that the 217,000 Nevadans who are receiving health care under the Medicaid expansion remain covered?
- 11. The Affordable Care Act guarantees coverage vital to preventative services for women, including cancer screenings and birth control. What steps do you plan to take to ensure that the Affordable Care Act's coverage guarantees remain intact for women's health?
- 12. The Affordable Care Act guarantees that Nevadans with pre-existing conditions will not be denied health care and ends lifetime minimums on coverage. It also allows younger people, many of whom are saddled with college debt and cannot afford insurance, to stay on their parents' insurance until they are 26. What steps do you plan to take to preserve those coverage guarantees?

Answer: If confirmed, I will work to ensure that any legislation enacted by Congress is implemented with the utmost care for Nevadans. I am fully committed to ensuring all Americans have access to affordable health care of the highest quality that meets the unique and important needs of their families.

Questions for the record from Ranking Member Ron Wyden

Corporate Relationships:

- 1. As discussed in the hearing and in news media accounts, you and your firm, SVC, Inc., contracted with the following firms: Electronic Data Systems (EDS), Hewlett Packard Enterprises (HP), Milliman, Inc., Highpoint Global, Roche Diagnostics, Health Management Associates (HMA) and Maximus, which provide health program services and products to the State of Indiana, or represent that they have.¹ Please provide the following for each of these corporate relationships:
 - a. The dates you or your firm entered into contracts or subcontracts with each of these companies.
 - **b.** The scope of work you or your firm performed for each contract or subcontract with these companies.
 - c. The amount of money you or your firm was paid for work that was completed under each such contract or subcontract.

Firm	Dates	Scope	Approximate Revenue		
Electronic Data	See Fn. 2 ²				
Systems (EDS)					
Hewlett Packard	2008-Present	Training, communications,	\$725,000 (invoices		
Enterprises		analysis of federal/state	2011 to present only)		
		actions			
Hewlett Packard	2015-Present	2015-Present Communications assistance \$10			
Enterprises		specific to federal/state			
		regulations and compliance			
Milliman Actuaries	2013-Present	Development of 1115 and	\$1,500,000		
		1915c/b waivers			
Milliman Actuaries	2012-Present	1915 waiver development,	\$5,000		
		ACA impact analysis, and			
		policy implementation support			
Milliman Actuaries	2015-Present	1115 waiver drafting and	\$150,000		
		managed care regulation			
		impact analysis			
Milliman Actuaries	2013-2014	Technical assistance for	\$10,000		
		waiver implementation			
Highpoint Global	2016-Present	Provide subject matter	\$350,000		
		expertise for training materials			
		with CMS Assister Program			
Roche Diagnostics	2010-2012	Development of launch plan	\$30,000		

Answer:

¹ Inside Health Policy, <u>February 10, 2017;</u> IndyStar, <u>August 26, 2014</u>; Associated Press, <u>February 15, 2017</u>

² Due to the age of this work, specific responsive information was not located.

		related to Accu-Chek platform	
Health Management	2006-2011	Development of uninsured	\$300,000
Associates (HMA)		program	
Maximus	2016-Present	Provide curriculum	\$10,000
		development support for	
		Maximus Training Services	

Corporate Ethics Agreements/Disclosures:

- 2. For each of the corporate relationships identified in Question 1, please provide the following:
 - a. Copies of any ethics agreements you entered into with these companies, or ethics guidelines or contract terms you received from these companies, governing conflicts of interest for your engagement with them.

Answer: There were no separate ethics agreements entered into with these companies.

b. Any documentation showing the processes you were to follow if and when you were to recuse yourself with regard to conflicts of interest involving each company.

Answer: None, and none was required.

c. Any documentation showing any situations in which you actually recused yourself from matters related to these companies pursuant to these policies, guidelines, or terms.

Answer: None. Other than with respect to HP, there was not a situation for which my recusal was appropriate. I did not supervise any of the work performed by these other companies.

Post-Confirmation Corporate Recusals:

3. In its annual report to the Securities and Exchange Commission, Maximus says they are the largest provider of Medicaid and CHIP enrollment services in the U.S.³ In the same filing, Maximus states that HP is one of their major competitors in the health services sector. You have current contracts with both of them. As you've reported on OGE Form 278, you also have current contracts with HighPoint Global and Milliman, Inc. All four engage in activities funded through CMS. Your Ethics Agreement states you will need to get special approval to consider matters involving seven of the states for which you did consulting work, but it is completely silent on the question of what is required for you to consider matters involving your consulting work for these companies. The only specific corporate recusal in your Ethics Agreement relates to HMA, which is buying your consulting firm. Please describe your understanding of the

³ Maximus, Inc. SEC 10-K, November 21, 2016

extent to which you would need to recuse yourself from matters involving these other four companies.

Answer: My understanding is as stated in my Ethics Agreement and the Ethics Pledge. These documents are quite specific regarding my ethical obligations with respect to these four companies. My Ethics Agreement states: "I will not participate personally and substantially in any particular matter involving specific parties in which I know *a former client of mine is a party or represents a party*, for a period of one year after I last provided service to the client, unless I am first authorized to participate pursuant to 5 C.F.R. § 2635.502(d)." (emphasis added). The Ethics Pledge states: "I will not for a period of 2 years from the date of my appointment participate in any particular matter involving specific parties that is directly and substantially related to my former employer or former clients, including regulations and contracts."

State of Indiana Contracts:

4. Please identify, by contract number and date, each of your contracts with the State of Indiana and any related amendments thereto. Also, please provide the total award value of those contracts, to the present, and the total revenue amount from those contracts, to the present.

Contract Number	Date	Amendment(s)	Award Value
57464-000	July 19, 2011	57464-001	\$2,978,527
		57464-002	
		57464-003	
		57464-004	
		57464-005	
		57464-006	
80287-000	July 23, 2014	80287-001	\$4,851,400
		80287-002	
		80287-003	

Answer:

The approximate revenue from these contracts to date is \$5.3 million.

Oversight of Contractors in Indiana:

5. According to a recent press report, you were a member of a "group of health officials" that unsuccessfully pitched former Governor Mitch Daniels on health reform in 2006. You were also identified as "leading" that same group when it later successfully convinced Daniels to move forward with health care reform.⁴ In your biographical materials, you have also discussed your role as the architect of the Healthy Indiana Plan (HIP). As discussed in the hearing, it appears that you were advising the State at the same time that you had contracts with other vendors, including HMA. You also provided the Committee with a statement from then Secretary of the Indiana Family

⁴ CNN, <u>February 16, 2017</u>

and Social Services Administration (FSSA), John J. Wernert, which included the sentence: "Additionally, no consultant is allowed to oversee the work of a contractor with whom they have a separate professional relationship."

a. It appears that on or about May 1, 2006, you and your firm became a subcontractor to HMA on a contract HMA held with the State of Indiana to provide consulting services to FSSA. A May 1, 2008 amendment to a contract between Indiana and HMA shows that you received payments from the consulting firm for subcontract work beginning May 1, 2006.⁵ The original May 1, 2006 contract does not appear to be available in the State's public disclosure database. Please provide a copy of the original HMA contract with the State and a description of the scope of work HMA performed and that you performed under that contract, as well as under the subsequent contract amendment.

Answer: A copy of the contract is attached. Under that contract, HMA developed an uninsured program for the State of Indiana. The scope of work that SVC performed solely included provision to HMA of professional consulting services related to HMA's development of that uninsured program. I did not oversee HMA's work on this contract.

- b. On or about January 22, 2007, your firm received a sole source FSSA contract for coordinating development of a Request for Proposal to procure the services of a vendor to administer the "Governor's Plan for a Healthier Indiana."⁶ That same day, HMA received a sole source FSSA contract to develop and draft the Request for Proposal for the "Governor's Health Care Plan."⁷ It appears that the work scope in your contract required you to oversee the work of HMA contrary to FSSA policy. Please provide the following:
 - i) A description of the work you performed under your contract with the State.

Answer: It is not correct that the scope of work in the SVC contract included oversight of the HMA work under its contract. SVC and HMA had parallel but distinct roles, both under the oversight of state officials. Through SVC, I provided consulting services regarding preparation of an RFP for a vendor to administer the Governor's Plan for a Healthier Indiana. I provided project management services, technical assistance to contractors and to FSSA, and other assistance to the state in its development of the RFP, including reviews of drafts of the RFP.

ii) The justification provided for SVC, Inc. having been awarded a non-competitive contract.

Answer: The justification, as drafted and approved by State officials, was: "The contractor has been involved in the development of The Governor's Plan for a Healthier Indiana from its inception, and has intimate knowledge of its many parts. With the rapid timeframe required to develop the RFP, the State does not have the resources to bring another consultant up to speed.

⁵ Indiana SVC Contract (EDS: <u>A129-6-49-06-XE-2020)</u>

⁶ Indiana SVC Contract (EDS: <u>A129-7-49-07-XE-2730)</u>

⁷ Indiana Health Management Associates Contract (EDS: <u>A129-7-49-07-XE-2020)</u>

SeemaVerma Consulting is Indiana-based and has keen knowledge of the Indiana health care market place, which will be critical to developing the RFP. We have worked with her over the past 2 years and feel very comfortable with the quality of her work product."

iii) A description of your understanding of the scope of work that HMA was to perform and an explanation of how you interacted with HMA on this task.

Answer: As stated in HMA's contract, HMA was to "[D]evelop the draft and final version of the 'Request for Proposal' for the Governor's Health Care Plan. The contractor will review current commercial carrier Health Savings Account Plan structures, propose alternatives and opinions, conduct research as necessary, assure compliance and coordination with existing FSSA regulations, and provide technical assistance as required by FSSA or its contractors."

iv) A description of any role you played, if any, in the award of this HMA contract, including any documentation of any recusals related to the award or performance of this contract.

Answer: I had no role in the award of the HMA contract.

v) Please explain how you coordinated development of the State's RFP for HIP while HMA—with whom you had a prior financial relationship—drafted that RFP, without violating FSSA policy as described in Secretary Wernert's statement.

Answer: As the contracts make clear, I worked in conjunction with HMA on this effort but I did not oversee its work. When the State of Indiana develops RFPs for something as large and important as the Governor's Health Care Plan, it often procures services from several vendors who are assigned distinct tasks; that was the case here, such as actuarial services, and procurement specialists.

c. A fourth amendment to the HMA contract, prepared on April 20, 2012, appears to show that HMA billed Indiana for work with the Office of Medicaid Policy and Planning (OMPP) including for your firm's hourly rate from May 1, 2010 to June 30, 2011.⁸ Please provide the following:

i) A description of the consulting work performed under this contract by HMA for OMPP.

Answer: HMA provided "financial and/or business consulting services related to health care services to four (4) divisions of FSSA." Full details of the scope of these services are provided in the amendment to the contract.

ii) Confirmation of whether you and your firm were an active subcontractor on this contract during this period, or in the alternative, please provide the period of performance by you and your firm.

⁸ Indiana SVC Contract (EDS: <u>A129-6-49-06-XE-2020</u>)

Answer: Confirmed.

iii) A detailed description of the scope of work SVC, Inc. performed under this contract, specifically with OMPP between May 2010 and June 2011, and revenue received.

Answer: HMA and its subcontractors provided consulting services to Indiana Family and Social Services Administration in four areas: Transformation of Aging Services and operational and programmatic work for the Division of Aging; operational and financial management services for the Division of Mental Health and Addiction; and waiver system administration for the Office of Medicaid Policy and Procedures. The revenue received by SVC, Inc. between May 2010 and June 2011 for this subcontract was approximately \$500,000.

iv) Any documentation showing if you recused yourself when potential conflicts arose under this contract.

Answer: None. There was no potential conflict for which recusal was necessary or appropriate. SVC's separate work for FSSA did not involve oversight of this HMA contract and SVC played no role in FSSA's decision to award the contract to HMA.

- d. In December 2007, EDS was awarded a contract to "provide fiscal agent services for the Medicaid program for FSSA." You were included in the EDS contract, and paid through this contract as a subcontractor.⁹ These contracts were subsequently continued through HP. On February 21, 2012, an existing 2011 SVC, Inc. contract was increased by \$475,000 and amended to broadly increase the scope of SVC's work, including specifically overseeing "MMIS (HP) technical changes."¹⁰ It appears that the scope of work in this expanded contract required you to oversee work performed by HP contrary to FSSA policy. Please provide the following:
 - i) A description of the work, you performed under this contract with the State of Indiana with regard to MMIS.

Answer: Regarding MMIS, SVC worked with the State of Indiana and its vendors, including HP, to design systems for implementation of the Healthy Indiana Plan. We helped vendors translate the policy and waiver language into system operations. We did not oversee HP or any other vendor in this regard, and did not negotiate or participate in change orders or contract amendments. To the best of my recollection, State officials participated in all meetings with HP regarding the Healthy Indiana Plan work at which SVC representatives were also present.

- ii) A description of your understanding of the scope of work that HP was to perform and an explanation of how you and your firm carried out your work regarding HP on this task.
- ⁹ Id.

¹⁰ IN Contract EDS: <u>A129-1-29-11-ZN-1758</u> (first amendment).

Answer: HP prepared systems for the implementation of the Healthy Indiana Plan and all Medicaid programs. My firm and I worked with HP and the state's other vendors on this task, helping them to understand the program so they could make the appropriate technical changes to the system. In addition, please see the previous answer.

iii) A description of the work you and your firm performed under the EDS/HP contracts.

Answer: My firm and I performed a substantial amount of work on a variety of subjects; a comprehensive description of the scope of work is contained in the contract.

iv) Documentation of any recusals related to the performance of your State of Indiana contract with regard to EDS/HP.

Answer: None, and none was required.

State of Indiana Ethics Procedures:

6. In response to Senator Wyden's question regarding conflicts of interest during your time working with the State of Indiana, you responded that you recused yourself from meetings in which a potential conflict could arise: "I've been in meetings, where we were talking about contractors and talking about implementing a program. And when it came to a vendor that we had a relationship with, I would recuse myself. I would get up and leave the meeting so that there was never any issue."

In a written response—to the 2014 Indianapolis Star article regarding Hewlett Packard—provided to the Committee, you similarly stated "(i)f any issue between HP and the State presented a conflict between the two, I recused myself from the process."

a. Please describe the process for determining when a matter constituted a conflict. What agency official or officials determined such a conflict existed?

Answer: Consistent with the ethics opinion that I received, I recused myself from any matters related to HP's contract, the scope of its work, any change orders, its compensation, etc. Agency officials were fully aware of and supported this approach. I do not recall any other formal determinations regarding potential conflicts.

b. Please provide any written policies, agreements, or other communications documenting the nature of this conflicts process.

Answer: None.

c. Did this process apply to all of your clients, namely EDS, HP, Milliman, HMA, Roche Diagnostics, and Maximus? If not, which clients were not subject to this process and why?

Answer: Yes, I was alert to potential conflicts regarding all of my clients.

d. You have stated that you did recuse yourself. In which instances did you do so? Were these recusals documented? And if so, please provide this documentation.

Answer: I recused myself from any matters related to HP's contract, the scope of its work, management issues, any change orders, etc. If these issues arose during a meeting, I would remind the state employees of my relationship with HP and made clear that I would not be involved, and would leave the meeting.

e. In 2012, you requested an ethics opinion from the Indiana Ethics Commission with respect to your work for Hewlett Packard. Did you request ethics opinions for your work with EDS, Milliman, Inc., HMA, Roche Diagnostics, or Maximus? If so please provide copies of those opinions.

Answer: No. The scope of SVC's work for those other companies was narrower than the work involving HP.

f. Copies of any ethics agreements you entered into or ethics guidelines or contract terms you received from the State of Indiana for your work with the State governing conflicts of interest.

Answer: None, other than that previously provided.

Representation before State Agencies:

7. In two separate news articles, the former head of the FSSA in Indiana, Debra Minott, indicated that you represented Hewlett Packard in a billing dispute before a State agency—FSSA—for which you were a consultant. In an Indianapolis Star article, dated Aug. 26, 2014, which Senator Wyden quoted in the hearing, Ms. Minott is herself quoted:

"We had delayed paying an HP invoice because of an issue we were trying to resolve, and HP sent Seema to our CFO to resolve the issue on their behalf," Minott said. "I was troubled because I thought Seema was our consultant."

That article was updated and republished on November 29, 2016. More recently, the Associated Press published a story on Feb. 14, 2017, in which Ms. Minott reiterated that you had represented HP in this dispute. The AP article states:

"It was never clear to me until that moment that she, in essence, was representing both the agency and one of our very key contractors," said Minot(t), who was removed as head of the agency by Pence over her disagreements with Verma. "It was just shocking to me that she could play both sides."

a. Did you represent HP in a billing dispute with the FSSA as reported?

Answer: No. The only source for this allegation is Ms. Minot, a disgruntled former employee; to my knowledge, no one else has provided support for her assertions. Indeed, HP has made clear, as stated in the same AP article, that "it can find no one in its company with any recollection of such a meeting."¹¹ Further, Ms. Minot participated in a tour and briefing at HP's facilities on November 21, 2013 in which the HP-SVC partnership was specifically discussed and written materials were provided that documented the relationship. With that knowledge, Minot approved increases in the amount of SVC's contracts with the State thereafter. At no time during her tenure at FSSA did Ms. Minot ever express any concerns to me about SVC's work for HP.

b. Did you ever represent HP in any other matter before any Indiana agency or office? If so, when and in what capacity?

Answer: No.

c. Did you ever represent any other client, specifically EDS, HMA, Milliman, Roche Diagnostics, or Maximus, in any matter before FSSA or any other state agency or office? If so, when and in what capacity?

Answer: No.

Waiver Transparency:

- 8. The ACA required HHS to issue regulations that ensure the public has a meaningful opportunity to provide input on proposed Section 1115 waivers, including new applications and applications for waiver extensions. The rule HHS promulgated in February 2012 requires states to provide a 30-day public notice and comment period, set up a website for their proposal, and hold public hearings around the state, among other provisions. States are also required to submit an annual report to HHS that includes an evaluation of the changes' impact.
 - a. Do you believe that the details of a state's waiver request should be made available to the public in advance of the state submitting the waiver request to CMS?
 - **b.** Do you support requirements for the state and CMS to obtain and respond to public comments prior to a state deciding on whether to submit or CMS to approve or deny the request?
 - c. Will you maintain the Section 1115 transparency provisions that seek to improve public accountability and bring waiver negotiations from behind closed doors?
 - d. What additional steps will you take to ensure public participation in the waiver process and transparency in the negotiations between CMS and states seeking waivers?
 - e. Will you continue CMS's current practice of timely posting of waiver applications, approvals, and all supporting documents on the CMS website?

¹¹ <u>http://www.indystar.com/story/news/politics/2014/08/25/powerful-state-healthcare-consultant-serves-two-bosses/14468683/</u>.

- f. Will you require that every waiver application at a minimum provide a description of the demonstration and a specific listing of the waiver authorities requested and the intended use of the waiver requested?
- g. When issuing approvals, will you require that these approvals specifically list the waiver authorities that are approved and their approved use?
- h. Do you think amendments should be subject to the same transparency requirements?

Answer: If confirmed, transparency and consistency in the waiver process will be priorities for CMS. It is imperative that states are able to partner with CMS in a joint effort to update and modify their Medicaid programs to better serve their citizens. Clear and fair rules of the road are crucial for states' planning purposes as well as for the longevity and success of their Medicaid programs. If states are mired in paperwork and forced to redirect resources to unnecessary federal requirements, that means less resources are available to their most needy citizens. I pledge to work with states to make this process easier, more transparent and more efficient for both states and all impacted parties. Additionally, it is crucial that stakeholders receive an opportunity to provide input, so I look forward to communicating and collaborating with them, whenever appropriate.

- <u>President's January 20th Executive Order:</u> 9. On January 20th, the President issued an Executive Order instructing the Secretary of Health and Human Services and the heads of all agencies—which includes the CMS Administrator—to do everything possible to roll back the Affordable Care Act (ACA). If confirmed as CMS Administrator, you will be responsible for carrying out this **Executive Order.**
 - a. Based on your understanding, what are the specific actions that the CMS Administrator could take to carry out the President's January 20th Executive Order regarding the ACA?
 - b. If confirmed, which of those actions would you take as CMS Administrator to carry out the President's order?

Answer: If I am confirmed, I plan to review prospective options with CMS staff and others within HHS and the administration to better determine what can be done to undo or mitigate the harms created by the ACA. Once I evaluate the options, we will act accordingly to help Americans suffering from higher costs, fewer choices and less access to quality care.

Prescription Drug Prices:

10. Ms. Verma, during your nomination hearing I asked for one specific action you would take as CMS Administrator to curb the rising prices of prescription drugs, but you did not provide one specific idea.

As CMS Administrator you will have broad power, independent of Congress, to impact the cost of prescription drugs. For example, each year CMS publishes the Part D Call Letter and Rate Notice and also is able to propose changes to regulations regarding payment for physician administered drugs. Within CMS, the Center for Medicare and

Medicaid Innovation also has broad authority to test new payment models that could involve prescription drugs.

a. Please provide one specific action you would take as Administer to address the rising costs of prescription drugs.

Answer: I appreciate that drug costs are an important pocket book issue for many Americans. If confirmed, I will work with the CMS staff to evaluate potential options and ensure that beneficiaries' access to high quality and affordable drugs is a top priority for CMS. I look forward to reviewing relevant implementation issues, including items such as PBM contracts, when appropriate.

Medicaid Reform and Opioids/SUDs:

11. Opioid abuse (including heroin and prescription pain relievers) is contributing to a public health epidemic of significant consequence. In 2015, there were 20,101 prescription drug-related overdose deaths and 12,990 heroin-related overdose deaths. Medicaid is the primary payer for all substance use disorder services in the country and will be critical in the fight against the opioid epidemic.

Thanks to Medicaid expansion under the Affordable Care Act (ACA), an additional 11 million adults now have access to Medicaid. Over one million of these adults gained access to treatment for opioid abuse and other substance use disorders (SUDs). In states that expanded Medicaid, there are more physicians who can prescribe the drugs needed (e.g., buprenorphine) to help individuals overcome their addiction to opioids. Without the Medicaid expansion, fewer people would have access to Medication-Assisted Treatment (MAT) for opioid abuse and other substance abuse treatment. Furthermore, the ACA included addiction treatment as an essential health benefit that must be covered in all health plans.

a. Will you commit to advising against repeal of the Medicaid expansion resulting in over a million Americans with SUDs losing access to essential addiction treatment services?

Answer: It is critical that all Americans suffering from mental health and substance abuse disorders have access to the care they need. If confirmed, to the extent I am not required to recuse from a particular matter under the terms of my Ethics Agreement, I am committed to ensuring that access is not diminished.

b. Will you commit to advising against cuts to state Medicaid programs through block grants and per capita caps that put individuals struggling with SUDs at risk of losing access to their Medicaid coverage or benefits?

Answer: I support ensuring Americans have access to quality health care. It is critical that all Americans suffering from substance abuse disorders have access to the care they need. If confirmed, to the extent I am not required to recuse from a particular matter under the terms of my Ethics Agreement, I am committed to ensuring that access is not diminished.

c. Will you commit to ensuring states are required to cover behavioral health benefits such as treatment for SUDs as they cover services for physical health conditions?

Answer: If confirmed, I will implement the law as designed by Congress and I look forward to realizing reforms that put patients and their doctors in charge of their health care decisions, whether they involve physical or mental health conditions. As noted in my Ethics Agreement, referenced above, because of my husband's practice as a psychiatrist with the Indiana Health Group, Indianapolis, Indiana, and his financial interest in the Indiana Health Group, I have agreed not to participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the Indiana Health Group, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). Under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required to recuse myself from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group, or the discrete and identifiable class of persons or entities that includes the Indiana Health Group. To the extent that I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

d. What are your specific plans to address the opioid epidemic? What role should CMS play in this fight?

Answer: If confirmed, I will work with CMS to ensure that Americans suffering from mental health and substance abuse disorders have access to the care they need. Americans in CMS programs should have access to high quality health care and I look forward to partnering with HHS and other departments and agencies to address the opioid epidemic.

Medicaid Lock out:

12. During your nominations hearing, I asked about your Healthy Indiana Plan (HIP) 2.0.

a. Will Indiana be able to maintain eligibility under HIP 2.0 if the Medicaid expansion is repealed or if federal financial support of the expansion population is drastically reduced?

Answer: I cannot speculate as to what impact legislative changes that Congress has yet to make will have on Indiana's Medicaid program.

b. To clarify for the record, does your Healthy Indiana Plan 2.0 lock out an individual making \$12,000 a year from coverage if they cannot pay their premium for two months?

Answer: The state of Indiana's Healthy Indiana Plan's contribution requirements are not designed as a punitive measure but as a way to promote personal responsibility among members which has resulted in better health outcomes than traditional Medicaid. Only members above the poverty line are at risk of losing coverage for non-payment. Where HIP members are locked out

of coverage for six months for non-payment, those who fail to pay Marketplace premiums may have to wait until the next open enrollment period to regain coverage, which can be up to nine months, unless they have a change in circumstance that makes them eligible for a special enrollment period. On whole, HIP's non-payment policies for individuals above the poverty line are at least comparable to, if not more lenient than, the policies governing the Marketplace. Moreover, only 5 percent of former HIP members indicated they left the program due to affordability issues. Additionally, more than 80% of HIP members have indicated they would be willing to pay *more* to stay in the program, while more than half of those who left the program due to non-payment successfully transitioned to private health insurance coverage.

Family Planning:

- 13. Medicaid is the largest payer of reproductive health care and provides coverage to approximately 1 in 5 women of reproductive age. Family planning services and supplies, in particular, are provided special protections under the law. Not only are family planning services and supplies a mandatory covered service for both traditional and expansion populations, but federal law also protects the ability of Medicaid beneficiaries to choose any qualified family planning provider who participates in the Medicaid program, even if they are not in a health plan's network. The federal government matches family planning services at a rate of 90 percent to ensure that states provide robust coverage of birth control methods and related services.
 - a. Do you commit to maintaining the requirement that Medicaid beneficiaries have the freedom to choose their family planning service provider?

Answer: As a woman, I support ensuring access to health care for both women and men and a healthcare system that will provide access to quality care while ensuring patients are able to make decisions that work best for them.

b. Do you commit to ensuring that family planning services, including access to a person's preferred contraceptive methods, including IUDs, birth control pills, and implants, will remain available to all women?

Answer: I support a healthcare system that will allow women to make the decisions about what works best for them.

c. Do you commit to maintain the 90 percent federal matching rate for family planning services?

Answer: Changes in the federal matching rate are determined by Congress, so I look forward to enforcing the law as written by Congress.

Behavioral Health:

14. Ms. Verma, during your nomination hearing you did not answer Senator Menendez's question regarding essential health benefits and children with autism because you are recusing yourself from the topic of behavioral health due to your husband's profession

as a psychiatrist, pursuant to your Ethics Agreement. In order to clarify the issue, please answer the following:

a. What specific actions as Administrator will you be required to recuse yourself from that involve behavioral health? For example, implementation of MACRA involves physicians treating patients with behavioral health. How would you separate behavioral health issues from other patient groups while working on physician payment issues?

Answer: As noted in my Ethics Agreement, which was previously provided to the Senate, because of my husband's practice as a psychiatrist with the Indiana Health Group, Indianapolis, Indiana, and his financial interest in the Indiana Health Group, I have agreed not to participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the Indiana Health Group, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). Under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required to recuse from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group, or the discrete and identifiable class of persons or entities that includes Indiana Health Group. To the extent that I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

b. Will you meet with advocates for and providers of behavioral healthcare?

Answer: If confirmed, there will be certain situations where I would be able to meet with a particular provider of behavioral healthcare (or its advocates) and certain situations where I will be required to recuse. For example, if one specific provider of behavioral healthcare services, that is not the Indiana Health Group, requests a meeting to discuss settlement of litigation against that provider, I would be able to meet and listen to that provider's concerns. On the other hand, if a group of behavioral healthcare providers, requests a meeting with me to discuss health insurance coverage in the small group market for mental health services as an essential health benefit (EHB), I would recuse from this meeting. If I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

c. Behavioral health also includes substance abuse, including addiction to opioids. Are you recusing yourself from any issue related to opioid abuse?

Answer: As noted above, under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required to recuse from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group, or the discrete and identifiable class of persons or entities that includes Indiana Health Group. There will be certain situations where I would be able to participate in substance abuse matters and certain situations where I will be required to recuse. The analysis of my recusal obligation for a particular matter will be made on a case by case basis. To the extent that I have questions on how to apply my recusal

obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

d. What other specific patient types and/or issues will you recuse yourself from because of your husband's medical practice?

Answer: If confirmed, because of my husband's practice as a psychiatrist with the Indiana Health Group, Indianapolis, Indiana, and his financial interest in the Indiana Health Group, I have agreed not to participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the Indiana Health Group, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). Under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required to recuse from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group, or the discrete and identifiable class of persons or entities that includes Indiana Health Group. To the extent that I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

e. For each area you are recusing yourself, please provide the names and/or positions of the individual to whom you expect to delegate responsibility for such issue on behalf of CMS, or do you intend to seek waivers from the recusal requirement?

Answer: If confirmed, matters from which I am recused will be elevated to the HHS Deputy Secretary or the HHS Chief of Staff, as appropriate, for disposition without my input or recommendation. Additionally, once they are appointed I would designate certain members of my administrative staff and other appropriate CMS officials within my immediate office to screen matters that are covered by my recusal obligation, so that these matters are not given to me for action.

Alternative Payment Models in Medicare:

- 15. The previous Administration set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payments by the end of 2016 and tying 50 percent of those payments to alternative payment models by the end of 2018. CMS achieved its goal to alternative payment models into 30 percent of Medicare payments in March 2016—nine months earlier than expected.
 - a. Will you commit to supporting the previous Administration's goal of making 50 percent of Medicare payments through alternative payment models by 2018?
 - **b.** If so, what specific actions will you take—if confirmed as CMS Administrator—to reach that goal?

Answer: I look forward to reviewing the actions taken by health care providers and CMS to achieve this goal in order to determine what has worked and what we can improve upon

going forward. Additionally, it is crucial that we communicate with providers and stakeholders and seek their input as early in the process as appropriate.

Actuarial Soundness and Network Adequacy in Medicaid Managed Care:

16. In the final Medicaid Managed Care rule, released in May 2016, CMS strengthened actuarial soundness requirements for plans that contract with state Medicaid programs to provide health care services. The actuarial soundness provision requires states to pay health plans at a rate that is sufficient to provide, "for all reasonable, appropriate, and attainable costs," that are required under the terms of the contract and for successful operation of a managed care entity providing services to Medicaid beneficiaries. The final Medicaid Managed Care rule included provisions to increase the transparency and accountability in the development of health plans' capitation rates.

The final rule also includes important beneficiary protections. The new rule proposes important changes to increase the adequacy of provider networks in Medicaid managed care. States are required to set "time and distance" standards to limit how long or how far a Medicaid beneficiary has to travel in order to receive services from all types of providers. For long-term services and supports (LTSS) providers, who travel to beneficiaries, states must set similar time and distance standards. In addition, states must establish continuity of care policies for beneficiary transitions into or between managed care plans.

- a. Do you commit to maintaining the actuarial soundness requirements in the provision of Medicaid managed care?
- **b.** Do you commit to maintaining the increase in transparency and accountability in the capitation rate development process?
- c. Do you commit to maintaining time and distance standards to strengthen network adequacy for Medicaid managed care enrollees?
- d. Do you commit to maintaining the requirement for time and distance standards to be applicable to the 11 categories of providers specified in the final rule?
- e. Do you commit to maintain the requirement for states to consider the number of network providers who are not accepting new patients, the geographic location of network providers, the ability of network providers to communicate in non-English languages, and the ability of network providers to ensure accessible, culturally competent care to people with disabilities when setting their time and distance standards?
- f. What specific actions will you take to assure proper oversight of the implementation of the final Medicaid Managed Care rule?

Answer: If confirmed, I commit to thoroughly reviewing the rule with the utmost regard for the accessibility of high quality health care for all impacted Medicaid beneficiaries as well as state flexibility, efficiency and cost effectiveness.

Periodic updates regarding Affordable Care Act outreach and enrollment:

17. At Marilyn Tavenner's confirmation hearing for CMS Administrator, Chairman Hatch asked her to commit to providing bi-weekly updates on the establishment of the

Affordable Care Act (ACA)'s Exchanges and on enrollment. I request that you make a similar commitment to provide periodic updates to the Finance Committee.

- a. Will you commit to providing the members of the Finance Committee with periodic updates—both written progress reports and briefings—in the months leading up to and during ACA open enrollment periods?
- b. In addition to any available enrollment numbers, I would ask that those updates address technology functioning; marketing and outreach plans; operation of the call center, in-person assistance and staff working with the states; and any improvements or changes being made to the enrollment process. Do you agree?

Answer: If confirmed, I am committed to working with Congress to ensure you are updated on CMS activities. If I am confirmed, communication and collaboration with Congress will be a major priority for me and the agency.

1115 Waivers:

- 18. Under Section 1115 of the Social Security Act, the Secretary of Health and Human Services may waive certain statutory requirements of major health programs such as Medicaid as long as they further the purposes of the program. States have historically used waivers to expand coverage, strengthen benefits, and innovate in payment and delivery systems.
 - a. Do you agree that section 1115 experimental projects must "promote the objectives of the Medicaid Act?"
 - b. Do you agree that the objective of the Medicaid Act is to furnish medical assistance to low-income people and to furnish "rehabilitation and other services to help such ... individuals attain or retain capability for independence or self-care?" (42 U.S.C. § 1396-1).
 - c. Do you agree that a proposal that will clearly reduce access to medical assistance is inconsistent with the objectives of Medicaid?
 - d. Do you agree with the criteria the Centers for Medicare & Medicaid Services (CMS) currently uses to evaluate when a demonstration project promotes the objectives of Medicaid—that the demonstration will:
 - increase and strengthen overall coverage of low-income individuals in the state;
 - increase access to, stabilize, and strengthen providers and provider networks available to serve Medicaid and low-income populations in the state;
 - improve health outcomes for Medicaid and other low-income populations in the state; or,
 - increase the efficiency and quality of care for Medicaid and other low-income populations through initiatives to transform service delivery networks"?

Answer: I agree that experimental projects and demonstrations within the Medicaid program should reflect the overall objectives of the program, as defined by Congress. If confirmed, I look forward to reviewing any proposal put before me to determine whether and how it could impact beneficiaries in addition to ensuring the demonstration project is budget neutral to the Federal government.

President's January 30th Executive Order:

19. On January 30th, the President signed an Executive Order requiring the federal agencies revoke two existing regulations during Fiscal Year 2017 for every new rule they issue.

On Wednesday, February 15th, CMS released a proposed rule regarding the individual and small group health insurance markets.

- a. If confirmed as CMS Administrator, which two existing CMS rules or regulations would you repeal to account for the release of this proposed rule?
- b. For additional rules that CMS is statutorily required to publish this year, if confirmed as CMS Administrator, would you require that CMS publically identify which two regulations it plans to repeal at the same time as the new rule is proposed? If not, within what time frame will those two regulations be identified?
- c. What are some examples of current rules you would eliminate to comply with the arbitrary two for one rule reduction requirement? Would you rescind rules to comply with the executive order that protect public health or patient safety? How would you determine which rules would be rescinded when new rules are issued?

Answer: If confirmed, I will work with HHS and CMS staff to review all rules and regulations and ensure compliance with the President's Executive Order.

Home and Community-Based Services:

20. Federal Medicaid law provides states with flexibility to provide long-term services and supports (LTSS) through home and community-based services (HCBS) rather than in nursing homes or other long-term care facilities. To date, almost every state offers HCBS services to older adults and people with disabilities through waivers. HCBS waiver programs have helped 1.5 million Americans stay at home rather than move into a nursing home.

Section 2401 of the Affordable Care Act also authorized the Community First Choice Option to provide home and community-based services for people who otherwise would have to move into a nursing home. To encourage states to adopt the program, federal financial participation is increased by six percent. Today, eight states, including Oregon, and over 300,000 people are served by the program.

Baby boomers are reaching retirement age, and Americans are living longer. By 2030, older Americans will account for 20 percent of the nation's population. As a result, the demand for long-term services and supports including those offered at home and in the community is expected to increase dramatically.

a. Do you think the federal government should help states address the needs of a highcost, aging population?

- b. How do you think HCBS wait lists will fair with a 30-plus percent cut to Medicaid funding through block grants or per capita caps, which HHS Secretary Price proposed in his 2017 budget proposal as House Budget Committee Chairman?
- c. Do you support extending the Money Follows the Person program at current funding levels?
- d. Do you support the Community First Choice state option with the current federal matching levels?

Answer: Long-term services and supports are a vital part of the Medicaid program and will increase with the aging baby boomer population. I look forward to reviewing CMS's previous actions and prospective options to ensure our commitment to Americans with long-term care needs is met and that states have the flexibility to implement innovative programs that work best for the populations they serve.

Questions for the record from Senator Debbie Stabenow

1. Because of Medicaid expansion in Michigan, 650,000 people have insurance and uncompensated care has been cut by at least 50%. 30,000 jobs have been created and the state will end the year with \$432 million more than it invested in the program. Unfortunately, the one thing in common about every Republican proposal in front of Congress right now is cuts to Medicaid funding.

Do you support cutting funding to states to run Medicaid programs?

Answer: I support ensuring all Americans have access to quality health care. Medicaid's financing structure is determined by Congress so I look forward to collaborating with Congress and implementing the law as written.

- 2. A repeal of Medicaid expansion in addition to the block grant proposal supported by Speaker Ryan, Secretary Price, and many others would cut about \$2 trillion from the Medicaid program over the next 10 years.
 - a. Having worked closely with states and state budgets, including working with Michigan during implementation, if the Medicaid program was cut by \$2 trillion how would you advise Michigan absorb the loss?
 - **b.** Do you think it is possible to do without dropping eligibility, cutting services and providers, or raising state taxes?
 - c. Waivers are used to promote innovation how do you innovate without harming people if your budget is being decimated?
 - d. When you talked about state flexibility from federal regulations, should that include the ability to not follow federal mental health parity law?
 - e. Can you commit that you would not approve any waiver or regulation that reduces mental health protections under the Medicaid program?

Answer: If confirmed, to the extent that I am not required to recuse from a specific waiver or regulation under the Ethics Agreement I signed on January 31, 2017, I would evaluate each waiver that is elevated to the level of the CMS Administrator to ensure it meets the requirements

set out by law and to evaluate its impact on beneficiary access as well as budget neutrality requirements.

- 3. During the ACA debate, I was the lead sponsor of a provision that ensured maternity and newborn coverage would be guaranteed for women and their babies. Last Congress I led a bill with Senator Grassley called the Quality Care for Moms and Babies Act, which passed the Finance Committee. The bill would address performance measurement gaps in Medicaid and CHIP and create maternity care quality collaborates to share and adopt best practices.
 - a. Can you commit to work with me on this legislation, and work on driving down the maternal mortality rate?

Answer: If confirmed, CMS will be happy to provide technical assistance related to this legislation as well as other priorities of yours. Improving maternal and child health outcomes has been something I have focused on in my career so I look forward to working closely with your office on matters of great importance, such as the maternal mortality rate.

b. More generally, do you agree that it is critical to continue investing in health care quality improvement and measurement? How would you engage stakeholders from across the health care system to participate in the effort?

Answer: I believe that we should constantly be monitoring data and outcomes to ensure that patients are receiving quality care that improves health care outcomes.

- 4. One of the greatest threats to the Medicare program is Alzheimer's disease. We need a cure and research dollars to help us get there, but we also need the Medicare program to provide coordinated, thoughtful care to people living with Alzheimer's disease and their caregiver who shoulder so much of the burden. We made progress last year, as I was able to get a care planning benefit included in the program, which will help ensure better delivery of care.
 - a. Do you agree we could help shore up Medicare financing by tackling Alzheimer's disease care?
 - **b.** What steps would you take as CMS administrator to help families struggling with the diagnosis of Alzheimer's disease?

Answer: If confirmed I stand ready to partner with Congress, the FDA, NIH, and stakeholders to ensure that Medicare beneficiaries suffering from Alzheimer's are treated with dignity and compassion. Curing Alzheimer's would revolutionize the American health care system for the millions of families impacted by this disease.

5. The Patient Access and Medicare Protection Act helped stabilize patient access to radiation oncology services delivered in community-based clinics. The legislation also requested a report from CMS on the development of alternative payment models in radiation oncology by this summer. Radiation oncologists in my state are currently

working to develop alternative payment models that incentivize high quality care for cancer patients.

As Administrator, how would you consult with radiation oncology stakeholders, and others, on the development of APMs to ensure stability, patient access, and appropriate reimbursement?

Answer: If confirmed, I would ensure that CMS is consistently engaging stakeholders as policies and programs are developed and implemented to ensure we are achieving the best outcomes for patients. It is critical that we have open communication to understand their perspective, what they are going through, and what their challenges are.

6. How would changes to the Medicaid financing structure, such as a block grant system, affect Indian health programs?

Answer: Every state is unique with a different population and different needs. Congress ultimately decides how to reform Medicaid's financing structure, and I look forward to implementing whichever reforms they enact with the utmost care for those affected by those changes, including families in Indian health programs.

7. Would you protect the 100% FMAP for services provided through an IHS/Tribal facility?

Answer: If confirmed, I look forward to implementing the law as written by Congress. Questions related to the percentage of federal assistance are determined by Congress, so I stand ready to work with you and the rest of Congress to ensure the law is implemented appropriately.

- 8. In 2010, then Secretary Sebelius established the "Secretary's Tribal Advisory Committee" for HHS to hear directly from tribes on departmental policy development and budget proposals.
 - a. What, if any, input would you seek from tribes and urban Indian health organizations about proposed administrative changes to the Medicaid and Medicare programs?
 - b. As CMS Administrator, what methods would you employ to ensure proper consultation occurs?

Answer: If confirmed, I will proactively engage stakeholders, including tribes and urban Indian health organizations, on the front-end regarding proposed administrative changes to the Medicaid and Medicare programs. Additional perspective on how CMS policy could impact their beneficiaries and families is of great value to CMS. Communication and collaboration early on in the process ensures that caregivers and families have an opportunity to discuss their priorities, questions or concerns.

9. In November 2016, the IHS released the outline of its plan to improve care at its facilities. The framework includes 5 priorities – strengthening organizational capacity,

maintaining facility accreditation, improving patient experiences, ensuring patient safety, and identifying potential risks earlier.

What role do you see CMS having in these efforts as the framework moves forward?

Answer: If confirmed as Administrator of CMS, I will diligently collaborate and coordinate with all HHS sister agencies, including the Indian Health Service. CMS will continue to conduct Medicare certification surveys for IHS hospitals, and will stand ready to provide technical assistance or other support whenever appropriate.

Question on behalf of Senators Stabenow and Bennet:

10. The Protecting Access to Medicare Act (PAMA) included requirements that ordering physicians consult appropriate use criteria prior to referring Medicare patients for advanced diagnostic imaging services.

If confirmed, do you intend to implement the appropriate use criteria provisions according to existing statute? Would you start the program on January 1, 2018?

Answer: If confirmed, I will follow the laws as passed by Congress and implement them accordingly. I look forward to closely monitoring challenges associated with this implementation process, while identifying and evaluating specific burdens that have the potential to limit patient access.

Questions for the record from Senator Maria Cantwell

Questions on Medicaid:

1. You have worked extensively on state Medicaid policy and financing issues. In your view, when states face budget shortfalls, what do they typically do to reduce costs in their Medicaid programs, in the absence of additional federal or state revenue? In other words, what are the "levers" available to states to reduce Medicaid costs? Moreover, which of these levers are most frequently used?

Answer: The current system is inflexible with states required to receive CMS approval for routine changes. We need to allow states to be innovative and deliver better outcomes while holding states accountable. If confirmed as Administrator of CMS, I will work to allow more flexibility to the states, allowing for innovation in the Medicaid waiver process.

2. You have stated that Medicaid does not always produce good outcomes for patients. In your view, what specific outcomes -- clinical, financial, or otherwise -- should states strive for in their Medicaid programs?

Answer: I support state innovations to increase coordination of care, improve access to preventative care, improve drug adherence and lower emergency room usage, all with the goal of improving access to high quality healthcare and improving patients' outcomes. Outcomes can be

measured in a variety of ways but should focus on the patient experience and impact of the program on beneficiaries. I look forward to working with you to reach these goals, if confirmed as Administrator of CMS.

3. Does the federal government have a role to play in encouraging those outcomes, and if so, what is that role?

Answer: We can do better to improve health outcomes. Our goal is to ensure that all Americans have access to high quality healthcare with choices that fit their needs and the needs of their family. If confirmed, I look forward to working with you to realize better health outcomes through encouraging innovation, reducing redundant paperwork and allowing for providers to spend more of their time on their patients while also holding states and providers accountable.

Questions on Long Term Care:

4. Do you support federal "rebalancing" initiatives, such as the Balancing Incentives and Money Follows the Person programs in the Affordable Care Act?

Answer: I support Americans being in charge of their healthcare and choosing what works best for themselves and their family. Every state is unique with a different population, different needs and different challenges. If confirmed, I am committed to working to provide states more flexibility to pursue measures that fit the needs of their citizens.

5. Do you believe that, if well-implemented, "rebalancing" programs such as the Balancing Incentives Program can improve the care experience for patients and reduce state Medicaid costs?

Answer: Every state is unique and design flexibility is an important component. What works in one state may not work as well in other parts of the country, so if confirmed, I am committed to working to provide states more flexibility to pursue innovative measures that allow states to make the most of available resources and serve their citizens with the highest quality of care.

Questions on the Basic Health Program:

6. The Basic Health Program (Section 1331 of the Affordable Care Act) is a state option that is providing health insurance and access to care to more than 750,000 working low-income individuals in New York and Minnesota. States that have taken advantage of this voluntary program are seeing lower costs for beneficiaries, higher enrollment, and net state budget savings, compared to not implementing the program. Through the Basic Health Program, states are price-makers, not price-takers. Do you support the Basic Health Program as a way to empower states to negotiate a better deal on health insurance for their citizens?

Answer: I support state innovation to make the most of available resources and serve their citizens with the highest quality of care. Programs that work well in one state might not translate to other parts of the country. From my experience working with states, I learned that one-size-fits-all solutions won't work so I am committed to increased state innovation and accountability to the citizens they represent.

7. If confirmed, will you commit to funding and administering the Basic Health Program as required under current federal law?

Answer: If confirmed, I will follow the laws as passed by Congress and implement them accordingly.

8. If Congress repeals parts of the Affordable Care Act, will you commit to "not pulling the rug out" from the 750,000 low-income individuals who are benefiting from the Basic Health Program?

Answer: I support Americans being in charge of their healthcare and choosing what works best for themselves and their family. Our goal is to ensure that all Americans have access to high quality healthcare with choices that fit their needs and the needs of their family. I am committed to implementing the law as written and I am committed to implementing it with careful attention to those Americans who may be impacted.

9. Will you use your administrative discretion as HHS secretary to not rescind funding for state Basic Health Programs, unless a rescission of that funding is explicitly required by a change to the statute?

Answer: If confirmed as Administrator of CMS, I will follow the laws as passed by Congress and implement them accordingly, including the directions from Congress related to appropriations measures and other sources of funding for health care programs.

Questions on Delivery System Reform:

10. Washington state and the Pacific Northwest have led the way in pioneering nationally-recognized innovations in the delivery of health care – whether it is the Qliance Direct Primary Care medical home model, Group Health Cooperative's highly popular integrated coverage and care model, the Everett Clinic's price transparency initiatives, Boeing's Accountable Care Organizations, or Virginia Mason's team-based care. Despite their innovations, health care providers in my state are paid nearly \$2,000 less (per Medicare enrollee, per year) than the national average, based on CMS spending data compiled by the Kaiser Family Foundation. I would argue that, due to our current volume-based system, my constituents are paid less specifically because they are efficient and because they do a good job of keeping patients healthy. Should the federal government reward such high-value health care providers, as long as we clearly define and agree upon metrics for what constitutes "high-value" care?

Answer: If confirmed as Administrator of CMS, I will follow and implement laws, such as MACRA, related to payment to high-value health care providers.

11. Does the current fee-for-service system encourage unnecessary health care spending? If so, can you please explain specifically how this system encourages unnecessary health care spending, including in which specialties of medicine, and in which settings of care? **Answer:** The current system can encourage unnecessary spending by putting too many health care decisions in the hands of a distant federal bureaucracy rather than in the hands of doctors and their patients. All health care providers, from primary care providers to specialists, should be encouraged to provide value to their patients.

12. Under the Obama Administration, HHS Secretary Burwell and CMS Administrator Slavitt set a goal of providing 50 percent of Medicare fee-for-service spending through alternative payment models. If confirmed, will you continue, rescind, or modify that goal?

Answer: If confirmed, I look forward to reviewing the actions taken by health care providers and CMS to achieve the initial goal to better understand what has worked and what we can improve upon in the implementation of laws such as MACRA. Additionally, it is crucial to communicate and collaborate with providers and stakeholders throughout the process.

13. In 2015 Congress passed and President Obama signed into law the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA incorporated the Value-Based Payment Modifier, which I authored in the Affordable Care Act, into Medicare's new physician payment system, the Quality Payment Program. Will you commit to working with Washington state health care providers to help them succeed in Medicare's Quality Payment Program, as outlined in regulations by CMS, including Advanced Alternative Payment Models?

Answer: If confirmed, I am committed to working closely with the Secretary of HHS to ensure MACRA is implemented fairly and so that it is easy to understand and minimizes burdens, especially on smaller and rural providers.

14. Will you commit to fund and administer Medicare's Accountable Care Organizations, including the Medicare Shared Savings Program under Section 3022 of the Affordable Care Act, and will you commit to helping health care providers participate in these models, should they choose to do so? Will you commit to not taking any administrative action that would make it more difficult for Medicare beneficiaries or health care providers to participate in this voluntary program?

Answer: If confirmed, I will follow the laws set forth by Congress related to Medicare's ACOs and I intend to work with the Secretary of HHS to ensure, as we move forward, that we learn from the results of ACOs and chart a path forward based on an understanding of what is and what is not working.

15. Will you commit to fully fund approved grants under the Center for Medicare and Medicaid Innovation (CMMI), and will you continue to fund and administer future payment initiatives under CMMI, consistent with the legislative intent of Congress in the Affordable Care Act?

Answer: I look forward to reviewing current CMMI projects, consistent with Congressional actions.

16. Health care researchers and providers in Washington state, such as the AIMS Center at the University of Washington and Iora Health, are working to integrate behavioral health services into the primary care experience in order to provide a more seamless care experience, reduce the stigma of behavioral health conditions, and fill historical gaps in access to care. Do you support the integration of primary care and behavioral health into the same care setting?

Answer: If confirmed, to the extent I am not required to recuse from a particular matter under the terms of my Ethics Agreement, I will work to implement the laws passed by Congress. I support flexibility for states to design innovative care programs that improve health outcomes. Both primary and behavioral health care are key components to providing comprehensive care to patients and I support innovative approaches that drive better health care.

Questions on Specific Health Care Legislation:

17. I have authored bipartisan legislation (S. 2259 in the 114th Congress) to make it easier for rural health care providers to participate in the Medicare Shared Savings Program by allowing CMS to adopt a broader beneficiary assignment method than is provided under current law. Will you commit to providing me and my office responsive and accurate technical assistance on this legislation?

Answer: I am committed to open communication, collaboration, and bipartisanship. If confirmed, I will work with you and be responsive to your inquiries and concerns and provide information on the beneficiary assignment for the Medicare Shared Savings Program.

18. I have authored bipartisan legislation (S. 2373 in the 114th Congress) to require CMS to cover an essential preventive product, compression therapy items, for Medicare beneficiaries who experience swelling from lymphedema. Will you commit to providing me and my office responsive and accurate technical assistance on this legislation?

Answer: I am committed to open communication, collaboration, and bipartisanship. If confirmed, I will work with you and be responsive to your inquiries and concerns and provide information on the Medicare coverage and payment process.

19. I have cosponsored bipartisan legislation (S. 3129 in the 114th Congress) to preserve patient access to outpatient therapeutic services in Critical Access Hospitals and other rural hospitals. Similar legislation has been signed into law the last three years. Will you commit to working with me, my staff, and bill sponsors and cosponsors, on this issue?

Answer: I am committed to open communication, collaboration, and bipartisanship. If confirmed, I will work with you and be responsive to your inquiries and concerns to ensure that critical access hospitals continue to provide quality health care to rural populations.

20. Will you commit to providing me and my office responsive and accurate technical assistance on any future legislation I author or on which I seek assistance?

Answer: I am committed to open communication, collaboration, and bipartisanship. If confirmed, I will work with you and be responsive to your inquiries and concerns.

Questions on Washington state's section 1115 Medicaid waiver:

21. On January 9, 2017, CMS approved Washington state's proposed Medicaid waiver ("Medicaid Transformation Project, No. 11-W-00304/0) under section 1115(a) of the Social Security Act. In securing agreement on this waiver, Washington state health officials and CMS spent countless hours over more than a year in good-faith negotiations. This approved waiver will help Washington state pursue a smarter and more innovative Medicaid program that reflects changes in health care delivery, technology, and the preferences of patients. Specifically, the waiver will help my state integrate behavioral health and primary care services, and re-orient the care experience away from higher-cost institutional settings to lower-cost community based settings. Will you commit to honor this approved waiver and not take any administrative action to rescind, weaken, or de-fund its components?

Answer: If confirmed, I am committed to working to provide states more flexibility to pursue innovative waivers that fit the needs of their citizens. Our goal is ensure that all Americans have access to have high quality healthcare with choices that fit their needs and the needs of their family.

Questions on Graduate Medical Education:

22. The vast majority of Washington state counties are Health Professional Shortage Areas (HPSA's) according to HHS's HRSA. In response to an aging population and impending physician shortages, two new medical schools have opened in Washington, each focused on training more physicians to practice in shortage specialties and in medically-underserved communities. Do you agree with an established body of research illustrating that there are physician shortages in the United States, especially in primary care specialties and in rural communities?

Answer: Coverage doesn't always translate to access and access to care is a critical issue in many areas of our country, especially in our rural areas where there are challenges in attracting workforce. If confirmed, I will work with the Congress, the Secretary of HHS and the Health Resources and Services Administration (HRSA) to address physician shortages as they relate to Medicare and Medicaid programs.

23. Given your experience in health care policy, what is your view of the role the federal government should play to promote an adequate and balanced physician workforce in the United States? Or should that role be left to the states?

Answer: When considering new rules and regulations, we all (federal and state) should be mindful of the workforce shortage, particularly in our rural areas where there are unique challenges in attracting medical providers. We all should proactively engage providers on the front-end for valuable feedback and take into account the fact that they may have limited time and resources to implement regulations.

24. As the practice of medicine transforms, how should Medicare's financial support for graduate medical education (GME) adapt, or should it remain the same?

Answer: If confirmed, I look forward to working with you and other Members of Congress on your priorities to see that our GME programs work well for a 21st century medical work force.

Questions on Medicare Reimbursement:

- 25. CMS recently finalized a regulation implementing Section 603 of the Bipartisan Budget Act, which effectively reduces Medicare payment rates for certain newly-established, off-campus hospital outpatient departments to the payment level under the physician fee schedule or ambulatory surgery center fee schedule. If confirmed, how will you approach implementation and interpretation of Section 603 of the Bipartisan Budget Act?
- 26. What exceptions, if any, are appropriate to "site neutral" payment reductions?
- 27. Do you support "site neutral" payment policies in Medicare? If you do in part, could you explain in what settings they are appropriate, and in what settings they are not?

Answer: If confirmed, I will support the implementation of the site-neutral payment rules that Congress has enacted or will enact. Ensuring that patients can access quality care in all kinds of health care settings is a priority for Congress, CMS and the American people. It is essential that beneficiaries have robust choices in their providers and I look forward to implementing policies that ensure we attract providers to deliver quality care.

Questions for the record from Senator Bill Nelson

1. On January 30, President Trump issued an Executive Order that requires some federal agencies to repeal two regulations for every new one issued. Given the sheer number of rules and regulations that CMS must issue every year, how do you envision this Executive Order functioning so that CMS can continue to do its job? Can you give me examples of two specific regulations that you would repeal as CMS Administrator?

Answer: If confirmed as Administrator of CMS, I look forward to reviewing existing regulations and any new proposed regulations to determine applicability to the President's Executive Order.

2. Over four million seniors in Florida rely on the health and financial security provided by the Medicare program. I've consistently opposed efforts to convert Medicare to voucher program, which would fundamentally change the program and leave seniors exposed to higher out-of-pocket costs. How would you propose to help people on Medicare and their families with the rising cost of medical care and long-term care?

Answer: I support offering choices for seniors and opportunities for additional benefits. Ultimately, the direction of Medicare is up to Congress and if confirmed as Administrator of CMS, I will follow the laws as passed by Congress and implement them accordingly. I hope we can work together to make the program more sustainable. 3. Then-Congressman Price introduced a bill [the Medicare Patient Empowerment Act] to allow practitioners to enter into private contracts with their Medicare patients and charge higher fees than what is currently allowed under the Medicare program. Currently, when seniors in Medicare see their doctors they are responsible for a set amount of costs and physicians participating in Medicare cannot bill their patients for any outstanding costs. Do you support this change in policy?

Answer: I support offering choices for seniors and putting Americans in charge of their healthcare and choosing what works best for them and their family. Medicare policy-making is in large part done by Congress, so I look forward to working with you on Medicare issues.

4. The ACA includes provisions designed to improve treatments for people with substance use disorders, including opioid addiction. It included mental health and substance use disorder treatment as an essential health benefits; it expanded access to treatment services; it eliminated lifetime limits on behavioral health services; and ended discrimination by insurers based upon pre-existing conditions.

According to the CBPP, 1.3 million people with serious mental illness and 2.8 million people with substance use disorders would lose health coverage under ACA repeal. Would you recommend that President Trump and Congressional Republicans maintain the provisions listed above in any replacement plan? Beyond keeping the ban on discriminating against people with pre-existing conditions, what are the elements that any replacement plan must include?

Answer: My goal is to ensure that all Americans have access to high quality healthcare with choices that fit their needs and the needs of their family. If confirmed, I will follow the laws as passed by Congress and implement them accordingly.

5. As CMS Administrator, what administrative actions would you take to address the opioid epidemic?

Answer: If confirmed as Administrator of CMS, to the extent I am not required to recuse from a particular matter under the terms of my Ethics agreement, I will work closely with the Secretary and the Substance Abuse and Mental Health Services Administration (SAMHSA) whose duty is to advance behavioral health and reduce the impact of substance abuse and mental illness on America's communities. It is critical that all Americans suffering from mental health and substance abuse disorders have access to the care they need.

6. The Medicare Advantage program is an affordable option offering out-of-pocket spending caps, additional benefits like vision and dental, and often prescription drug coverage at no additional cost for many of my constituents. As Administrator, what specific actions would you take to strengthen and build upon this vital part of the Medicare program? How will you ensure that the \$1.6 million seniors in Florida, and the 18 million that enrolled across the nation are protected?

Answer: I am committed to preserving and strengthening the Medicare Advantage program as it offers additional benefits and provides additional choices to seniors. If confirmed, I look forward to working with you and other Members of Congress to support the program.

7. A CMS Medicare Graduate Medical Education (GME) rule prevents a number of hospitals that hosted—for a very brief period of time—medical residents from another facility's teaching program from establishing their own full-time Medicare support residency programs. Under current CMS policy, hospitals considered by CMS as "new" teaching hospitals are permitted to establish a permanent full-time (FTE) resident cap and per resident amount (PRA), which allows for reimbursement by CMS for Medicare's share of the hospital's training costs. I have heard from a small number of community hospitals in my state that inadvertently triggered a very low resident and/or PRA though hosting resident rotators for short periods of time. Do you commit to working with me to fix this glitch? Does CMS have the authority to fix this problem without Congressional action?

Answer: If confirmed, I commit to looking into this issue with you and helping you evaluate the options at both the legislative and executive level.

8. In 2016, CMS announced a new pre-claim review demonstration (PCRD) for home health services in five states. The demonstration began in Illinois in August, with plans to expand to Florida, Texas, Michigan and Massachusetts. Because of problems experience by beneficiaries and providers in Illinois, program expansion was delayed. It is now scheduled to be implemented in Florida on April 1, without any changes. Do you plan to continue this demonstration in Illinois? Do you plan to move forward with the demonstration in Florida? If so, will you amend the scale of the demonstration and provide additional safeguards for providers?

Answer: If confirmed, I would review current demonstrations as well as the results of other similar demonstrations to understand the challenges and any lessons learned that may be applied to the Pre-Claims Review Demonstration. I look forward to working with you to address your concerns.

9. When the Medicaid program was created in 1965, there were fewer service delivery settings and options available for consumers. As a result, nursing home care was made a mandatory benefit within the program. Since then, service innovations and technologies have enabled care to be safely and effectively delivered in home and community-based settings, yet the Medicaid program still retains the mandate for nursing home placement. States must seek a waiver in order to enable consumers to receive home and community-based care. How do you intend to use administrative power to facilitate beneficiaries have access to high-quality, cost-effective home and community based services? How would cuts to state Medicaid programs through block grants and per capita caps impact the ability of states to deliver high quality home and community-based services to an aging baby boomer population that wants to receive long-term services and supports at home and in their communities?

Answer: I support Americans being in charge of their healthcare and choosing what works best for themselves and their family. Every state is unique with a different population and different needs and the Medicaid program should be more flexible to address the changing health care landscape and population needs with the goal of improving health outcomes. If confirmed, I am committed to working with states, in accordance with the laws passed by Congress, to provide more flexibility to pursue innovative measures that fit the needs of their citizens. At the same time, states must be held accountable to standards that result in better health care quality and access. Our goal is to ensure that all Americans have access to high quality healthcare with choices that fit their needs and the needs of their family.

Questions on behalf of Senators Nelson and Menendez

10. Puerto Rico's economic recession has caused the number of Puerto Rico residents migrating to the states to reach staggering levels. The situation is made worse by physician shortages, a Medicaid program facing chronic funding shortfalls, and across-the-board disparities in Federal health programs.

Puerto Rico's Medicaid program serves about 1.4 million residents— over 40 percent of the island's population. The Affordable Care Act provided Puerto Rico with a one-time funding boost of \$6.4 billion set to expire at the end of Fiscal Year 2019. This funding will be depleted in 2017. Once this money is gone, Puerto Rico will go back to receiving its annual set Medicaid allotment, about \$350 million in FY 2018.

a. Do you believe Puerto Rico should be treated the same as states under federal Medicaid laws?

Answer: As you acknowledge in your question, Puerto Rico's fiscal challenges are much broader than those pertaining to their Medicaid program. It is my hope that leaders in the Commonwealth and in Congress will be able to adequately fund Puerto Rico's Medicaid program while addressing their overall fiscal situation. If confirmed, I will follow the laws as passed by Congress and implement the law accordingly.

b. Do you support extending the Medicare Part D LIS program to seniors residing in Puerto Rico and the other territories? If you do not believe low-income seniors in Puerto Rico should have access to the LIS program, why?

Answer: Extending the Medicare Part D LIS program to seniors residing in Puerto Rico and other territories would require a change in statute. Therefore, this is a legislative matter and I defer to Congress to address this issue. I will faithfully administer the Medicare Part D program as written in statute.

c. In order to use their supplemental allotment, the Puerto Rico government must pay a 45 percent local match. During the last three years, the Puerto Rico government drew down only half of its federal allotment funds because it could not generate its match. Do you believe CMS should remove or waive the local matching

requirement so that Puerto Rico can fully access the allotment funding? If you do not believe this matching requirement should not be waived, why?

Answer: Access to quality health care for the people of Puerto Rico is an important issue that I look forward to working with Congress and the Commonwealth to appropriately address in accordance with the law. Puerto Rico's broader economic challenges impact the Commonwealth's health care financing capabilities, so I am hopeful that these issues can be addressed in order to make Puerto Rico fiscally sound and healthy.

d. Last year, we had the honor of serving on the bipartisan, bicameral Congressional Task Force on Economic Growth in Puerto Rico. The Task Force was responsible for identifying steps to help stabilize and grow Puerto Rico's economy. The Task Force recommended that Congress enact fiscally-responsible legislation to address the Medicaid cliff established by the ACA. Will you commit to taking up the Task Force's recommendation to ensure that going forward federal financing of the Medicaid program in Puerto Rico should be more closely tied to the size and needs of the territory's low-income population? What specific actions would you take to help achieve this goal?

Answer: I look forward to reviewing the Task Force's recommendations and implementing the laws as designed by Congress related to the financing of Puerto Rico's Medicaid program.

e. Will you commit to enacting the Task Force's recommendation that CMS undertake any additional administrative steps necessary to ensure that Medicare Advantage plans in Puerto Rico are being fairly and properly compensated for the services they provide to beneficiaries? What specific administrative steps will you recommend CMS take?

Answer: Every effort should be made to ensure that Medicare Advantage plans in Puerto Rico are being fairly and properly compensated for the services they provide. If confirmed, I will carefully study and consider the Task Force's recommendations, and work closely with Members of Congress in order to determine how best to proceed on this important matter.

f. The Obama administration established a working group that included HHS and CMS officials and Puerto Rico health care stakeholders to jointly propose solutions to the ways in which the funding crisis is manifested. This includes, among other critical policies, dealing with the statutory cap on Medicaid expenditures and the lack of a low-income drug subsidy. Do you commit to ensuring CMS continues its focused and meaningful participation in this working group to ensure that we address Puerto Rico's disparate treatment under federal health programs?

Answer: I commit to working with you and all parties involved to ensure that the people of Puerto Rico are able to access high quality health care plans and receive the proper attention of CMS as we evaluate our options and provide technical assistance for legislative matters as appropriate.

Questions for the record from Senator Robert Menendez

Recusal from Mental Health Issues:

1. In the hearing I asked you a question about the ACA's Essential Health Benefit package as it pertains to coverage of behavioral health services, specifically for autism services. In your response you mentioned that you were recusing yourself from mental health policy in light of your husband's work as a psychiatrist.

According to your letter to the Associate General Counsel for Ethics at the Department of Health and Human Services, you say that you "will not participate personally and substantially in any particular matter that to [your] knowledge has a direct and predictable effect on the financial interest of the Indian Health Group" at which your husband practices.

a. Can you provide more detail about exactly what you plan to recuse yourself from, if confirmed?

Answer: As noted in my Ethics Agreement, which you reference above, because of my husband's practice as a psychiatrist with the Indiana Health Group, Indianapolis, Indiana, and his financial interest in the Indiana Health Group, I have agreed not to participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the Indiana Health Group, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). Under the federal ethics regulations, I am not required to recuse from consideration or adoption of broad policy options that are directed to a large and diverse group of persons. I will be required to recuse from matters that involve deliberation, decision or action that is focused upon the interests of the Indiana Health Group. To the extent that I have questions on how to apply my recusal obligations to a particular matter, I will consult with the HHS Ethics Office for guidance on the scope of my recusal obligations.

b. Does this recusal include your work on any/all work to oversee and enforce federal mental health parity laws?

Answer: Although I will consult with the HHS Ethics Office as needed for guidance, the mental health parity rules are focused on insurance coverage for mental health services and/or substance use disorder services, these rules may impact entities such as the Indiana Health Group and service providers in the Group, including my husband, that receive insurance reimbursement for mental health and substance use disorder services. Accordingly, I will recuse from this work.

c. Will you recuse yourself from dealing with any Medicaid waiver applications that include mental health components, such as the Comprehensive 1115 Waiver in New Jersey which is largely about the ID/DD population?

This is of particular importance given the massive changes to the Medicaid program you have previously championed and will, presumably, continue promoting. Seeing

as the Indiana Health Group refuses to treat individuals enrolled in Medicare, Medicaid and CHIP, can you confirm your recusal from these issues?

Answer: The 1115 Medicaid Waiver application for New Jersey is a particular matter involving New Jersey as a specific party. Resolution of that waiver will be state specific. Accordingly, under the ethics regulations, my ethics obligation will not require my recusal from this waiver.

d. Since my question during the hearing was actually about insurance benefit design generally, not about anything specific to do with payment to providers of any kind, can you clarify your views on whether or not a child's access to insurance coverage (not only for behavioral health and autism services, but any health service) should be based on the state in which they live?

Answer: Children are some of our most vulnerable citizens and I support ensuring that they receive quality health care through the most effective means available.

Medicare Packaged Payment Policies:

2. As you may be aware, Medicare Part B hospital and ambulatory surgery center payments account for medications which cost more than a nominal amount to be reimbursed "at cost" rather than getting "packaged" into the procedure code payment. This is because, according to CMS, because packaging certain types of drugs "might result in inadequate payments to hospitals, which could adversely affect Medicare beneficiary access to medically necessary services."

However, in recent years, CMS seemed to forget this rationale and finalized a series of rules to package certain "drugs that function as a supply when used in a surgical procedure" and that "function as a supply in a diagnostic procedure." This package payment policy, which has nothing to do with the actual price of the drug or the amount Medicare pays for the drug, has made several critical treatment options out of reach for beneficiaries due to the sharp decrease in reimbursement resulting from the packaging policy.

- a. If confirmed as Administrator, will you commit to revisiting this policy in the upcoming rulemaking cycle and conduct an in-depth evaluation of the impact this packaging payment policy has had on beneficiary access to the services the current regulations single-out for packaged reimbursement?
- b. Additionally, if this evaluation demonstrates decreased access to care for Medicare beneficiaries or an increased burden on providers that make providing these services more difficult, will you commit to make changes to ensure access is restored?

Answer: If confirmed, I commit to thoroughly reviewing the rules to ensure they are implemented consistently with the law and with the utmost regard for the accessibility of high quality health care for all impacted Medicare beneficiaries.

Proper oversight of Medicare Contractors:

3. As you might know, CMS contracts out several administrative activities, such as processing Fee for Service claims, medical record review, provider enrollment and the establishment of local coverage determinations (LCDs), to Medicare Administrative Contractors (MACs). MACs are divided up by region and serve as the agency's primary contact agent with Medicare providers. It has recently come to my attention that the MAC covering New Jersey is implementing a prior-authorization requirement for certain services, specifically hyperbaric oxygen therapy (HOBT). While I generally support the idea of prior-authorization in certain cases, the New Jersey MAC has issued an LCD, and further guidance on its website through a Frequently Asked Questions page, that is having a significant impact on beneficiaries' ability to receive this important therapy and that contradicts well-established medical and scientific practices. Additionally, it appears that the MAC is implementing this prior-authorization differently in New Jersey than other MACs in other states, causing provider confusion and unequal access to care across the country.

If confirmed as Administrator, will you work to provide the necessary oversight of MACs and other contractors to ensure the policies they implement are both consist across the country and consistent with medical best practices?

Answer: I will strive to do so. If confirmed, I would be pleased to work with you on this issue. Our goal is to offer seniors access to the care they need. I appreciate the need to engage in oversight to identify and evaluate challenges associated with MACs and LCDs more generally.

Children's Health Insurance Program (CHIP):

4. Since 1997, the Children's Health Insurance Program (CHIP) has been essential for children and pregnant women in working families who cannot afford private health insurance. Today, CHIP provides affordable health coverage to over 8 million children and hundreds of thousands of pregnant women across the country. Taken together, CHIP and Medicaid have combined to reduce the number of low-income, uninsured children across the country by half. At the same time, the program has improved health outcomes and access to care.

As was mentioned during your hearing, the CHIP program needs to be reauthorized by Congress this year, and now-Secretary Tom Price stated that he supported an extension of up to eight years.

If confirmed as Administrator, will you commit to working with Congress to enact a long-term reauthorization of the CHIP program and to do so in a manner that maintains the program's success at providing comprehensive coverage to pregnant women and children and does not limit funding, coverage, access or quality?

Answer: It is important that every child has access to high-quality health coverage, and CHIP plays an important role in accomplishing this objective. CHIP plays a major role in this, but there is also a need to focus on family coverage in the private market and employer plans, and on giving states needed flexibility. Each state has different needs, and I believe CMS needs to work with states to ensure that, consistent with those needs, the CHIP program provide the best

possible coverage to their residents. If confirmed, I would work with Congress on CHIP reauthorization with these principles in mind.

Home Visiting Programs:

5. As you may know, evidence-based home visiting programs, working in conjunction with FQHCs, promote support and expand access to children and families, specifically those eligible for, or enrolled in, Medicaid. One such program is the Maternal, Infant, and Early Childhood Home Visitation (MIECHV) program. In 2015 along, MIECHV provided services to nearly 150,000 parents and children in more than 800 counties in all 50 states, all five territories, and the District of Columbia. However, coordination between MIECHV grantees and Medicaid is often difficult given that Medicaid is the payer of last resort in all cases except those with a specific exemption in law, such as what exists under the Maternal and Child Health Services Block Grant, Special Supplemental Nutrition Program for Women, Infants and Children and services provided as part of an Individualized Education Program or Individualized Family Service plan under the IDEA. Currently, MIECHV services do not have that explicit exemption, despite being focused on maternal and child health as the other exempted programs are. There has been no effort on the part of CMS to meaningfully address the issue of benefit coordination, causing confusion among service providers and impeding access for beneficiaries.

If confirmed as Administrator, will you commit to clarifying the funding relationship between the MIECHV and Medicaid programs?

Answer: If confirmed, I commit to working with you to better understand this relationship and to evaluate all options to address MIECHV and Medicaid issues at both the legislative and executive level with the goal of improving the health and well-being of mothers and their children.

(Question on behalf of Senator Menendez, Senator Brown, Senator Wyden, Senator Bennet and Senator Casey)

6. Congress passed the Protecting Access to Medicare Act (PAMA) in 2014. This bipartisan law included policies to update and change the way Medicare reimburses clinical laboratories under the Clinical Laboratory Fee Schedule (CLFS), moving the reimbursements towards a market-based payment methodology. Under the law, all "applicable" laboratories are required to report to CMS the payment rates and test volumes for their private payers.

CMS finalized PAMA regulations in June, 2016, and released further guidance in September, 2016, which impose an unrealistic reporting timeline for laboratories. Additionally, we have heard from our regional and community-based laboratories about significant concerns they have about their ability to report accurate data and how the current rules' exclusion of market data from hospital outreach labs and definition of "applicable laboratory" will impact the accuracy of CMS's data.

If confirmed, will you commit to looking at the current PAMA regulations and reporting requirements to ensure that independent, physician and hospital laboratories are appropriately and accurately accounted for in the market price data?

Answer: I appreciate your concerns regarding the implementation of PAMA. Certainly, we should strive for accuracy in this market data collection process. It is important that patients have access to community-based labs. Accordingly, I look forward to closely monitoring challenges associated with this implementation process, while identifying and evaluating specific burdens that have the potential to limit patient access.

Further, will you commit to evaluating the need to extend the March 31, 2017, reporting deadline to ensure that laboratories – especially smaller, community laboratories – are able to successfully collect and report the data required under the regulations?

Answer: I look forward to following up with CMS staff and regional and community-based laboratories to discuss workable solutions.

Questions for the record from Senator Thomas R. Carper

1. <u>Experience with Private Health Insurance Markets:</u>

As you know, the House and the Senate recently passed budget resolutions to repeal the Affordable Care Act and cut Medicaid funding by more than \$1 trillion. More than 20 million Americans gained health insurance as a result of the Affordable Care Act. Can you share your experience and background working with the individual and small group health insurance markets? If confirmed as Administrator of the Centers of Medicare and Medicaid Services (CMS), what specific actions will you take to "fix" our state insurance markets and ensure access to health insurance for the millions of Americans who gained coverage under the ACA?

Answer: I worked with states in preparing for the changes brought about by the ACA including working with state insurance departments and reviewing and implementing ACA regulations. If confirmed as CMS Administrator, I will work to ensure that every state insurance commissioner has as much flexibility as possible to repair their respective insurance markets.

2. Medicare:

Ms. Verma, you noted in your testimony that the American people are tired of politics and just want their health care system fixed. As you already know, we recently passed bipartisan legislation to reform the way Medicare reimburses physicians, moving from a fee-for-service system to payment based on better quality and improved outcomes. In your experience, what kinds of reimbursement systems do you believe are best suited to improving health outcomes and driving down costs? In your opinion, what are the strengths and weaknesses of accountable care organizations, bundled payments, and patient-centered medical homes? What other types of payment reforms should be implemented in Medicare to improve the quality of health care while reducing unnecessary costs?

Answer: We share the goal of improving Medicare by empowering providers to be creative and developing payment models that best suit the unique needs of their patients to ultimately improve patient care. For instance, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) establishes the Physician-Focused Payment Model Technical Advisory Committee to review proposals for physician-focused payment models that can ultimately be adopted by CMS. More generally, a fundamental principle for payment reforms is the centrality of the patient in the system and their ability to make choices about their care in consultation with their doctor and that we drive toward better coordination and improving quality and health outcomes.

3. Medicaid:

In the Healthy Indiana program, you strongly promoted the use of personal responsibility such as the use of co-pays and cost-sharing for Medicaid beneficiaries. For some extremely poor Medicaid beneficiaries, the premiums and co-pays are just \$1, which does not seem unreasonable. When one of these beneficiaries fails to pay their \$1 premium, how much does Indiana spend to collect this bad debt? Do beneficiaries with no income through no fault of their own, for example if their employer goes out of business, still have to pay premiums for their Medicaid benefits? When Medicaid beneficiaries lose their Medicaid benefits because of their inability to pay their premiums and goes to the hospital emergency room for care, what does it cost Indiana and American taxpayers? Does Indiana's Medicaid program fully recoup the dollars spent on managing this program?

Answer: The Healthy Indiana Plan's contribution requirements are not designed as a punitive measure but as a way to promote personal responsibility in members which has resulted in better health outcomes, including lower ER use, higher patient satisfaction, drug adherence and more primary and preventative care. Only members above the poverty line are at risk of losing coverage for non-payment. Where HIP members are locked out of coverage for six months for non-payment, those who fail to pay Marketplace premiums may have to wait until the next open enrollment period to regain coverage, which can be up to nine months, unless they have a change in circumstance that makes them eligible for a special enrollment period. On the whole, HIP's non-payment policies for individuals above the poverty line are at least comparable, if not more lenient, than the policies governing the Marketplace. Moreover, only 5 percent of former HIP members indicated they left the program due to affordability issues. Additionally, more than 80% of HIP members have indicated they would be willing to pay *more* to stay in the program, while more than half of those who left the program due to non-payment successfully transitioned to private health insurance coverage.

4. Obesity:

We know that the disease of obesity costs the health care system hundreds of billions of dollars a year in needless and potentially unnecessary treatments. The states you have worked with, such as Indiana, Kentucky, Tennessee and Iowa, have some of the highest rates of obesity in the country. It is long past the time that CMS adopt an "all-in" approach to fighting obesity. As CMS Administrator, how will you seek to maximize current obesity treatment programs and increase the treatments available to overweight or obese patients? Specifically, how would you increase access to nutritional counseling for overweight and obese individuals in the Medicare and Medicaid programs?

Answer: Obesity is a chronic condition, and I agree that it is an important priority for our health care system to address this condition for both children and adults. We need to strengthen the relationship between patient and doctor in order to address this disease on the front end and support providers in identifying best practices as well as supplying technical assistance as providers address this critical issue.

5. Program of All-Inclusive Care for the Elderly (PACE):

In Medicare, Medicaid and the private sector, we are seeing significant and accelerating change towards value-based care and reimbursement based on better quality and outcomes. Yet the Program of All-Inclusive Care for the Elderly (or PACE), which pioneered so many of the features we now seek to build into our health care system, is being constrained by outdated regulations. If confirmed, what will do you do to ensure that CMS updates these regulations quickly to provide more flexibility to PACE and to expand access to this program for medically frail seniors?

Answer: I look forward to reviewing the regulations currently in place and changes outlined in the proposed rule and working with Congress to eliminate any regulations that hinder efficiency or access to quality care.

6. Program of All-Inclusive Care for the Elderly (PACE):

It is important for CMS to issue a final rule that would update and improve the Program of All-Inclusive Care for the Elderly (PACE). A proposed rule to update PACE was issued in August 2016 to increase access to care, remove inefficiencies in the system and assure continuous care to many of the most vulnerable patients. An important change in the proposed rule would explicitly allow physician assistants (PAs) to be employees or contracted providers for PACE programs. While PAs currently provide high quality medical care and chronic care management to Medicare and Medicaid beneficiaries throughout the country, current CMS rules exclude PAs from being an employee or contracted provider in the PACE program. Will you continue work to strengthen the PACE program and ensure it is modernized in a way that effectively uses PAs and other health care providers, who provide high quality, affordable healthcare services?

Answer: I look forward to reviewing the changes outlined in the proposed rule, and I agree that PAs are a vital part of our healthcare system and should be used to provide high quality, affordable healthcare services.

7. Improving the Value of Health Care:

Improving the value of healthcare has been a shared bipartisan priority for several decades, as the share of our economy dedicated to health care has continued to rise, but not necessarily in sync with the overall quality of health care and health outcomes. Implementation of the quality reporting and performance programs is an important tool for increasing the quality of health care, improving health outcomes and lower unnecessary costs. How will you advance health care quality reporting and

value-based purchasing programs in Medicare, Medicaid, and in private health insurance plans?

Answer: I look forward to reviewing our current quality reporting and performance programs to ensure that they provide the data needed to improve patient outcomes while not becoming so burdensome that they reduce providers' ability to give quality care. Ensuring transparency so that patients can make informed decisions about the care they receive is a crucial component of this and I look forward to working with Congress on this issue.

8. <u>Health Care Costs and Quality:</u>

The United States spends nearly twice as much on health care as other developed countries, such as Japan, but fails to provide insurance coverage for all Americans. Health outcomes and quality, such as infant mortality, preventive care, and overall lifespans, often lag behind other countries as well. What are three specific health care programs or public health strategies utilized by other countries' health care systems that you would seek to emulate in the Medicare, Medicaid, and private health insurance programs and how would you adapt them to fit demographic trends, cultural norms, and logistical challenges unique to the United States.

Answer: The United States is a world leader in medical research and medical innovation and performs well in key health indicators, such as cancer survival rates. We should focus on how we can provide access to quality healthcare for all Americans with local solutions that work best for individual patients and their families. Data-driven decisions based on price and quality transparency should be afforded to American patients as we learn from other countries and their efforts in those areas.

9. Affordability:

For many Americans, the affordability of health insurance continues to be a significant barrier to accessing basic health care. How would you seek to increase the affordability of health insurance, lower insurance premiums, and reduce deductibles and co-pays, while also ensuring that all Americans have comprehensive, high quality, and dependable health insurance plans? Do you think that health insurance plans should be able to apply annual and lifetime limits on health insurance coverage?

Answer: As this is a matter for Congress, I look forward to working with Congress to make sure that every American has access to affordable healthcare.

10. Federally-Qualified Health Centers:

Federally-qualified health centers (FQHCs) play fundamental roles in communities across the United States providing individuals and families with access to high quality health care who might otherwise find access to health care to be unaffordable. How will you work to protect reimbursement rates to FQHCs in Medicare, Medicaid, and private health insurance plans? How will you work to increase the number of FQHCs throughout the country?

Answer: I look forward to working with Congress to implement reimbursement policies that expand health care access to all Americans in a wide range of health care settings, including FQHCs, which play an important role in our health care safety net.

11. Contraception:

Do you believe that all women should have access to all forms of contraception and family planning services without additional cost? How would you seek to expand access to and increase utilization of contraception for all women and their families in the United States?

Answer: Women should have the healthcare that they need and want. As we work to replace the ACA, we should build on a system that gives women affordable options, not mandates, and puts women at the center of their own health care.

(Question for the Record from Senators Casey and Carper)

12. Nutrition and Malnutrition:

Improving nutrition and lowering malnutrition are two areas that do not receive sufficient attention in Medicare, Medicaid, and private health insurance quality reporting programs. For example, even though there are many quality measures in place for other health conditions, there are no measures in place relating to malnutrition. How do you view the role of nutrition in improving health care, and how do we prioritize nutrition and malnutrition care as low cost solutions in improving clinical health outcomes? Do you believe that nutrition/malnutrition care should be part of the quality reporting and performance programs for Medicare, Medicaid, and private health insurance plans?

Answer: I agree that nutrition is an important part of overall health and I look forward to reviewing current reporting and performance programs for Medicare, Medicaid, and private health insurance plans to make sure that we get the data we need to improve health outcomes and to understand the impact of determinants of health, such as nutrition.

Questions for the record from Senator Benjamin L. Cardin

Center on Medicare and Medicaid Innovation (CMMI):

1. A) Do you support continuing the work of the Center on Medicare and Medicaid Innovation (CMMI) to identify alternative payment models (APMs) which achieve savings and improve quality of care?

B) Will you allow CMMI to continue implementing the various demonstration projects currently underway and expand them if they prove successful at reducing costs without harming quality of care?

Answer: I support innovation in whatever format it can be encouraged in accordance with the law. I also believe that we should work in partnership with the States and that CMMI

demonstration projects should be carefully considered on criteria involving their scale and the voluntary nature of the respective demonstration. I look forward to reviewing current CMMI projects, consistent with Congressional actions.

Children's Health Coverage in Medicaid:

2. Medicaid is one of the largest and most important components of the nation's healthcare safety net, offering a pathway to health coverage for low-income and medically vulnerable Americans. In my home state of Maryland, over 478,000 children receive essential health care through the program. That's one in three children in my state who can see a provider when they are sick and get the preventive health screenings they need to stay healthy.

I am particularly concerned about the impact of a Medicaid block grant or per capita cap on the program's Early Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, under which children enrolled in the program receive both regular wellness visits, preventive services, and coverage for all medically necessary treatments, for example pediatric dental care, that a child needs. In FY 2014, over 40 million children nationwide were eligible for EPSDT benefits. In Maryland, over 705,500 children were eligible for EPSDT benefits in 2015- more than 171,000 of whom became eligible through the Patient Protection and Affordable Care Act's Children's Health Insurance Program (CHIP)-Medicaid expansion.

Experts contend that if Medicaid expansion is repealed, states would no longer be required to provide coverage of this comprehensive benefit for children, and/or could eliminate the requirement that EPSDT services be provided without a copayment.

If confirmed as CMS Administrator, do you commit to ensuring the Medicaid EPSDT benefit and coverage for vital pediatric services remain intact for the millions of children who rely on it?

Answer: Our goal is to ensure every single American has access to the coverage they want for themselves or their children and dependents, and children are, and will continue to be, a high-priority population within the Medicaid program. States are well-positioned to determine the most appropriate ways to ensure access to the highest quality care for children, which may include diagnosis and screening procedures and the illnesses and conditions they uncover. As this is a matter for Congress, I look forward to working with Congress to improve our Medicaid system.

Emergency Health Services:

3. The Balanced Budget Act of 1997 requires Medicaid managed care organizations (MCOs) and others, to cover emergency services without prior authorization and established a federal "prudent layperson standard." This standard defines an "emergency medical condition" as one that manifests itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine, could reasonably expect the absence of

immediate medical attention to result in placing the health of the individual in serious jeopardy, serious bodily functions, or serious dysfunction of any bodily organ or part.

- A) Do you support this federal policy?
- **B)** Will you ensure the Centers for Medicare & Medicaid Services continues to enforce the prudent layperson standard for all Medicaid MCOs?

Answer: If confirmed, it would be my duty to implement the law as passed by Congress.

Kidney Care:

4. The 2011 revisions of the end-stage renal disease (ESRD) payment system stressed the importance of protecting access to all treatment modalities and transplant for dialysis patients in the Medicare program. I share the concerns of many dialysis patients in my state, that efforts to repeal or replace the Patient Protection and Affordable Care Act will limit access to the modality of their choice or the full scope of transplant options.

In recent years, CMS has reduced the in-center dialysis payment rate to increase an add-on for home dialysis training. I support the ability of ESRD patients to successfully manage their disease at home and while it may be appropriate to increase the rate for training home dialysis patients, we must find a way to ensure that individuals who require care at dialysis centers are able to do so.

What will your approach be to protecting access to all dialysis modalities, as well as transplantation?

Answer: As this is a matter for Congress, I look forward to working with Congress to make sure that patients with renal disease have access to high quality, affordable treatment.

(Question on behalf of Senator Cardin and Senator Nelson)

5. The 21st Century Cures Act, which was recently enacted into law, includes a provision I authored with Senators Crapo and Nelson, which requires Medicare Advantage (MA) plans to accept individuals with end-stage renal disease (ESRD). Federal law concerning when Medicare Supplemental Insurance carriers (Medigap) must be offered to individuals, does not require insurers to offer plans to people under the age of 65, including those with ESRD (although some states do require this).

Do you believe that Medigap coverage should similarly be extended to those under the age of 65, including individuals with ESRD?

Answer: As this is a matter for Congress, if confirmed, I will implement the laws passed by Congress and I look forward to providing any technical assistance which might be needed as Congress considers reforms.

Medicare:

6. People under the age of 65 with disabilities generally have a two-year waiting period from when they first start receiving Social Security Disability Insurance (SSDI) before they are eligible for Medicare coverage. The Patient Protection and Affordable Care Act (ACA) provided an important protection for people in this waiting period who otherwise could not obtain coverage. If the ACA is repealed, do you think these individuals should be forced to again fend for themselves until Medicare coverage kicks in?

Answer: As this is a matter for Congress, if confirmed, I will implement the law as passed by Congress.

NOTICE Act:

7. With our growing, aging population, Medicare must evolve to meet the country's most pressing healthcare demands. One issue we've started to address is hospital observation status for Medicare beneficiaries. Often, Medicare beneficiaries who receive care in hospitals, even for several days, may be surprised to learn that they have not actually been admitted as inpatients. Instead, these patients are classified as "observation status" or outpatients.

Observation status is particularly concerning for Medicare beneficiaries who may require skilled nursing facility (SNF) care after being discharged from the hospital. Currently, Medicare only covers SNF care for patients who have a three-day inpatient hospital stay.

Do you believe that seniors deserve to know when their hospital care is classified as "observation status"?

Answer: If confirmed, I look forward to working with Congress to ensure that seniors have the information available to make the best decisions about their care, including CMS' implementation of the NOTICE Act, which requires hospitals to notify patients of their observation status.

8. Last Congress, my colleague Senator Enzi and I introduced the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act, which became law in December 2015. This legislation requires hospitals to give each Medicare patient who receives observation services as an outpatient for more than 24 hours an adequate oral and written notification within 36 hours.

In December 2016, CMS finalized the NOTICE Act rule requiring hospitals to give patients the standardized Medicare Outpatient Observation Notice (MOON) beginning March 8, 2017. CMS anticipates that more than one million patients will receive the MOON annually.

Will you commit to implementing this final rule to ensure that seniors are able to make informed health care decisions?

Answer: If confirmed, I look forward to reviewing that rule to make sure that CMS acts in accordance with federal law and to working with you on any concerns you may have.

Oral Health (questions on behalf of Senator Cardin and Senator Stabenow):

- 9. Oral health and related illnesses have a significant impact on the severity of chronic diseases, which are the most burdensome for older people and people with disabilities, and costly for the federal government. The serious health risks and costs associated with untreated oral disease are increasingly apparent. For example, because they heighten the risk of systemic infection, unresolved oral health problems can preclude, delay, and even jeopardize the outcome of medical treatments such as organ and stem cell transplantation, heart valve repair or replacement, cancer chemotherapies, and placement of orthopedic prostheses. The relationship between periodontal disease and chronic conditions such as diabetes, arthritis, and heart disease is also well established.
 - A) While Medicare statue precludes coverage of "routine" dental services, would you agree that untreated oral health problems, in these examples at least, would be medically necessary rather than "routine"?

Answer: If confirmed, I will review what services have been classified as "routine" and what services have not.

B) Are you committed to using your authority as the CMS Administrator to ensure that Medicare covers medically necessary oral health care, as currently allowed by the statute?

Answer: If confirmed, it will be my duty to follow federal law including the implementation of laws related to Medicare Advantage plans which can provide quality oral health care.

C) Will you commit to evaluating proposals to expand oral health coverage for Medicare beneficiaries more broadly?

Answer: I would be happy to evaluate any proposal that will lead to affordable, high quality healthcare.

<u>Program for All-Inclusive Care for the Elderly (PACE) (question for Senator Cardin and</u> <u>Senator Carper):</u>

10. Johns Hopkins has been on the forefront of innovative care for the most fragile and complex individuals. The Program for All-inclusive Care for the Elderly (PACE) is widely recognized as the gold standard for fully-integrated, comprehensive care. Researchers have shown that the community-based, comprehensive and accountable care offered by PACE delivers quality care, improved health, and value for the health care system. For over 30 years, regulations have limited the population served by the program.

Given our growing, aging population, would you please describe in detail how you plan to enhance the successful work of PACE and other models to ensure that frail elderly patients who want community-based care, as opposed to institutional care, can get it.

Answer: I look forward to working with the staff at CMS to get their input on how we can better serve our aging population as we implement PACE or other related policies enacted by Congress.

Payment Reforms:

11. Patients, providers, as well as public and private payers benefit when valid, reliable, and risk-adjusted scientific measures are used to assess functional outcomes, support evidence-based clinical decision-making, and measure quality. Using these tools also assures the best value for dollars spent. Under your leadership will CMS continue to pursue further expansion of the Merit Based Incentive Payment System (MIPS) to other eligible providers such as physical and occupational therapists?

Answer: I look forward to working with providers to implement MACRA as designed by Congress. I will work with the staff at CMS and providers to evaluate whether the MIPS program is achieving Congress's goals while ensuring that the impact on patients and the providers who care for them are at the center of any future reform efforts. It is especially important that we carefully consider feedback from providers on the frontlines of health care, especially those smaller providers or those providers in rural settings.

Prescription Drugs:

12. The Patient Protection and Affordable Care Act's numerous patient protections have greatly helped beneficiaries, especially those living with chronic and serious health conditions such as HIV/AIDS and hepatitis, access the care they need to stay healthy. Of particular importance to the patients I represent, the regulations implementing the law's Essential Health Benefits (EHBs) and Non-discrimination provisions require health plans to use Pharmacy & Therapeutics committees to develop and regularly update their formularies; cover a minimum number of drugs in each therapeutic class; provide cost-sharing, tiering, and utilization management information to enrollees and potential enrollees; have an exceptions and appeals process for accessing non-formulary drugs; and design and implement their benefits in a way that does not discriminate against or discourage enrollment by individuals living with particular health conditions.

As CMS administrator, would you ensure that the critical patient protections afforded by the ACA remain and are enforced at the federal level?

Answer: If confirmed, it will be my duty to implement the laws passed by Congress and I look forward to evaluating the impact on patients and working with you to ensure patients are able to access high quality care.

<u>Therapy Caps (questions on behalf of Senator Cardin, Senator Casey, and Senator Brown):</u>

13. As you may know, limits on outpatient rehabilitation therapy services under Medicare were first imposed in 1997 as part of the Balanced Budget Act without regard to its impact to access on needed therapy services. Congress has acted several times to prevent the caps from going into effect by passing moratoria. Later in 2006, Congress created an "exceptions process" for beneficiaries whose conditions required more care than the annual limits would allow and at the end of 2015 year, Congress again extended the exceptions process by one year. The current therapy cap for occupational therapy (OT) is \$1,920 and the combined cap for physical therapy (PT) and speechlanguage pathology services (SLP) is \$1,920.

A) What is the impact on seniors that hit the cap?

Answer: If confirmed, I look forward to looking into the impacts of these statutory caps on seniors. It may be that other approaches to therapy provide greater quality care at reduced cost with more respect for the individual needs of each patient in consultation with their doctor. If confirmed, I will look at our Medicare system holistically to make sure that we are delivering access to quality, affordable healthcare to our citizens.

B) Do you support repealing Medicare cap on therapy services?

Answer: If confirmed, I look forward to working with Congress on this issue and providing technical assistance that you or others interested in Medicare therapy caps may need.

Questions for the record from Senator Sherrod Brown

1. <u>Medicaid Expansion and Addiction Treatment in Ohio:</u>

Your consulting firm, SVC, has played a role in developing Medicaid waiver proposals for a number of states including Ohio's proposal, the Healthy Ohio Program, last year.

As you know, CMS denied Ohio's waiver application citing concern that monthly premiums and late payment penalties would "not support the objectives of the Medicaid program, because [they] could lead to a substantial population without access to affordable coverage."

At a time when Ohio is at the height of an opioid epidemic, it is important to maintain coverage and access to care for the more than 500,000 Ohioans receiving mental health and addiction treatment through the Medicaid—including more than 150,000 who now have coverage through Medicaid expansion.

When Ohio submitted its waiver plan, data included in its application estimated that the policies proposed would lead to more than 125,000 Ohioans losing coverage.

Given the opioid epidemic across the nation and the critical role Medicaid plays in helping individuals access needed care, including medication assisted treatment, it is critical that the Administrator of CMS evaluate state waiver requests to ensure that no individual struggling with addiction or a mental health condition loses coverage or access to affordable coverage.

Question: Would you approve a state's Medicaid waiver request if the resulting waiver would result in a loss of coverage or access to coverage for individuals struggling with addiction or other mental health conditions – yes or no?

Answer: To the extent I am not required to recuse from a particular matter under the terms of my Ethics agreement, I will carefully review any waivers on a case-by-case basis. I will consider all factors as required by law including evaluating the state's waiver request to ensure that all individuals struggling with addiction or a mental health condition continue to have access to treatment.

Question: If confirmed, will you continue to support innovative models to improve treatment outcomes for individuals seeking addiction treatment, such as through the 1115 waivers, home health models, and the Innovation Accelerator Program?

Answer: To the extent I am not required to recuse from a particular matter under the terms of my Ethics agreement, I will support effective, best practice, innovative treatment models. Opioid addiction has had a severe and devastating impact on communities and families across the country. If confirmed, I am committed to working with states to protect access to treatments and help low-income adults with mental health and substance use disorders through existing and evidence-based innovative solutions for these problems. To the extent I am not required to recuse from a particular matter under the terms of my Ethics agreement, I will work with states to ensure that access to treatment is not diminished.

2. Infant Mortality and Tobacco:

Ohio has one of the highest infant mortality rates in the country. In 2015 our state ranked 42nd in the nation for infant mortality, and even worse for African American babies.

We don't know exactly why Ohio does so poorly when it comes to infant mortality, but one thing that we do know is that health complications caused by preterm births are the leading causes of infant mortality.

We also know that a major factor in premature births is tobacco use, and Ohio's smoking rate among pregnant women is nearly twice the national rate.

In addition to providing coverage to an additional 20 million Americans, the Affordable Care Act also strengthened Medicaid coverage of services that help tobacco users to quit. Local groups have taken advantage of these provisions in their fight against infant mortality.

Medicaid covers nearly 50% of births in this country.

Question: Do you support the current requirement that state Medicaid programs provide pregnant women with effective tobacco cessation services without cost sharing – yes or no?

Question: Will you work within the Administration and with Congress to maintain this requirement so that all pregnant women – regardless of their income – have access to tobacco cessation services – yes or no?

Answer: The science is clear that tobacco use during pregnancy is risky for both moms and babies. States should have maximum flexibility to prioritize critical health risks such as smoking during pregnancy. The decision to maintain this requirement, however, is a legislative matter that rests with Congress.

3. Fair Pay / Homecare Workers:

The majority of the home care workforce – or those individuals who provide services to older Americans and individuals with disabilities who receive home and community-based services through Medicaid – is made up of female workers.

If confirmed as CMS Administrator, will you commit to working with your colleagues at the Department of Labor to support and advance policies to ensure women across the healthcare workforce and reimbursed by CMS are paid fairly – and treated equally as compared to their male counterparts – regardless of their job – yes or no?

The homecare workforce is primarily paid through Medicaid and, on average, states pay these workers just \$13,000 a year. This means that those women caring for the disabled and elderly are often forced to rely on Medicaid themselves.

In order to provide the highest level of quality care to our most vulnerable Americans – the elderly and those with disabilities – do you agree that those home care workers providing this care full-time should be paid more than \$13,000 a year by their state Medicaid program – yes or no?

Past leadership at CMS committed <u>in writing</u> to exploring federal actions under its current authority that could work with states to strengthen and support home care workers. It is important to me that this issue remain a priority for the current Administration.

If confirmed, will you commit to continuing this work to ensure fair pay and advancement opportunities for the home care workforce – yes or no?

Answer: I firmly believe that women should be compensated based on their ability and their contribution to the workforce, not based on their sex. If confirmed, I look forward to working with HHS and CMS staff as well as the Department of Labor to evaluate these important issues.

4. <u>EPSDT:</u>

The Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit became an additional benefit for children in the Medicaid program in 1967. The EPSDT benefit establishes guidelines which ensure unlimited access to medically-necessary, ageappropriate screenings and preventive care for children, including well-child exams.

Providing preventive care services through EPSDT is essential for ensuring that every child has the opportunity to become a healthy adult. Are you committed to maintaining existing standards for child health care in the Medicaid program?

Are you committed to ensuring that states enforce EPSDT so that children are able to access the services they need?

One major threat to the EPSDT benefit and the health of children in this country is the possibility of restructuring Medicaid into a block grant or per capita cap, proposals which you have supported.

If confirmed, can you guarantee that you will uphold the current standards of coverage, affordability, and especially of pediatric-appropriate benefits for children through the Medicaid program?

Answer: Our goal is to ensure every single American has access to the coverage they want for themselves or their children and dependents, and children are, and will continue to be, a high-priority population within the Medicaid program. States are well-positioned to determine the most appropriate ways to ensure access to the highest quality care for children, which may include diagnosis and screening procedures and the illnesses and conditions they uncover. As this is a matter for Congress, I look forward to working with Congress to improve our Medicaid system.

5. EPSDT Lead Testing Standards:

One important provision in the EPSDT benefit is screening and testing for lead poisoning. More than a half a million children between the ages of one and five are estimated to have blood lead levels above the level at which the CDC recommends public health actions be taken.

Despite these numbers, millions of at-risk children are never screened and tested for high lead levels despite early childhood lead screening and testing requirements. In fact, a Reuter's investigation last year found that less than half of the one- and two-year-olds enrolled in Medicaid – just 41 percent – are tested for lead exposure as required.

Last year, I led a letter to CMS with more than 40 of my Senate colleagues to urge the Agency to improve lead screening and testing across at-risk communities and do everything it can to help healthcare providers quickly identify and track children who have been exposed to lead. Administrator Slavitt responded positively to that letter, and CMS put out an informational bulletin at the end of the year to help states improve their screening rates.

If confirmed as Administrator of CMS, what specific next steps will you take to improve blood lead testing covered by the Medicaid program and ensure adherence to the EPSDT benefit for both screenings and follow-up treatment services?

Answer: The Flint water crisis has highlighted the inherent dangers of lead poisoning and the importance of avoiding such exposure particularly for the young, elderly, and infirm. If confirmed as CMS Administrator, I look forward to working with my CMS colleagues to learn more about potential deficiencies in the EPSDT's lead testing standards and potential solutions for such problems.

6. <u>Preventive Services with Medicare:</u>

As you know, the ACA eliminated cost-sharing for preventive services covered under Medicare. Since the change took effect in 2011, Ohio seniors have benefited from access to life-saving screenings and wellness visits at no cost to them. In fact, more than 885,000 Ohio seniors had at least one preventive Medicare service in 2015.

Question: Are you in favor of repealing the ACA provisions that expanded cost-free preventive services in Medicare? If so, do you acknowledge that this will increase Medicare beneficiaries' out of pocket expenses?

Question: Which preventive services that are currently provided to Medicare beneficiaries without any copay do you believe should continue to be offered at no out-of-pocket cost?

Considering President Trump's executive order to "ease the burden" of the ACA,

Question: how will you ensure that Medicare beneficiaries do not lose coverage of services they have relied upon – and in some cases, services that have saved lives – for the last six years?

Answer: Should I be confirmed as Administrator of CMS, my duty will be to execute the law as passed by Congress and signed by the President. Ultimately, the question of ACA repeal is a legislative matter for Congress to decide.

7. Medicare Advantage under the ACA:

Your history in Indiana shows an interest in expanding the use of private insurance in the Medicaid space. This option is increasingly utilized in Medicare through Medicare Advantage plans. Previously, Medicare Advantage plans paid over 110% of the cost of a service compared to traditional Medicare spending, but this provision was removed through the ACA. If the ACA is repealed, it is assumed that these spending differences would be re-instated.

Question: Do you believe that Medicare Advantage plans should be paid more than what traditional Medicare spends on a given patient? Why or why not?

Question: Will you support or allow unequal reimbursement as compared to FFS Medicare through overpayments by CMS to Medicare Advantage plans?

Question: What will you do to ensure taxpayer dollars are utilized appropriately under the Medicare program when it comes to parity between FFS Medicare and MA?

Answer: Medicare Advantage provides an important option for Medicare beneficiaries to access coordinated care and greater benefits. If confirmed as CMS Administrator, I would seek to ensure Medicare Advantage remains a stable option for beneficiaries and that Medicare Advantage issuers are afforded the flexibility to design plans that beneficiaries want and give them the coverage they want. It is my intention to fairly and accurately monitor the quality and effectiveness of our entire care system, including Medicare Advantage and original FFS Medicare.

8. Medicare Advantage Bill of Rights:

As you know, the Medicare Advantage population is approaching one-third of all Medicare enrollees, and continues to grow. Last month, CMS published a review of more than 50 Medicare Advantage organizations that showed widespread inaccuracies in their provider directories published online.

Inaccuracies ranged from listing the wrong location for a provider to including providers who were not accepting new patients even though the website said they were. This is a clear problem for an increasing number of consumers that should be addressed.

Question: If confirmed, what tools will you use to hold Medicare Advantage plans responsible for complying with program rules?

Question: Since oversight is one of the primary responsibilities of the Administrator for CMS, what specific proposals do you have to strengthen consumer protections in Medicare Advantage?

In addition to getting away with publishing inaccurate provider directories, Medicare Advantage plans can also drop providers mid-year without warning their beneficiaries.

That's why I have previously introduced legislation, the *Medicare Advantage Bill of Rights*, to prohibit Medicare Advantage from dropping providers without cause midyear. It would also require Medicare Advantage plans to finalize their provider networks 60 days before open enrollment so that patients have the information they need before signing up for a plan. This fix does not require legislation. CMS can actually make this change on its own.

Question: Will you commit to strengthening beneficiary protections in Medicare Advantage by ensuring Medicare Advantage insurers are prohibited from dropping providers mid-plan year without cause? **Answer:** Medicare Advantage provides an important option for Medicare beneficiaries to access coordinated care and greater benefits. CMS should always make sure that seniors are in the driver's seat of their health care and have necessary, timely, and accurate information to make health care decisions. Oversight is an important responsibility of CMS. If confirmed as CMS Administrator, I would seek to ensure Medicare Advantage plans comply with regulations and laws to ensure it remains a stable option for beneficiaries and that Medicare Advantage issuers are afforded the flexibility to design plans that beneficiaries want and give them the coverage they want.

I would also look forward to working with my CMS colleagues to learn more about the options for strengthening beneficiary protections in Medicare Advantage, including improving the accuracy of provider directories. I welcome recommendations, particularly those that are evidence-based, that would achieve these results.

9. <u>Nursing Education – [submitted jointly with Sen. Portman]:</u>

The demand for nurses is on the rise, and the Bureau of Labor Statistics estimates that the United States will face a 1.2 million nurse shortage by 2020. Ohio is home to 12 hospital-based nursing programs that receive Medicare pass-through funding for nursing education, which will help supply qualified professionals to meet the demands for the growing nursing workforce. Unfortunately, these hospital-based institutions are in jeopardy as they face competing qualifications between CMS's regulations and evolving accreditation requirements.

To combat this threat to the funding of nursing education, we have introduced legislation in past Congresses – the *MEND Act* – which would simply ensure continued CMS support of nursing education through pass-through funding at hospital-based nursing schools.

Question: If confirmed, will you commit to working with us on ways to ensure these institutions do not lose access to their pass-through funding, both through administrative action and through working with legislators to craft and quickly implement a solution that will allow for the continued education of nurses at hospital-based nursing programs?

Answer: I look forward to working with you on this issue to share feedback and technical assistance on policies relating to nursing education funding, which has a broad geographic scope and impact. If the laws on the issue are enacted, and if confirmed, I will work to implement the laws on the timeline Congress imposes.

10. <u>Laboratory Payments under PAMA – [submitted jointly with Sen. Menendez, Bennet,</u> <u>Casey and Wyden]:</u>

Congress passed the Protecting Access to Medicare Act (PAMA) in 2014. This bipartisan law included policies to update and change the way Medicare reimburses clinical laboratories under the Clinical Laboratory Fee Schedule (CLFS), moving the

reimbursements towards a market-based payment methodology. Under the law, all "applicable" laboratories are required to report to CMS the payment rates and test volumes for their private payers.

CMS finalized PAMA regulations in June, 2016, and released further guidance in September, 2016, which impose an unrealistic reporting timeline for laboratories. Additionally, we have heard from our regional and community-based laboratories about significant concerns they have about their ability to report accurate data and how the current rules' exclusion of market data from hospital outreach labs and definition of "applicable laboratory" will impact the accuracy of CMS's data.

Question: If confirmed, will you commit to looking at the current PAMA regulations and reporting requirements to ensure that independent, physician and hospital laboratories are appropriately and accurately accounted for in the market price data? Further, will you commit to evaluating the need to extend the March 31, 2017, reporting deadline to ensure that laboratories – especially smaller, community laboratories – are able to successfully collect and report the data required under the regulations?

Answer: Accuracy in reporting and data collection is essential for a market to thrive. In this case, we should certainly strive for accuracy in this market data collection process. I look forward to following up with CMS staff and regional and community-based laboratories to discuss workable solutions.

11. CDS under PAMA:

In addition to the issue in my previous question related to PAMA, I have heard from Ohio constituents who have concerns over the clinical decision support (CDS) mechanisms included in PAMA as it relates to advanced diagnostic imaging tests for Medicare Part B, including the use of appropriate use criteria (AUC) in the decisionmaking process. I have heard concerns that CMS's new regulation threatens PAMA by putting severe limitations on the diagnostic imaging provision by limiting CDS to just 8 priority clinical areas (PCAs).

Question: Given your knowledge and previous work with CDS, if confirmed, will you work to implement CDS as fully intended by Congress? What specific actions will you take to ensure uptake of CDS in all PCAs?

Answer: If confirmed as CMS Administrator, I would have a duty to implement laws as passed by Congress.

12. DIR Fees:

In your hearing, you mentioned that Pharmacy Benefit Managers (PBMs) are negotiating prices for Part D, and you're glad that they do. I think that more can be done to negotiate lower drug prices for our seniors, and there is a lack of transparency with the status quo. This lack of transparency and limited capacity to negotiate results in higher costs for consumers and can result in significant challenges for small community pharmacies and long-term care pharmacies. These pharmacies are facing increased uncertainty because of Direct and Indirect Remuneration (DIR) fees imposed by PBMs.

CMS has recognized some of these issues, and in January released a fact sheet showing that the use of DIR fees by Part D sponsors has been "growing significantly in recent years" and has led to an increase in beneficiary cost-sharing, an increase in subsidy payments made by Medicare, and an overall decrease in plan liability for total drug costs.

What role do you believe retroactive DIR fees have on exacerbating closures and consolidation across the delivery system?

If confirmed, what specific steps would you take to improve transparency between plans and pharmacies in the use of DIR fees in the Medicare program?

Would you make it a priority to re-visit the September 2014 proposed guidance (Proposed Guidance on Direct and Indirect Remuneration and Pharmacy Price Concessions) to standardize the timing of how these fees are reported, that has not yet been finalized?

Answer: If confirmed, I will welcome the opportunity to work with Congress and all stakeholders, including small community pharmacies and long-term care pharmacies, to preserve seniors' access to drugs. Additionally, I look forward to working with you to consider how to resolve this pending guidance issue. I would be happy to discuss the September 2014 Proposed Guidance on Direct and Indirect Remuneration and Pharmacy Price Concessions and other related issues with you.

13. Provider Status:

It is estimated that by 2020, the United States will face a shortage of more than 91,000 doctors, which will be particularly painful in rural underserved areas like we have in Ohio and you in Indiana. I am an original cosponsor on a recently introduced bipartisan, bicameral bill, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which would recognize pharmacists as providers in the Medicare program. This would allow pharmacists to serve beneficiaries in underserved areas by utilizing their advanced education, training, and consultation abilities to provide many Medicare services in addition to their essential role in administering and educating patients about their prescription medications.

As CMS Administrator, what will you do to support the utilization of pharmacists to their full scope as a way to improve access to care and keep costs low for Medicare beneficiaries in underserved areas?

Answer: If confirmed, I would be open to various solutions to address the impact of the ongoing physician shortage in underserved areas. Where permitted by law, I would consider the possibility that paying pharmacists in rural areas to engage in certain medical services could

work well in those states where pharmacists have such licensure and a setting appropriate for the services, where primary care doctors continue to be involved in care, and where there is a patient and consumer demand for such services.

14. Observation Status :

During your hearing, I tried to engage you on the issue of observation status for Medicare beneficiaries. As I mentioned, the *NOTICE Act* will initiate MOON notice requirements in just a couple of weeks, but this legislation does not address the underlying problem imposed by the 3-day stay rule.

To follow-up from the hearing, I hope you have had time to review the obstacles facing our seniors' access to affordable care in SNFs under current regulations. My *Improving Access to Medicare Coverage Act*, which I plan to reintroduce next month, would enable time that beneficiaries spend in the hospital under observation to count toward the three-day requirement for Medicare coverage. I appreciate that you are willing to work with me on this huge issue for Ohioans, and hope that you will support my legislative efforts with this reintroduction.

Have you had time to review this provision of law and provide some suggestions on ways to improve this issue for Medicare beneficiaries?

Should you be confirmed, will you commit to swiftly issuing an opinion on CMS' authority in this regard?

If confirmed, will you work to administratively correct this billing technicality that adversely impacts Medicare beneficiaries and work with Congress to correct this issue via legislation, if necessary?

Answer: If confirmed, I will monitor the implementation of the NOTICE Act and the utilization of the Medicare Outpatient Observation Notice (MOON) I will also work to identify if more may need to be done with regard to this observation status issue to improve seniors' access to care in SNFs. And if the best path forward involves legislation, I would be pleased to work with you and provide technical assistance on that as well.

15. Medicaid and CHIP Quality of Care:

Over a decade ago, Congress enacted legislation to begin shifting the metrics in our health system away from paying for volume to paying for quality and safety. In recent years, this shift towards quality has shown improvement in important areas like rates of hospital acquired infections and hospital readmission.

However, there is still much work to be done, especially for our most vulnerable populations. That's why I have introduced the *Medicaid and CHIP Quality Improvement Act* (MCQA) in past Congresses, to encourage data collection and define quality assessments for the more than 80 million Americans who currently receive care through these programs with no structured quality measures.

I know that you understand the value of quality measures and holding states accountable for improving quality for Medicaid beneficiaries. I also know that you understand how collecting data for quality assessments of the Medicaid and CHIP populations is tremendously challenging given the wide variation across states.

Do you believe that Congress and the Administration should know the defined quality of care that state Medicaid and CHIP programs are delivering for that investment?

Answer: Yes, and we should hold states accountable for achieving outcomes. To this end, we must ensure that state Medicaid programs are not beset by unnecessary administrative burdens that could impede progress on achieving this goal.

Would you be willing to work with Congress to try to implement and improve quality measurements for these vulnerable Americans across different structures and delivery mechanisms of the program?

Answer: Yes. If confirmed as CMS Administrator, ensuring high-quality care in Medicaid and CHIP will be one of my top priorities.

16. Medicare Quality of Care:

If confirmed, as Administrator of CMS, you would also have authority over the Medicare program and its budget of close to \$600 billion dollars. This includes the ability to enact regulations and establish guidelines for reporting requirements.

How would you specifically encourage collaboration between the federal government and individual states to identify program standards and incentives in Medicare programs?

Some plans, including my MCQA legislation, champion incentivizing state performance in quality metrics. How would you oversee any such incentives programs?

Answer: The states are well positioned to provide for the unique healthcare needs of their residents. If confirmed, I would work to see that CMS is a helpful resource to the states. CMS can offer clarity regarding state flexibility, technical assistance, and provide support as needed to promote effective policies and practices.

17. Accountability:

In your work with SVP you have worked with states to craft Medicaid programs that require beneficiaries to pay premiums and potentially lock individuals out of coverage if they do not pay. Your website states that you have developed reform programs and waivers for other states, including Kentucky.

Last year, Kentucky Governor Matt Bevin submitted a proposal modeled on Indiana's Medicaid expansion waiver that would go even further than Indiana's proposal by instituting a work requirement as a condition of eligibility for some beneficiaries. CMS has not approved this waiver, and has stated that work requirements are not consistent

with the original intent of the Medicaid program or consistent with federal Medicaid law.

Studies have shown that the main effect of work requirements likely would be the loss of health coverage for substantial numbers of people who are unable to work or face major barriers that prevent them from holding part-or full-time employment. Additionally, state Medicaid agencies would be stretched just covering the basic costs of administering and enforcing these requirements.

As CMS Administrator do you plan to uphold the agencies previous decisions of not approving work requirements under federal Medicaid law?

Do you believe a child should be held responsible – and potentially lose health insurance coverage – if their parent does not pay a Medicaid premium or participate in a work requirement as required under some of the programs you have helped draft?

Answer: Studies have confirmed the value of work to individual health and sense of well-being, and Medicaid has an historic role as part of a broader anti-poverty effort. If confirmed, I look forward to working with states to consider innovative strategies that improve outcomes. Every potential policy should consider the impact on the different Medicaid populations, while ensuring appropriate protections are in place for vulnerable populations like children.

18. <u>CMMI:</u>

As acknowledged during both your and Secretary Price's testimonies, CMMI is an important tool that exists within CMS for the testing and development of new, patient-centric, value-based payment models. These models will be critical to informing the future of care delivery.

Are you committed to preserving CMMI?

Answer: If confirmed, I plan to work with the Secretary to ensure that CMMI, or the "Innovation Center," -- after consultation with Congress, the States, healthcare stakeholders, and Innovation Center staff -- tests appropriate innovative models that reduce costs and improve quality for Medicare and Medicaid beneficiaries. As such, I look forward to reviewing current CMMI projects, consistent with Congressional actions.

How do you plan to involve both stakeholders and Congress in the development and implementation of models?

Answer: Stakeholder engagement is crucial in the development of innovative models. For instance, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) establishes the Physician-Focused Payment Model Technical Advisory Committee, to review proposals for physician-focused payment models that can ultimately be adopted through the Innovation Center. Communication and collaboration with Congress and stakeholders throughout the process is a major priority as CMS moves forward with implementing the law and fostering innovation.

19. Dual Eligibility / CMMI / Medicare standards:

ASPE recently released a report that concludes dual status is one of the most powerful predictors of outcomes and that, with time, outcomes can be improved.

What additional actions can and should CMS take to do more to help support programs and the integration of Medicare and Medicaid for duals?

Answer: Sound integration between Medicare and Medicaid requires that regulations and administrative processes properly align. If confirmed, I will work to ensure that CMS continues to make progress in this area.

20. Medicare / Health System Transformation:

As Congress and the Administration work to incentivize new models of care, it is important that we collect information from states and providers to help inform policy decisions and ensure quality and access.

If confirmed, how will you ensure CMS is monitoring beneficiary access to care across new delivery system models? What factors will you use to measure access to care?

Answer: Our goal is to ensure access to affordable, quality healthcare for all Americans, including individuals in rural or underserved areas. Accordingly, the best metric in the end is one that measures the extent of access to actual care, not just coverage, and the quality of that care as determined by patients working individually with their doctors. I look forward to partnering with states to best determine the real-life impact of health care policy at the local level. We must hold states and providers accountable for enabling access to quality care.

If beneficiary access is hindered, how do you envision addressing these issues and ensuring access to care?

Answer: I intend to work expediently with the Congress, the Secretary and CMS colleagues to strive for improved access to care, especially when access to care may be threatened. Our decisions must be data-driven and made with a focus on addressing the unique needs of the patients in question.

What advocacy organizations – and specifically consumer groups – will you engage in evaluating these alternative payment models throughout the stages of development and implementation?

Answer: I appreciate feedback across the healthcare industry to ensure workable payment models are being pursued. Organizations that represent consumer groups are especially important to engage with to understand the impact of the models on beneficiary care, both on the front end and throughout the development and implementation of the models.

How will you ensure CMS hears directly from impacted beneficiaries and resolves issues immediately so that access is not affected?

Answer: The fundamental metric for knowing that our system is on the right track is the centrality of the patient in the system and their ability to make choices about their care in consultation with their doctor. Restrictions on access to care threaten this principle and ought to be swiftly examined. I look forward to working with CMS to ensure we have an open line of communication with beneficiaries.

21. Out-Of-Pocket Protections for Medicare Population:

Seniors are often on fixed incomes, and their yearly income certainly does not grow at the rate of medical inflation, however, out-of-pocket costs as a share of income continues to rise for Medicare beneficiaries each year. While the ACA helped protect Americans from caps on annual and lifetime out-of-pocket caps, this consumer protection does not exist for Medicare beneficiaries.

What will you do, if confirmed, to help keep costs low for beneficiaries and protect seniors on fixed incomes from growing out-of-pocket costs?

Answer: I would convey to Medicare beneficiaries that I look forward to working with Congress to make certain that we preserve and strengthen Medicare for seniors.

22. Medicare 2-year waiting period:

As I'm sure you know, individuals who are under the age of 65 with a disability are generally required to wait for two years after receiving SSDI before they are eligible for Medicare coverage. Thanks to the ACA, individuals who are waiting for Medicare based on SSDI eligibility can sign up for insurance through the individual exchanges while they are waiting for Medicare eligibility to kick-in.

If the ACA is repealed, what will you do as Administrator of CMS to ensure coverage options for these vulnerable individuals?

Answer: Our goal is to ensure access to affordable, quality healthcare for all citizens, including individuals with disabilities. As such, I look forward to implementing the laws passed by Congress to enable affordable, quality care for individuals with disabilities.

23. Medicare Prescription Drug Prices:

During your hearing, Senator Wyden asked you about soaring drug prices affecting seniors through Medicare Part D. I think you agree with many of us, and many Americans as you noted, that the prices of these prescription drugs are out of control and it should be a goal to make these drugs accessible and affordable to all Medicare beneficiaries.

It is imperative that the American public and legislators know, if confirmed as CMS Administrator, how (specifically) will you address this drug pricing issue?

Do you intend to use CMMI authority to test new methods to bring down Medicare drug spending? If so, how might you direct this authority?

Answer: The issue of drug costs is one of great concern to all Americans. You have my commitment that I will work with you and others to make certain that Americans have access to the medications that they need. I share your concern regarding the importance of individuals and families being able to afford the prescription drugs they need. If confirmed, I look forward to working with HHS, CMS, and FDA to consider potential options to address the issue of access to, and the affordability of, prescription drugs.

24. Medicaid Churn:

Medicaid churn – or the continual disenrollment and re-enrollment, which can be caused by changes in income or changing life circumstances – can interrupt continuity of care and access to important services in the Medicaid population. This can particularly disruptive for Medicaid beneficiaries using care coordination and care management services, which are interrupted every time a beneficiary is disenrolled.

In your work with Medicaid, how have you helped mitigate the negative impacts of churning?

Answer: One way to mitigate the impact of Medicaid churn is to institute enrollment and payment policies and procedures that are as consistent as possible with the commercial health insurance market. Coordination between state workforce development programs that help Medicaid members become more upwardly mobile can also help eliminate churn.

How will you ensure that eligible individuals will remain covered in Medicaid, even when there are changes in their life circumstances at no fault of their own?

Answer: It is important that Medicaid's enrollment and payment policies strike the right balance between fairness and responsibility and contain the appropriate safeguards that consider changing circumstances for families.

25. Physician Reimbursement:

On average, Medicaid pays providers about 70 percent of what a Medicare provider receives for the same service. The only difference is the age of the patient being served.

There are 45 million children and 30 million adults enrolled in Medicaid. As you noted in your hearing, you want all patients to be able to access any doctor they choose, but typically low Medicaid payments – that are set by states – can impede the ability of providers to accept more patients – both pediatric and adult – covered through this program.

Along with Sen. Murray, I have worked to introduce the *Ensuring Access to Primary Care for Women and Children Act* in past Congresses, legislation that would solidify parity between Medicare and Medicaid reimbursements for primary care. If confirmed, you would oversee the budgets of both Medicare and Medicaid, and would be looked to for guidance on the issue of appropriate Medicaid reimbursement rates.

Do you believe that a child's care should be valued at only 70% of that of an adult?

Answer: No. Medicaid has a complex financing and payment system that includes base rates set by states, supplemental payments to providers, and other federal and state funding sources for care to the Medicaid or uninsured populations.

If a state's Medicaid budget is cut by a per-capita-cap or block grant proposal, how will you prevent states from cutting reimbursement rates for providers to even worse than they are now?

Answer: I look forward to working with Congress on the specifics of any new Medicaid financing and payment proposals in order to hold states accountable to ensure patient access to high quality health care.

26. Preexisting Conditions:

As Senator Wyden said during your confirmation hearing, Americans cannot afford to go back to the days of when healthcare was only for the healthy and wealthy. I strongly believe that if pieces of the ACA are repealed, any replacement must ensure that every American – regardless of whether they are a woman, have cancer, ESRD, or any other condition or preexisting condition – has access to affordable, comprehensive coverage equal to or better than coverage options currently available through the ACA, regardless of their income.

I'm concerned that a one-sized-fits-all approach, like high risk pools, leaves those who truly need high quality and affordable health care out of luck.

How will you ensure that those with the greatest needs will have continued access to high-quality health care?

Answer: I believe it is important that we as a nation make sure that every American has access to the kind of health care and health coverage that best meets their needs. Additionally, it is imperative that all Americans have access to affordable coverage and that no one is priced out of the market due to their diagnosis. Nobody ought to lose insurance because they get a bad diagnosis. If confirmed as CMS Administrator, I intend to implement the laws passed by Congress to ensure access for all, including those with pre-existing conditions, is affordable.

27. Medicaid guardrails:

Through your work at SVC, you have helped several states attempt to change their Medicaid plans.

In your experiences, what evidence have you seen that Medicaid guardrails help beneficiaries gain employment, transition off of Medicaid onto different health insurance coverage, and achieve other stated goals of the individual programs?

Is there any evidence that these requirements increase burdens by adding costs to the programs or by increasing administrative challenges and inefficiencies?

Answer: I have been fortunate to be involved in many proposals and initiatives to help Medicaid beneficiaries along the lines described. In my experience, meeting federal requirements like guardrails can be a limitation on state innovations and do not necessarily improve health outcomes. If confirmed as Administrator, I would endeavor to ensure States are given the flexibility to pursue innovative approaches that fit their needs while ensuring access to care.

28. Biosimilars:

During your hearing, Senator Roberts asked you about the need for CMS and FDA to work together to promote the uptake of biosimilars and enhance innovation across agencies to reduce costs of prescription drugs. I agree collaboration between agencies on this issue is important. I have also introduced legislation in the past that would help achieve this by shortening the patent exclusivity period for expensive, brand-name biologic drugs and allow biosimilars to enter the market sooner. Biosimilars, which are equivalent in safety and efficacy to their reference biologics, have the capacity to reduce prescription drug costs, yet physicians must be willing to prescribe them and patients need the information necessary for them to be confident in taking them.

As CMS Administrator, how would you work with FDA to develop this burgeoning market and promote biosimilar uptake?

As you mentioned multiple times in your hearing, you want to make sure all patients have access to the drugs that they want to take. Because the costs of drugs is an important factor in that decision, increasing the availability of biosimilars is an important step in that process and will ensure beneficiaries have access to choices when it comes to their prescription drugs.

Educating patients and providers is an important component to ensure the widespread use of biosimilars. It is vital that providers are well informed about how a biosimilar can be prescribed, and how and when an interchangeable product can be substituted for another biological product. Simultaneously, it is imperative that patients, too, have confidence in the safety and efficacy of a given FDA-approved biosimilar.

Please describe specific examples of patient and provider education efforts that you will encourage the FDA to engage in regarding biosimilars, if you are confirmed.

Answer: If confirmed, under my leadership, CMS will work with the FDA to help ensure that Medicare and Medicaid beneficiaries have guidance on biosimilars. I understand that this will be increasingly important as more of these products are expected to become available to U.S. patients in the coming years.

29. <u>Therapy Caps – [submitted jointly with Senator Cardin]:</u>

As you may know, limits on outpatient rehabilitation therapy services under Medicare were first imposed in 1997 as part of the Balanced Budget Act without regard to its impact to access on needed therapy services. Congress has acted several times to prevent the caps from going into effect by passing moratoria. Later in 2006, Congress created an "exceptions process" for beneficiaries whose conditions required more care than the annual limits would allow and at the end of 2015 year, Congress again extended the exceptions process by one year. The current therapy cap for occupational therapy (OT) is \$1,920 and the combined cap for physical therapy (PT) and speechlanguage pathology services (SLP) is \$1,920.

What is the impact on seniors that hit the cap?

Do you support repealing Medicare cap on therapy services?

Answer: If confirmed, I look forward to reviewing the impact of the statutory caps on seniors. It may be that other approaches to therapy provide greater quality care at reduced cost with more respect for the individual needs of each patient in consultation with their doctor. If confirmed, I will look at our Medicare system holistically to make sure that we are delivering quality, affordable healthcare to our citizens.

Questions for the record from Senator Michael F. Bennet

1. This week, I worked with Senator Grassley to reintroduce the Advancing Care for Exceptional (ACE) Kids Act. The bill would help hospitals and other providers coordinate and standardize care across state lines for children with complex medical conditions. As you may know, Medicaid covers about two-thirds of the three million children with complex medical conditions. This represents nearly 40% of Medicaid costs for children. The bill is expected to reduce the burden on families who are often managing multiple specialists, improve outcomes, and lower costs.

Does the Administration support this concept? What are some other ways the Administration may seek to help families who must care for children with complex medical conditions.

Answer: If confirmed, I would support efforts to help coordinate care. I would start by working with my colleagues across the Department to identify all the ways in which HHS aims to help these children in need. And I would hope to encourage our use of existing authorities and funding to better align resources to meet this challenge, especially at CMS. I would also work with you and other Members of Congress on their ideas on this important topic.

2. I worked with Senator Portman to introduce the Medicare PLUS Act, which would set up a pilot program to help the top 15% of the highest-cost Medicare beneficiaries by coordinating their health care needs. As you may know, 15% of Medicare beneficiaries have six or more chronic conditions and account for 50% of total Medicare spending.

Would the Administration consider piloting such a program through the CMS Innovation Center?

Answer: If confirmed, I would explore what voluntary options we can make available to the Medicare beneficiaries with the greatest needs and their physicians. I think many will appreciate the opportunity to work with a care manager and possibly others who will spend the time and effort needed to help the patient make different choices to manage their own care. I would seek

to work with you on your proposal to explore how it and others like it can be a path to empowering those who are subjected to the most uncoordinated and challenging aspects of our health care system.

- 3. Colorado has a strong commitment to community living and home and community based services. This includes a Community Mental Health Supports waiver, an Elderly, Blind, and Disabled waiver, and a Children with Autism waiver. We have several others that support the most vulnerable in the community.
 - a. How can we support older Americans and individuals with disabilities who choose to live in the community?
 - b. What additional flexibility do states need to innovate through waivers?

Answer: The goal of CMS is ensure access to affordable, quality healthcare for all citizens. This, of course, includes people with disabilities who depend on Medicaid. If confirmed, I hope to implement the law so as to allow states the flexibility to approach this population in a way that makes sense for their program and its beneficiaries, so long as it is done in accordance with federal law.

- 4. Colorado has participated in many multi-payer initiatives like the Comprehensive Primary Care Initiative and the State Innovation Model and has worked closely with the Center for Medicare and Medicaid Innovation. Our Medicaid program is also participating in the demonstration project for individuals dually enrolled in Medicare and Medicaid. The state also has a highly successful Accountable Care Collaborative delivery system model.
 - a. Moving forward, how do you foresee CMS preserving these types of innovations?
 - **b.** What steps will you take to ensure that CMMI models increase quality and access to care for patients?
 - c. How will you ensure that innovative demonstrations are developed with input from clinical experts and interested stakeholders?

Answer: While I cannot comment on specific demonstrations at this time, if confirmed, I plan to work with the Secretary to ensure that the Innovation Center, -- after consultation with Congress, the States, healthcare stakeholders, and Innovation Center staff -- tests appropriate innovative models that reduce costs and improve quality for Medicare and Medicaid beneficiaries. As such, I look forward to reviewing all current CMMI projects, consistent with Congressional actions.

5. Over 700,000 Coloradans live in a rural community. The Medicaid Expansion provided some financial stability to rural hospitals that were on the brink of closure before we A the Affordable Care Act. In fact, hospitals in Colorado saw a 30% drop in uncompensated care. I have heard from rural hospitals in our state that several will

face significant financial challenges if the law is repealed. This is concerning, considering that there are counties in Colorado without access to a clinic or a hospital.

- a. Would you support an Affordable Care Act replacement bill that reduced access to health care in rural communities?
- **b.** How would a replacement ensure that these communities continue to have access to quality health care?

Answer: Oftentimes rural health care providers and patients are overlooked in the broader discussion of national health care issues. Significant health disparities exist for rural populations for a variety of reasons, including challenges with access to affordable coverage and health care services. Moreover, small rural providers face a unique set of challenges depending on where they are, who they serve and what federal and state requirements they are subject to. If confirmed, I will work tirelessly to address the health care needs of all Americans, rural or urban. I look forward to working with Congress to implement the laws they pass to ensure every single American has access to the coverage they want for themselves and that individuals who lost coverage under the Affordable Care Act get or maintain coverage. This of course includes individuals who access care at rural hospitals or clinics.

6. A Colorado-based orthopedic practice is participating in one of CMMI's voluntary demonstration projects, the Bundled Payments for Care Improvement (BPCI) program. Under the program, healthcare organizations enter into payment arrangements that include a new revenue structure based on financial and performance accountability for entire episodes of care, in this case joint replacements. The program is showing promise for Colorado patients, who are seeing improved outcomes.

There are concerns with the implementation of the program, specifically the National Trend Factor, which continuously updates the target prices set by CMS. Providers have asked for increasing clarity from CMS and CMMI.

As CMS Administrator, how would you address these issues so that providers continue to participate in voluntary demonstration projects that improve outcomes for patients?

Answer: If confirmed, I plan to work to ensure that the Innovation Center -- after appropriate consultation with Congress, the States, healthcare stakeholders, and Innovation Center staff – address such concerns in testing innovative models that reduce costs and improve quality for Medicare and Medicaid beneficiaries. I look forward to reviewing current CMMI projects, consistent with Congressional actions.

7. Reforming the Stark Law has been a topic of discussion over the past few years as we move toward alternative payment models that pay for value.

In your role as CMS Administrator will you recommend updates to Stark Law when alternative payment models are used?

Answer: While there are a number of legitimate concerns regarding physician referrals and compensation, I think it may be appropriate to examine regulations implementing the Stark Law and its impact on reform efforts. In some cases, the Stark Law may discourage coordination of care, and lead to a more fractured health care system. I would consider these situations closely, in consultation with Congress and in context when considering what changes might be needed. I look forward to working with Congress to implement the law on critical issues related to APMs and the Stark Law.

- 8. Current CMS health reform efforts are based on the concept of the triple aim -improving the patient health care experience, improving the health of the population at large, and reducing the per capita costs of health care.
 - a. If confirmed as CMS Administrator, will the triple aim remain a central tenant of CMS efforts?
 - b. What metrics will you use to ensure these goals are met?

Answer: The triple aim includes the goals we all share for our health care system and, if confirmed, I would work to ensure its elements would remain important to CMS' work. The fundamental metric for knowing that our system is on the right track is the centrality of the patient in the system and their ability to make choices about their care in consultation with their doctor. Without that, the most impressive facilities and technology are not serving our people's needs, nor is the most efficient system doing what is most important. With the patient at the center of the system as a foundation, all else is possible and achievable.

- 9. Physicians have noted that the lack of interoperability between electronic health record (EHR) systems has been a key barrier to complying with requirements for meaningful use of health IT.
 - a. How do you plan to address the ongoing challenges related to EHR interoperability?
 - b. How do you plan on restructuring the incentives for meaningfully using EHRs?

Answer: If confirmed, I look forward to working with Congress to implement laws related to improving the use of EHRs. Patients and providers depend on the fast exchange of information across health systems. Having access to a patient's complete medical record enables a medical professional to better diagnose and treat a patient. Doctors know best how to treat their patients and we should think of EHRs as a means to enable that better care. As Congress considers options to improve the interoperability of this system so that the burdens on physicians do not hinder their ability to practice medicine, I will stand ready to provide technical assistance and support through that process.

Questions for the record from Senator Robert P. Casey, Jr.

1. Elected officials on both sides of the aisle have said they strongly support the ACA's provision allowing young adults to stay on their parents' insurance until age 26. As you know, there is a parallel provision in Medicaid law allowing youth aging out of foster

care to maintain health coverage until they turn 26, given they have no parents to provide that benefit for them.

Do you agree that foster youth – children who were removed from their homes due to abuse and neglect – should have the same federal health coverage protections as children who are fortunate enough to be able to stay on their parents' health coverage?

Answer: This would be a part of the new legislation that Congress will be voting on, so that decision is in Congress' hands. If confirmed, I will work to ensure that CMS appropriately implements the statutes within its purview.

2. The Children's Health Insurance Program (CHIP) has been an enormously successful program and has helped, along with Medicaid and the Affordable Care Act, to bring children's insurance rates up to 95 percent – the highest rate ever. The program currently covers about 8 million children per year, is popular, and has enjoyed significant bipartisan support from Congress. It is also due to be reauthorized this year.

Will you pledge to work with Congress to reauthorize and fully fund the CHIP program in a timely manner?

If confirmed, will you guarantee that under your leadership, CHIP will continue to be a viable option for America's children, and that it will continue to cover medically necessary care for the children who are enrolled?

Answer: It is important that every child has access to high-quality health coverage. CHIP plays an important role in accomplishing this objective, but there is also a need to focus on family coverage in the private market and employer plans, and on giving states needed flexibility. Each state has different needs, and I believe CMS needs to work with states to ensure that, consistent with those needs, the CHIP program provides the best possible coverage to their residents. If confirmed, I look forward to working with you on this issue to share feedback and technical assistance on policies relating to CHIP. I will work to implement CHIP reauthorization as passed by Congress.

3. At the end of last year, the HHS Assistant Secretary for Planning and Evaluation (ASPE) put out a report that I and other members requested on the impact of socioeconomic status (SES) on the Medicare quality programs like hospital readmissions and the Medicare Advantage star ratings. All these ratings either reward or penalize monetarily for good or bad results and those that serve a high number of low SES individuals have a harder time achieving high quality ratings because of the complications of the populations. In this report ASPE discussed options on how to improve the quality programs and more accurately account for these populations.

What do you think we need to do, to improve how Medicare accounts for SES in the quality programs?

Answer: My work with vulnerable populations has highlighted for me the impact of social determinants of health and the role of life choices in managing one's own health. At the end of the day, health care programs for this population ought to empower and enable ownership of one's health care. If confirmed, we ought to explore ways that SES as well as the way other important factors impact quality programs and design the programs with the goal of ensuing patient empowerment front and center.

4. Many people with disabilities want to work and can do so with the services only available through Medicaid, to help them work. These services include supported employment for people with mental health disabilities or personal care attendants for those with intellectual or physical disabilities. Without these services, many people with disabilities will be unable to work.

How will you ensure that a person with a disability, mental health, intellectual, physical, sensory, or any other type of disability as defined by the Americans with Disabilities Act, has access to the services currently available through Medicaid?

Answer: Our goal is to ensure access to affordable, quality healthcare for all citizens. This, of course, includes people with disabilities who depend on Medicaid. Towards this end, I support the principles of community integration, beneficiary autonomy in decision making, and person-centered planning articulated in CMS' approach to Home and Community Based Services and the HCBS Settings Rule (with a compliance date in March 2019). If confirmed as CMS Administrator, I would rely on these principles in making decisions appropriate to CMS' role in administering Medicaid and working with Congress to implement and support efforts that help people work.

5. The Center for Medicare and Medicaid Innovation (CMMI) was created to test new payment models and encourage the Medicare and Medicaid programs to look beyond traditional payment systems and find new ways to help individuals benefit from the many advances modern medicine. These advances have been seen in the clinical setting and in the form of new, innovative therapies, some of which even offer potential cures for diseases that previously could only be managed with chronic therapies.

Would you be willing to work with Congress to develop alternative payment models that test these advances and examine the benefits these advances could have on Medicaid and Medicare beneficiaries, as well as how such alternative payment models could affect the cost of care over a decade or more, and work with Congress to remove any obstacles that might prevent those models from moving forward?

Answer: If confirmed, I plan to work to ensure that the Innovation Center -- after appropriate consultation with Congress, the States, healthcare stakeholders, and Innovation Center staff -- tests innovative models that reduce costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. I look forward to reviewing current CMMI projects, consistent with Congressional actions.

Questions for the record from Senator Mark R. Warner

1. 11% of Virginians rely on Medicaid for their health insurance, even without Medicaid expansion. This coverage is more efficient than most other forms of insurance; Virginia also operates the 3rd most efficient Medicaid program in the country, receives the lowest allowable federal matching rate, and the vast majority of beneficiaries are enrolled in a managed care plan. Block granting or imposing a cap on Medicaid would be damaging to states like Virginia. Do you oppose structural changes to Medicaid that shift costs onto the states like block granting or per capita caps?

Answer: If confirmed as Administrator, I intend to work with States and Congress to improve Medicaid and implement the laws enacted by Congress. From demographic and budgetary concerns to ensuring access for special populations, each State faces different challenges in Medicaid. A one-size-fits-all approach will not work and that is why flexibility for states in how they design their Medicaid programs is crucial. At the same time, states must be held accountable to standards that result in better health care quality and access. The mechanics of Medicaid reform will be a legislative decision that will need to account for how to encourage states to work together on making improvements to the program while increasing flexibility.

2. 77% of Virginia Medicaid enrollees are in families with where at least one individual is employed, and unfortunately many of the rest are forced to rely on the program not by choice, but because they are unable to work—perhaps requiring child care or job training, or have a disability. The evidence shows that imposing a work requirement actually has a limited impact on employment, especially in the long-term. Do you intend to require states, or make it easier through the waiver process, to include work requirements as a condition to receive Medicaid services? If you were to impose work requirements in Medicaid, would you also commit to supporting those enrollees who need access to child care, transportation, or job training?

Answer: If confirmed, I will coordinate with States to provide greater flexibility for determining how to care for their most needy citizens as we encourage work and opportunity.

3. Do you agree with President Trump's statement on the campaign trail that he would not reduce Medicare benefits, or make major changes to Medicare outside of eliminating waste, fraud and abuse? Would structural changes to Medicare maintain the basic Medicare guarantee, while also strengthening the program's solvency?

Answer: If confirmed, I will serve at the pleasure of the President and will support his policy initiatives within the bounds of the law. As Congress considers structural changes to Medicare, I will stand ready to provide technical assistance as needed if I am confirmed. Ultimately, the decision whether to enact structural changes to the program is the province of Congress. Whatever reforms are considered, CMS will put the patient first in our implementation of the reform in question.

4. I have worked with bipartisan members of the Finance committee to expand the use of telehealth, especially in Medicare, which lags most state Medicaid programs and the commercial sector. CMS already has the authority to lower some barriers for telehealth and remote patient monitoring in Medicare without Congress. What actions, especially

around alternative payment models such as ACOs, should CMS take to increase the utilization of technology in a way that improves quality while maintaining fiscal integrity? Under what circumstances should fee-for-service Medicare cover telehealth services? What evidence does CMS need to similarly increase access to remote patient monitoring services in fee-for-service Medicare?

Answer: I share your interest in promoting telehealth. Telehealth can provide innovative means of making healthcare more flexible and patient-centric. Innovation within the telehealth space could help to expand access within rural and underserved areas. If confirmed, I look forward to continued discussions on telehealth, including on the best means to offer patients increased access, greater control and more choices that fit their medical needs.

5. Despite the ACA lowering the percentage of uninsured by 8 percentage points in rural counties, rural hospitals are still facing immense challenges, serving older, sometimes more economically disadvantaged populations challenged by less access to primary, dental, and f health care than their urban counterparts. CMS threatened to reclassify Page Memorial Hospital in Luray so that it would no longer serve as a Critical Access Hospital, which would have effectively led to the hospital significantly reducing services such as treatments for heart disease and diabetes, which occur in Page County at far higher rates than statewide. I worked with CMS to ensure that Page kept its Critical Access Hospital classification As CMS Administrator, what improvements to the hospital classification system will implement to ensure that Critical Access Hospitals like Luray are adequately funded?

Answer: As you may be aware, roughly one-third of America's counties now have only one health insurer offering coverage on the individual market Exchange. The problem is especially acute in rural counties, as insurers continue to exit the market and costs continue to rise, making coverage less affordable and reducing choices for patients. Moving forward, our goal must be to ensure every American has access to the coverage they need, including those who access care at rural or Critical Access Hospitals. I believe the best metric in the end is one that measures the extent of access to care rather than simply looking at coverage. If confirmed, I look forward to working with CMS staff to evaluate the hospital classification system and to understanding the unique issues for your state and its hospitals.

6. The Obama Administration made significant progress to better align fee-for-service Medicare payments with value and quality, and I have spent the better part of two years working with bipartisan members of this Committee to improve care for Medicare beneficiaries with chronic illness. In what sector of the Medicare program will you focus on accelerating value-based purchasing or the broader move to align with value and quality?

Answer: If confirmed, I plan to evaluate the respective sectors of the Medicare program to understand how payment reforms are working – or not working – for providers and their patients, especially as we implement MACRA in accordance with the law. Measuring value and quality is a challenge that requires careful planning and broad collaboration among all involved stakeholders, especially the beneficiaries who are impacted most.

7. By moving toward a consolidated quality-reporting and payment system under MACRA, Physicians are incentivized through payment adjustments into alternative payment models, and those who remain in fee-for-service report on quality, resource use, clinical practice improvement, and use of electronic health records. Which of these metrics do you expect to be most challenging for providers to meet, and how quickly would you anticipate payment adjustments moving providers into alternative payment models?

Answer: For small providers, especially in rural Virginia and other rural locations around the country, change can be difficult. The implementation challenges created by new government-directed programs are different and oftentimes more significant for smaller health care providers than they are for larger providers who might have the resources and personnel to handle such changes. As we move forward with the implementation of MACRA it is critical that we collaborate and communicate with all providers on the frontlines to better understand what challenges they are facing and how we can support them through its implementation.

8. The Obama Administration made significant progress to better align fee-for-service Medicare payments with value and quality, and I have spent the better part of two years working with bipartisan members of this Committee to improve care for Medicare beneficiaries with chronic illness. The Annual Wellness Visit, or AWV, is an important preventative benefit for Medicare beneficiaries. One of the key required components of this visit is an assessment of the beneficiary's cognitive functioning, which could be particularly useful in detecting early signs of Alzheimer's or other forms of dementia, helping beneficiaries receive a timely diagnosis and access additional services and supports, like the new assessment and care planning services for beneficiaries. Despite existing for six years, as of last year fewer than 20 percent of Medicare beneficiaries utilized the Annual Wellness Visit. What concrete steps will CMS take to increase access to the Medicare Wellness Visit?

Answer: If confirmed, I look forward to working with you to enable better access to preventative care for Medicare beneficiaries. First, we should evaluate what is working well and what the areas are for improvement. Your counsel as we move forward in evaluating the AWV will be critical.

9. Effectively caring for patients at all stages of illness is an important part of moving Medicare into the 21st century. I have worked with Senator Isakson and others to ensure that conversations between patients and the care team help patients to navigate this difficult process: Improvements to care planning would give individuals and their families the ability to make smarter decisions, and provide information and support so they can make informed choices based upon their own values and goals. One CMMI demonstration provides hospice beneficiaries with the option to receive supportive care services typically provided by hospice while continuing to receive curative services, called Medicare Care Choices. What additional steps would you take to expand timely access to concurrent curative care and hospice services? What other steps would you explore to expand access to hospice and palliative care?

Answer: As you know, the Medicare hospice benefit covers services designed to provide palliative care and management of a terminal illness, including drugs and medical and support services. Under the current structure, hospice care is provided in lieu of most other Medicare services related to the curative treatment of the terminal illness. Through the Medicare Care Choices Model, the Innovation Center is piloting a new option for Medicare beneficiaries to receive hospice-like support services from certain hospice providers while concurrently receiving services provided by their curative care providers. Should I be confirmed as Administrator, I intend to carefully examine this Innovation Center model as well as look at other options for expanding access to hospice and palliative care.

10. The Center for Medicare and Medicaid Innovation (CMMI) is conducting several demonstration projects for alternative payment models in Medicare with the potential to save taxpayer dollars while maintaining or improving the quality of care for beneficiaries, including bundled payments for cardiac care, competitive bidding and value-based insurance design. With a voluntary approach, only those who are already efficient or performing well may participate. Out of the over 75 CMMI demonstrations, which two do you think have the most potential to improve care and lower cost? Please specify two additional demonstrations you would plan to build upon, if confirmed as CMS Administrator?

Answer: The Innovation Center provides significant opportunity for testing new models for healthcare financing and delivery. I cannot comment on specific demonstrations at this time, without examining the outcome data. However, if confirmed, I intend to examine the range of demonstrations currently underway, as well as look for potential new initiatives to explore innovative approaches to lower healthcare costs and improve quality for Medicare and Medicaid beneficiaries. I look forward to reviewing current CMMI projects, consistent with Congressional actions.

11. The Affordable Care Act included many provisions with budget savings, including increased revenue and Medicare savings. Fully repealing the Affordable Care Act, including revenue provisions and Medicare savings, would add significantly to the national debt, cost \$350 billion over 10 years under conventional scoring, and hasten Medicare's insolvency by 5 years. Are you in favor of an ACA repeal that will contribute to our national debt and deficit? Do you believe the revenues in ACA, much of which funded the coverage expansion, should be retained, set aside for a possible replacement, or fully repealed?

Answer: Should I be confirmed as Administrator of CMS, my duty will be to execute the law as passed by Congress and signed by the President. This includes ensuring that the Medicare program is well administered, effective, and available for eligible beneficiaries, and that it is sustainable for the future.

12. While we are moving towards paying for value in many areas of healthcare, in the drug space we have largely lagged behind. In the past year, some insurers and drug manufacturers piloted value-based arrangements that hold the manufacturer

accountable for how their product performs in the real world on an agreed upon set of metrics. In 2015, I led a letter to CMS asking them to examine the potential of using value-based arrangements in Medicare and other public programs. Will you commit to working with me to identify potential policy barriers that Congress should review in order to move towards reimbursement for value rather than volume in the drug space?

Answer: If confirmed, I look forward to working with you and providing technical assistance, when appropriate, as Congress considers legislation that impacts CMS and the beneficiaries served by Medicare and Medicaid.

13. As Governor of Virginia, I prioritized the Commonwealth's Children's Health Insurance Program (FAMIS), and streamlined the program so that it could fund coverage for 200,000 Virginia children each year, almost 98% of eligible children. ACA repeal could result in the loss of \$114 million from Virginia's Children's Health Insurance Program, and increase the uninsured rate among Virginia kids from 3% to 8%. Block granting or capping Medicaid would also damage the Commonwealth's ability to cover children, who represent half of Virginia Medicaid enrollees but only 20% of costs. Will you support any policy, regulation, or proposal that would increase the uninsured rate among children?

Answer: It is important that every child has access to high-quality health coverage, and CHIP plays an important role in accomplishing this objective. CHIP plays a major role in this, but there is also a need to focus on family coverage in the private market and employer plans, and giving states needed flexibility. Each state has different needs, and I believe CMS needs to work with states to ensure that, consistent with those needs, the CHIP program provide the best possible coverage to their residents. If confirmed, I would work with Congress on CHIP reauthorization with these principles in mind.

(Question on behalf of Senator Warner and Senator Isakson)

14. Over the past three decades, rural hospitals in Virginia and Georgia have lost out on millions of dollars of Medicare payments annually because of this skewed wage index formula. I worked with Senator Isakson and others to help rural hospitals in many parts of the country receive fair Medicare reimbursement, by introducing the bipartisan Fair Medicare Hospital Payments Act. The bill would level the playing field for at least 19 hospitals in rural Virginia and over 100 in Georgia. As CMS Administrator will you work with us to correct the gaming of the Medicare wage index, and ensure that we shore up rural hospitals nationwide?

Answer: If confirmed as Administrator, I intend to examine the impact of the statutory wage index, as well as the range of issues facing Medicare, as we look for ways to improve the program and make it sustainable for the future.

Questions for the record from Senator Claire McCaskill

1. Before the passage of the ACA it was legal for insurers in some states to use being a survivor of domestic violence as a pre-existing condition.

Question: Do you have a plan to ensure that survivors of sexual assault have access to affordable comprehensive insurance coverage and that they are not subject to discrimination or higher prices?

Answer: No one should have to pay higher health insurance rates due to being a victim of domestic violence or sexual assault. If confirmed, I look forward to taking steps to increase access to affordable, quality health care for all Americans, including those who are victims of domestic violence or sexual assault.

2. Question: Do you believe that the federal government should have access to state data in order to perform evaluations of the Medicaid program generally and Medicaid demonstration projects specifically?

Answer: If confirmed, I will work within the confines of the law to partner with states to exchange appropriate data in order to evaluate and improve our healthcare delivery systems. I am a strong proponent of state innovation and flexibility – and states must also be held accountable for ensuring the programs they operate provide access to high-quality care.

3. Earlier this month the CDC released data showing that the uninsured rate was 8.8 percent for the first nine months of 2016, which was a historic low.

Question: Will you advice against measures that increase the number of people without insurance?

Answer: I have fought for coverage and greater access to health care throughout my career. If confirmed, I will work with you and your office, the Congress and all interested parties to increase access to high-quality health care. However, we should not assume that just because people have an insurance card that they have access to health care. Many people have out of pocket expenses they cannot afford and others face limitations on the providers they can see. If confirmed, I will do everything I can to ensure that coverage results in better access to care.