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NOMINATION OF MARILYN B. TAVENNER

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

ON THE

NOMINATION OF

MARILYN B. TAVENNER, TO BE ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

APRIL 9, 2013

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NOMINATION OF MARILYN B. TAVENNER, TO BE ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

TUESDAY, APRIL 9, 2013

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

The hearing was convened, pursuant to notice, at 10:05 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Rockefeller, Wyden, Schumer, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, Hatch, Grassley, Crapo, Roberts, Enzi, Thune, Burr, Isakson, and Portman.

Also present: Democratic Staff: Mac Campbell, General Counsel; David Schwartz, Chief Health Counsel; Rory Murphy, International Trade Analyst; and Tony Clapsis, Professional Staff. Republican Staff: Chris Campbell, Staff Director; Jay Khosla, Chief Health Counsel Policy Director; and Kim Brandt, Chief Health Care Investigative Counsel.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

Douglas MacArthur once said, "A true leader has the confidence to stand alone, the courage to make tough decisions, and the compassion to listen to the needs of others." Testifying before us today is Marilyn Tavenner, nominated to be the Administrator for the Centers for Medicare and Medicaid Services, otherwise known as CMS.

Ms. Tavenner, you are being asked to draw on years of extensive experience to lead this agency and administer programs upon which millions of Americans rely. You will surely need confidence, courage, and compassion in this role.

The head of CMS has a great responsibility. CMS administers health coverage to roughly one in three Americans. That includes 50 million Medicare patients, 56 million Medicaid patients, and more than 5.5 million children through the Children's Health Insurance Program. Some 167,000 seniors and 8,300 military retirees in Montana rely on Medicare, the largest program you will oversee at CMS.

These Montanans are my employers, and they, as well as millions more across the Nation, are your employers as well, Ms. Tavenner, so I encourage you to never forget that you are working for them.

It is also important to remember who works for you. The Administrator of CMS oversees 5,800 employees. If confirmed, you must demand from these employees the utmost efficiency. Spread throughout 10 regional offices across the country, CMS employees are responsible for distributing more benefits than any other Federal agency.

Benefit outlays for fiscal year 2012 totaled $819 billion. The agency's administrative costs made up just one-half of 1 percent of this amount. That is significantly less than most private health care payers spend, and this efficiency must continue. There can be no room for error, no wasted time, effort, or taxpayers' dollars.

Ms. Tavenner, you have spent your entire career providing care to people in need. You started as a nurse, in my opinion one of the most important professions in the world. Then you rose up through the ranks to become a hospital administrator, and then Virginia's Secretary of Health and Human Services. You joined CMS in 2010 and became the Acting Administrator the next year. You have the knowledge, you have real-world experience, and I believe you have proven yourself to officially take the reins of CMS.

Some have pointed out that CMS has not had a confirmed Administrator in several years. I am glad we are moving forward today to change that. With new Affordable Care Act programs coming online, it is a critical time to have someone with your knowledge in charge of CMS. We need strong leadership for successful implementation of health insurance marketplaces and other key provisions of the health law.

As Administrator, you will have to make sure these programs are ready to go on, go up, and be working on day one. You need to ensure that the health care law's programs work for the people whom they are intended to serve. There will be a lot of people watching you, myself included. The administration and CMS need to implement health care reform the way Congress intended.

I was home in Montana the past 2 weeks, and I heard from small businesses that they need more clarity about rules. I heard this often. They need more information, more transparency. They are really quite concerned. I will be holding the administration's feet to the fire to ensure that this is all done correctly.

You also need to make sure America's health care safety net is working. Medicaid is going through a period of significant transformation. The program is changing everything from how income is counted to how care is delivered and eligibility determinations are made. Millions of low-income Americans will have access to coverage for the first time starting next year. Medicaid needs strong, stable leadership overseeing these changes to ensure they go smoothly.

Health reform also vastly improved the way Medicare delivers and pays for care. Medicare continues to slow its spending by transforming from a system that pays for volume to one that rewards value. CMS needs a leader focused on payment reforms that

incentivize providers to provide high-quality care in a cost-effective manner.

One of the highest priorities for the Finance Committee, a responsibility I take very seriously, is protecting the integrity of Federal health care programs by fighting fraud, waste, and abuse. The Affordable Care Act included significant new authority and tools for CMS to protect Medicare and Medicaid and save taxpayer dollars. A confirmed Administrator is necessary to oversee and use the new tools that prevent and fight health care fraud.

Last April, this committee held a hearing to examine what, at the time, was the biggest Medicare fraud take-down in history. Thanks to tools and increased resources from the Affordable Care Act, a joint HHS and Justice task force recovered $295 million.

The fraud involved 70 individuals across six cities. We held that hearing to learn lessons to apply to future cases. We learned that every dollar invested to fight fraud generates a 500-percent return. We need the next Administrator to continue making fighting fraud a top priority.

Your experience shows the ability to effectively administer health care programs and also an appreciation for the crucial services they provide. You are known as a pragmatist with an understanding of the ins and outs of health care administration.

I recently read a profile of you in the *Washington Post*. The article detailed an incident in the 1980s. You were working as a nurse in an intensive care unit at Johnston-Willis Hospital in Richmond. At 2 a.m., a young woman in her late 20s was brought to the hospital by a rescue squad. She had been in a horrific car accident and crashed through the windshield of her old VW Bug. Badly injured and having suffered massive blood loss, she was pronounced dead.

But you and the doctors went to work anyway trying to revive her. The surgeon on call told reporters, "Marilyn was very supportive in everything. We came up with a game plan, and it was right on target. We used about 60 units of blood, but the patient ultimately walked out of the hospital."

Ms. Tavenner, it sounds like you are someone who does not give up. Your experience is real and varied and will serve you well in your position. CMS faces a great task and requires a leader with the qualities General MacArthur described: confidence, courage, and compassion.

Ms. Tavenner, I believe you have what it takes and will do very well as Administrator. I look forward to your testimony.

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

The CHAIRMAN. Senator Hatch?

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

Senator HATCH. Well, thank you, Mr. Chairman. I want to thank Chairman Baucus for convening this hearing to consider the nomination of Marilyn Tavenner to serve as Administrator of the Centers for Medicare and Medicaid Services, CMS.

This is a critical agency and, for a number of reasons, has been without a confirmed Administrator since the fall of 2006. CMS is the world's largest health insurer. It has a budget of nearly $1 tril-

lion and processes over 1.2 billion claims a year for services provided to some of our Nation's most vulnerable citizens receiving Medicare and Medicaid.

If confirmed, Ms. Tavenner, you will have a daunting challenge ahead of you. While I believe you have the qualifications to do the job, there is still much that you will need to do in order to assure members of this committee that CMS is heading in the right direction and that your leadership will help steer the agency through the very turbulent times that lie ahead.

One of the greatest challenges facing CMS in the near future is implementation of the Federal and State-based health insurance exchanges. In a speech last June you said that the health insurance exchanges "keep you up at night." I can relate to that. They keep me up at night too, but probably not for all the same reasons.

There are numerous obstacles and issues that will need to be addressed as CMS works to implement the exchanges and bring them online later this year. To date, CMS has not been able to provide satisfactory answers to a number of questions posed by myself, the chairman, and other members of the Congress regarding the exchanges.

For example, we still know very little about how the exchanges will operate, what the key operational and implementation deadlines are, and how CMS is monitoring them to determine if things are on track or not. We are still waiting to see a breakdown of the budget for the federally facilitated exchange.

If you are confirmed, it is essential that you work with this committee to provide us with this level of detail so that we can assess the implementation of the exchanges and work with you to address issues as they arise. The costs associated with the exchanges are of critical importance to this committee, as we are already seeing evidence that health insurance premium costs are continuing to rise and are projected to be, on average, 32 percent higher in the individual market.

At the same time, the Congressional Budget Office has estimated that the number of people enrolled in the exchanges in 2014 will be 1 million lower than originally projected, and quotes from administration officials indicate that the number could be even lower than that.

This is a perfect storm of unanticipated consequences that are combining to make this part of the so-called Affordable Care Act seem more like what I prefer to call it, the Un-Affordable Care Act.

In addition to overseeing this massive new expansion of benefits, you will also be charged with helping to ensure the longevity and solvency of the existing Medicare trust fund, which is projected to go bankrupt in 2024. All told, between now and 2030, 76 million baby boomers will become eligible for Medicare. Even factoring in deaths over that period, the program will grow from approximately 47 million beneficiaries today to roughly 80 million in 2030.

Maintaining the solvency of the Medicare program while continuing to provide care for an ever-increasing beneficiary base is going to require creative solutions and a skillful Administrator at the helm. I believe that you will be up to that challenge, and I strongly support you.

Overseeing the complex infrastructure of an agency like CMS is not a job for the faint of heart. You will be expected to ensure that beneficiaries get the care they want from the providers they prefer, all while making sure that the claims get paid on time, that administrative and overhead costs are kept low, and that the congressional mandates are fully implemented.

So I wish you the best of luck as you work to address these challenges. As you continue going through the confirmation process, you are going to need it, and we will try to help you up here to the extent that we can.

Mr. Chairman, I would also like to take a minute to thank my colleagues, Senators Warner and Kaine, for being here to introduce Ms. Tavenner. I think it is great for you both to be here, and it means a lot to us.

I would especially like to express my gratitude to Majority Leader Cantor for taking time out of what I know is a tremendously busy schedule to be here this morning. This bipartisan gesture means a lot to the committee, and especially to me, so I am really grateful for you folks taking the time to be with us.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator. Thank you very much.

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

The CHAIRMAN. Congressman Cantor, Senator Warner, and Senator Kaine would like to introduce our witness. I would join Senator Hatch in thanking all of you for coming over here. But before you do introduce our witness, Ms. Tavenner, I would like you to take this opportunity to introduce any family you might have here with you, because they are all part of the same team.

Ms. TAVENNER. Thank you, Mr. Chairman. To my right, my husband Bob.

The CHAIRMAN. Bob.

Ms. TAVENNER. My son-in-law David Leadbeater, and my daughter Sarah Leadbeater.

The CHAIRMAN. Good. Let us give them all a round of applause. Thank you. [Applause.]

Congressman Cantor, why don't you proceed?

STATEMENT OF HON. ERIC CANTOR, A U.S. REPRESENTATIVE FROM VIRGINIA

Congressman CANTOR. Mr. Chairman, thank you very much, Ranking Member Hatch also. I appreciate the opportunity to be here before the Senate Finance Committee. To members, it is my pleasure to be here to join with my colleagues from Virginia in introducing and presenting to the committee for your hearing today Marilyn Tavenner.

I know that, Mr. Chairman, you, as well as Senator Hatch, spoke about her wealth of experience in the private sector, as well as her service to the people of the Commonwealth. I am here to just underscore my faith in Marilyn Tavenner as an individual who is eminently qualified to take on the challenges of which you speak when it comes to the health care complexities that our country faces.

I first met Marilyn when I served in the Virginia House of Delegates, and it was plain to me very early on that she not only came from the private sector experience, she understood people. As you rightly point out, Mr. Chairman, Marilyn started as a nurse with the Hospital Corporation of America, having served with that company for 20 years, and ultimately rising in 2001 to be CEO of the Central Atlantic Division.

Marilyn oversaw 20 hospitals. She really was a force to be reckoned with when it came to, not only the State legislature and the policies of Virginia at the time, but as somebody who was there to speak on behalf of patients. You pointed out the story of Marilyn's health care delivery in that very daunting situation that you spoke of in the profile, but it is my experience with Marilyn that she does approach problems of health care from the patients' perspective. Given her long experience in the private sector, I have complete faith that she is an individual who will be able to take on the challenges that we face on behalf of the constituents whom we represent.

You mentioned also—and I know that both former Governors, now Senators, are here. But Marilyn did serve as Secretary of Health and Human Resources in Richmond, overseeing the Commonwealth's health care agencies, including the Department of Medical Assistance Services, which is the State counterpart to CMS. It is a $9-billion agency and has 18,000 employees, so she has certainly stepped up to the task.

I would end with saying this, Mr. Chairman. I do not think there is any secret that I differ with the Obama administration on a lot of matters of health care policy, and obviously the issue of Obamacare remains one that is very controversial.

But if there is anyone whom I trust to try to navigate the challenges, it is Marilyn Tavenner. I feel that strongly about her, and that is why I am here. I am delighted to be here and say that I strongly endorse your confirmation of President Obama's nomination of Marilyn Tavenner to be the next Administrator of the Centers for Medicare and Medicaid Services. Again, I yield back.

The CHAIRMAN. Thank you very much, Congressman, for making the effort. I understand there was a little bit of traffic that you had to face coming here.

Congressman CANTOR. I apologize for the tardiness.

The CHAIRMAN. I deeply appreciate you making the extra effort to make it here. Thank you very much.

Senator Warner?

STATEMENT OF HON. MARK WARNER,
A U.S. SENATOR FROM VIRGINIA

Senator WARNER. Thank you, Mr. Chairman and Ranking Member Hatch. I want to echo the comments of my friend and colleague Eric Cantor, and I know they will be echoed as well by my friend Tim Kaine.

I want to also lend my support. I think the President has made a great choice in nominating Marilyn Tavenner to be head of CMS. I have known Marilyn for over 20 years and can echo firsthand that she is the real deal and I think is a phenomenal choice to lead CMS.

As has been mentioned, and I think will probably come back in questions time and again, she brings, I think, a pretty unique set of skills to this job. She grew up in Southside, VA, in a rural community, and worked her way through school. As has been mentioned already, she started as a nurse, worked her way up to become a hospital CEO, then became administrator of a major hospital company.

But Marilyn has always had a commitment to public service, always had a commitment to the people whom she served. She—and I know Tim will make mention of this—did a great, great job as the Commonwealth's Secretary of Health. She came in direct contact with the kind of administration of the major, at least Medicaid programs. At the beginning of this administration, she joined CMS, where she served at the highest levels.

So what I think she will bring to this job is not only a depth of background on the public sector side, but echoing what Majority Leader Cantor said, from her career in the private sector, I think she knows the impact that regulations and rules have on the real world and understands the importance, not just of achieving a policy goal, but making sure it actually works in practice.

I also think, and I know that she was this way when she served in Virginia and from my interactions with her at CMS, she knows that it is our job in Congress to hold her feet to the fire in this very important—as both you and Senator Hatch mentioned—and complicated entity. She has a history of welcoming fair, fact-based discussions and will be the first person to tell you that she wants things done in a right, fair way.

She is also held in extraordinarily high esteem by her peers. I think it is pretty remarkable that in February all the previous living Senate-confirmed CMS Administrators, the ones who really know what it takes to run that enormous agency, sent a letter urging her confirmation, noting that it was "hard to imagine a candidate more worthy of bipartisan support."

So, when you have the Majority Leader of the House and two Democratic Senators all coming together saying it is time to get a CMS Administrator fully confirmed so that she can go about her very important work, I commend her without reservation to this committee and look forward to having an opportunity to work with her in the future, and I thank the chairman for the opportunity to come and present her.

The CHAIRMAN. Thank you, Senator, very much. I deeply appreciate your confidence in Ms. Tavenner. Thank you.

Senator Kaine?

STATEMENT OF HON. TIM KAINE,
A U.S. SENATOR FROM VIRGINIA

Senator KAINE. Thank you, Mr. Chairman and Ranking Member Hatch, committee members. It is a treat to be here with my colleagues from Virginia on behalf of Marilyn Tavenner to be the first confirmed CMS Administrator since 2006.

I was the Mayor of Richmond, dealing with the challenges of an urban city and its health care safety net, when I first met Marilyn back in the late 1990s. When I was running for Governor, I made it a superstitious practice not to think about whom I might hire if

I became Governor, but Marilyn was one of the two people that I sort of broke my superstitious rule about and thought: if I ever get to be Governor, I would love to have her working on my team.

I asked Marilyn to be the Cabinet Secretary over the Health and Human Resources portfolio and came to know her skills very well, and I support her strongly for this position.

Four quick things. First, I support her because she is a nurse and she will always put patient care first. She was not a nurse in the past tense; she is a nurse in the present tense. There will never be an issue that she will wrestle with as the CMS Administrator where she will not be thinking primarily of patient care. Budgets are important numbers on a page, policy manuals are important, but everything this agency does deals with the real lives of people, many of them very vulnerable. Marilyn's nursing background is exemplified by the story, Mr. Chairman, that you recounted, and so many others that will make sure that she will always put that first.

This qualification is important for her, and I also think it is an important tribute to a profession that is increasingly at the core of health care. Her confirmation would send a wonderful signal.

Second, her experience, as recounted by Congressman Cantor and Senator Warner, gives her a real understanding of the practicalities of what CMS needs to do. Again, it is not just about numbers on a page or policy regulations or rules, it has to be able to be implemented in hospital waiting rooms and in doctors' offices, and it has to be simple to the folks in the public who are making claims. They have to be able to understand it. Marilyn is a person who has dealt her whole career with the practicalities and will carry out her mission at CMS in a very practical way because of that wide-ranging experience.

Third, I support her because she has proven again and again that she is a creative problem solver. As Governor, I gave all of my Cabinet Secretaries problems to solve: "Marilyn, why are we 10th in the Nation in per capita income and 35th in the Nation in infant mortality? You have to find out the answer to that and help us solve it. What can we do to reduce youth smoking in a State that has a historical connection, and a strong one, to tobacco? Why are we facing shortages among nurses; why are we facing shortages among physicians, and what can we do about it?"

Again and again, what Marilyn did was, in a non-ideological way, get the data, understand the problem, not just rely on conventional wisdom or anecdote, but understand the problem and then devise very specific and targeted solutions to go after the problem.

Some of the problems that I gave to her were in her areas of expertise, but she oversaw not just health care but also human resources areas where she had not worked in her professional career. We had a broken foster care system. That was not something that she had worked on in the past.

But I gave her that challenge, and she and her team did a wonderful job in helping reform Virginia's foster care system. That creative and innovative approach to solving problems is an important skill that she will need every day at CMS.

Finally, the reason I support her is the biggest challenge that I did not give to her, but the circumstances gave to her, was trying

to control costs. I have, I guess, not an accolade, it is sort of an achievement through no benefit of my own as Governor. I am the only Governor of Virginia who left office with a smaller general fund budget than the one I started with. I get no credit for it. It was constitutionally mandated, and I was Governor during a recession.

But I had to give to my Cabinet Secretaries the very difficult task of, not reducing the rate of growth, but actually even reducing the size of expenditures during a tough time. The health care portfolio was the second-largest one in State government after education. Again and again and again, we had to go back and sharpen pencils and erase and start over again and find savings.

I saw Marilyn and her team struggle very mightily with that. Her skill in doing that is a skill that is very precisely matched with the need of the moment: how to keep patient care first, because that is her first attribute, but nevertheless wrestle with difficult cost control issues not only for the good of the fisc, but also because, the more we control costs, the more affordable we make it for people and for businesses. Cost control is ultimately about health care access, and Marilyn understands that very, very well.

So, for those four reasons and many others, I am proud to be here to support her. Voting to confirm her is a vote that you will never regret. Whether you are for patient care or cost control or just managerial efficiency, a vote for Marilyn Tavenner is a safe vote, and I am proud to recommend her to you.

Thank you very much.

The CHAIRMAN. Thank you very much, Senator. We appreciate you taking the time.

Ms. Tavenner, why don't you proceed? As you know, our practice here is for you to submit your testimony for the record and then just summarize it, please, the best you can.

STATEMENT OF MARILYN B. TAVENNER, NOMINATED TO BE ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGT0N, DC

Ms. TAVENNER. Thank you, Mr. Chairman.

Chairman Baucus, Ranking Member Hatch, I want to thank you for holding the hearing today and for the committee's consideration of my nomination to be Administrator of the Centers for Medicare and Medicaid Services.

I would like to start by acknowledging what we are all aware of: CMS is a large and complex agency. We have a very large Federal budget, and we provide services that are critical to our Nation's health care. As such, this committee and all of Congress have a strong interest in the management of the agency, as they should, and as do I.

So I would like to explain a little bit about myself and my background, why CMS is so important to me, how I have spent the last 3 years managing the agency, and my vision for moving us forward.

I will begin with my mother, Ruby Martin. I just celebrated her birthday with her down in the small rural town of Fieldale, VA, where I grew up. As a strong woman who raised four children

while working full-time in the textile industry for over 40 years, she has been, and she continues to be, an inspiration in everything I do. She relies on Medicare, and not just Medicare. She relies on the Qualified Medicare Beneficiary (QMB) or QI program, as we tend to call it here in DC. That is critical for her health care needs.

My youngest child, Sarah, who is with me today, was diagnosed with type 1 diabetes at the age of 11. She, too, has been a strong inspiration in what I do, for different reasons. She relies on and needs access to health insurance, no questions asked.

I think all of us know someone who relies on either the traditional programs we have been administering at CMS or the ones we are embarking on in 2014, and that makes it personal for a lot of us. It underscores the fact that what we do at CMS directly affects the lives of so many.

I have been fortunate in my career path that it has given me a variety of perspectives on health care that I believe uniquely position me to lead CMS. I do have a clinical background from my early days as a staff nurse, a business perspective from my days as a hospital CEO and division president, and a government perspective both from my work as Virginia's Secretary of Health and also the previous 3 years at CMS.

Simply put, CMS needs an Administrator, and they need one with strong operational skills. While it is very important to have a vision for the agency, we also have an over $800-billion business to run that a large amount of the country has a stake in, from beneficiaries, to providers, to hospitals, to insurance companies, to Congress, to this administration, to the American taxpayer, and to our CMS employees and contractors. Therefore, I consider it essential to my leadership role at CMS to be a partner with all of those stakeholders, and I view my relationship with this committee and with Congress as a whole as a partnership.

I have personally met with most of the members of this committee, and I have appreciated the opportunity to engage with all of you in an open dialogue. While we may not always share the same views, we have worked together to resolve challenges, and I would like the chance to continue to do so.

My management style centers a lot around listening, pragmatism, and consistently trying to do what is right, even though it may not be the quickest or easiest path. This style has led to many achievements over the last 3 years, and I highlighted some of those in my written testimony, and I will not go over those now.

But in closing, I would like to share my vision and the three primary focuses that we have for moving the agency forward. The first one is, we need to operate CMS as a business and act like business partners. This means having an open-door policy and to work together and listen to the concerns of all the groups that we are accountable to, those groups I listed earlier.

Second, we have a large responsibility in the months ahead to implement key pieces of legislation to ensure all Americans have access to affordable health care coverage, whether it is through the health insurance marketplace, whether it is through Medicaid, CHIP, original Medicare, or Medicare Advantage.

Last, we need to leverage the tools that you all have granted us to both reduce overall cost of care and improve the health care de-

livery system. These tools include new payment strategies connected to performance, innovative new models of care, and enhanced tools to combat fraud.

Lastly, I would like to thank this committee and the staff for the respect and the working relationships we have built over the last several years. I want to thank you, Mr. Chairman and Senator Hatch, for holding this hearing and giving me the opportunity to speak before the committee and answer any questions. Thank you.

The CHAIRMAN. Thank you very much, Ms. Tavenner.

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

The CHAIRMAN. I would like to ask you a few questions about the Medicare secondary payment rule. I mention this because, living in Montana—I remember once I was visiting there about 10 years ago, and I met a group of folks there who are suffering from asbestos-related diseases, especially mesothelioma.

A large percentage of that town, unfortunately, has passed away because of the asbestos produced by the company W.R. Grace. That asbestos has affected people in Libby, MT as well as around the country, because asbestos is found in lots of insulation products.

When I visited them, one fellow there named Les Scramstad very much impressed me. We met earlier, and I told you about Les. I found a photograph for you I want you to have. Les said to me, "I am going to be watching you, Senator. A lot of people said they would help us, but they have not." I knew Les meant it. He did not have to say it.

Every once in a while you come across a situation where you are going to do whatever it takes to solve it. This was one. That is, make sure that people in Libby, MT can get justice. We have a photograph. There is Les. Les has passed away. He died of mesothelioma. When he came home from the mine caked with dust, he embraced his wife. His wife has the disease now too. The kids would jump in his lap. One of his children has now died because of mesothelioma.

I will not go through all the ins and outs of health care treatment in Libby. It is also one of the largest super-fund sites in the country, and it is very similar to that book, that movie, *A Civil Action*, in Woburn, MA. The company then was W.R. Grace. It is the same company here, frankly. The point is this: the administration, very correctly, declared a national health care emergency for the people in Libby. That meant that people received Medicare payments. Even though they are not 65, they get Medicare.

But as you know, under the Medicare Secondary Payer rule, if there is a settlement, as between folks in Libby and the company, the payments cannot be made pursuant to that settlement until Medicare determines what costs, if any, the person has to pay back to Medicare so that the settlement dollars get paid. There are many people in Libby who waited up to a year. There is one instance where a woman was waiting. Meanwhile, her husband died.

Finally, a year later, CMS made a determination under the Secondary Payer rule. Even by then, she had died. When the determination was made after she died, it turned out that there is no reimbursement necessary from her to CMS. So there are a lot of people caught in this situation. There have been so many levels of

injustice in Libby, MT, but this is one of them. It is the delays in the Secondary Payer rule. I would deeply appreciate it if you could tell me what you are going to do to speed up the process so that people there who suffer from asbestos-related diseases are going to get some medical care.

Ms. TAVENNER. Chairman Baucus, let me start by first of all thanking you on behalf of the residents of Libby. The work there has been amazing. When I first came to CMS, it was being done through the Health Resources and Services Administration, and obviously we were able to get coverage through the Medicare program. We have seen so many families benefit from the program. So, first of all, I personally thank you for that.

But second, the Medicare Secondary Payer has also been a program that I have been intimately involved with over the last several months. We had some performance issues. I think we have corrected those, both with staff that we have brought on and with contractors that we work with. But more specific to your question, we did have a large number of cases that needed to be resolved, that needed to be moved through the system, so that people could understand what they were eligible for.

I think by the end of this month we will have completed at least 100 individual cases that I am aware of. There is also another large group that is moving through in a large settlement, so I think we will have done a good job of eliminating most of the backlog. You have my commitment that I will stay on top of it going forward.

The CHAIRMAN. I appreciate it very much. I neglected to ask you four obligatory questions, which I will ask you before I turn it over to Senator Hatch.

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

Ms. TAVENNER. There is not anything I am aware of. I have signed recusals in two areas, and so I want to make the committee aware of those. The first area has to do with my—as you heard, I worked a long time for the Hospital Corporation of America, so I volunteered and asked for a recusal there in certain matters that are specific to HCA. But that was one that I initiated with our ethics department.

The second one is with the State of Virginia. Although I had completed my time with the Secretary of Health position and I could have participated in matters, my husband works with the legislative division within the State, so I have recused myself from specific matters with the State of Virginia.

The CHAIRMAN. You know, you are going to do a good job. You are the first witness who has answered that question without just saying "no." That is, you have explained it. That has never happened before. [Laughter.]

And Senator Grassley, who has been chairman of this committee for many years, just now said he could verify that. You are an impressive lady!

Second—we will see what you do with this one. [Laughter.]

Ms. TAVENNER. It can only go downhill from here.

The CHAIRMAN. Yes. [Laughter.]

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

Ms. TAVENNER. I do not.

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

Ms. TAVENNER. Yes, sir.

The CHAIRMAN. Good. One more.

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

Senator GRASSLEY. And answer fully in the first letter back.

Ms. TAVENNER. I will do my best. I know I have some areas of improvement there.

The CHAIRMAN. All right. Thanks very much.

Senator Hatch?

Senator HATCH. Well, if you do, you will be one of the first ones, is all I can say. We hope you will, because this committee takes these responsibilities really, really seriously. I am proud of you. I am proud of the work that you have done through the years. I am really pleased with the effort that you are putting forth at CMS and how important it is to you and how you value that agency, even though it is a very, very difficult agency to administer.

Let me ask you just a couple of specific questions. CBO recently estimated that 7 million people will enroll in the exchanges, which is 1 million lower than what CBO estimated at the time the law was being debated. Now, how much will the exchange user fees go up if enrollment targets are not met, and what is the lowest target enrollment that CMS anticipated when doing budget projections and will cause the agency to raise the user fees if the enrollment targets are not met?

Ms. TAVENNER. That is a great question. Senator Hatch, we have actually followed the CBO's guidelines, and so we are using the same estimate as the CBO. Our user fee was actually predicated on that number. When we were going through rulemaking, we had extensive discussions, so I think we believe that that number is appropriate and the user fee would cover that type of number.

Senator HATCH. All right.

Details on the implementation of title 1 of the Patient Protection and Affordable Care Act have been lacking, as you know, especially as it relates to the establishment of exchanges and efforts to educate consumers about enrollment.

Now, could you commit to providing a bi-weekly update on the establishment of exchanges and enrollment, including milestones, deadlines, and progress reports?

Ms. TAVENNER. Yes, sir. I think we have submitted some early work, but I certainly think at this point—you know, we are kind of going through four phases with the exchanges, and I think we are now entering the part where consumer outreach and education is becoming more important, so I think we will be able to give you bi-weekly updates.

Senator HATCH. We would like to have that because it is something that we are really concerned about, and we want to make sure that we are on top of it as well. In public speeches, you have

said that the Patient Protection and Affordable Care Act has some of the strongest health care anti-fraud provisions in American history.

Now, you mentioned in your testimony that the Centers for Medicare and Medicaid Services, the agency you are going to supervise, along with its partners, recovered a record $4.2 billion last fiscal year from individuals who tried to defraud the Federal health care program. Now, I think that is an impressive number, but I am interested in what CMS specifically did to contribute to that number and how much of it is attributable to CMS.

During your time at CMS, which PPACA provisions has CMS used to reduce fraud, and can you provide quantifiable results for the CMS-specific actions undertaken? Now, even though that $4.2 billion sounds like a lot, we know there is a lot more fraud than that, and we know that we are just beginning to really go after those who are defrauding our taxpayers. But if you could answer that for me.

Ms. TAVENNER. I will. I will try to talk a little bit about how we have looked at—you are right, the Affordable Care Act gave us several tools to work with. So we have kind of gone through an implementation period. I would say we started first with the work that was done around providers, making sure we had legitimate providers in the system.

Some of our early proposed and final rules dealt with that; also, assigning categories of risk to those providers, because I think, not only did we have a system that was probably a bit outdated, but it did not assign varying degrees of risk based on what we knew to be facts.

So we have done that. So, if you are in a moderate- or a high-risk category, you are going to have on-site visits. There are going to be a lot more things, because we believe whatever we can do to preempt fraud on the front end versus this pay-and-chase—and the $4.2 billion is a great number, and I am proud of that number—that is also what we want to prevent in the first place. So that was the first thing.

The second area that we went after, if you will, was the prepayment or our authorizations. The Affordable Care Act gave us the ability to withhold payment in the event of something suspicious, so we started doing that.

The third area which we are now approaching will be how we look at the moratorium. You all gave us the ability in the Act to actually impose moratoriums on certain providers, so we are starting to look at that as kind of the third natural stage. There is also work in the Small Business Act that was done around predictive modeling, and we have had that up and running. And we submitted our first report to Congress, but we have more work to do in that area.

So there are a lot of different tools, but I think our goal, our absolute primary goal, is to stop it before it happens. Once we are in the situation where the money has already been paid out, we have great working relationships with OIG and with DOJ, but it is much more difficult after the fact.

Senator HATCH. Well, thank you. Thank you, Mr. Chairman. I appreciate that you are willing to serve.

The CHAIRMAN. Thank you, Senator.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Ms. Tavenner, congratulations on your nomination, again.

Ms. TAVENNER. Thank you, Senator.

Senator MENENDEZ. As we discussed when we met, I look forward to working with you on ways that we can address reducing costs throughout Medicare and improving health care to the Nation's seniors. That includes moving past the SGR and finding new ways to pay physicians for the efficient, coordinated, and quality delivery of health care and utilizing methods that improve medication management, which has been shown to reduce unnecessary readmissions, provide significant savings, and improve health outcomes, and that includes using medications to their most efficient use and coordinating care delivery across the spectrum, especially for special populations like dual Medicare and Medicaid eligibles and those with severe disabilities so that both providers and patients are at the table to work together to improve health care.

So, as we work to fully implement health care reform, we need to continue to look forward to new and innovative ways to reduce costs while improving care. I appreciate some of the efforts you have already taken in that regard as the Acting Administrator.

I have a specific question with reference to one of the elements of the essential health benefits required of all plans offered in the exchange, or marketplace, which is coverage for behavioral health, including therapies for autism. It is a provision that I had the support of this committee on in including into the law. April is currently Autism Awareness Month.

I am hearing from families in New Jersey and throughout the Nation, especially those in States without an existing autism benefit requirement. We are nervous that the rules regulating the essential health benefits will allow insurance companies to skirt this requirement by substituting benefit categories and offering actuarial equivalence benefits that in reality do not really cover these incredibly important services.

So my question to you is, what specific steps will you take to ensure the intent of this committee and of the law to ensure that behavioral health benefits, especially those for autism and other developmental disabilities, are available in all qualified health plans, and that includes plans on federally facilitated exchanges and in States that lack existing State-level requirements?

Ms. TAVENNER. Thank you, Senator Menendez. I also share your concerns about reducing costs and improving medication adherence. We have some work under way in those areas, and I would love the opportunity to come talk to you about those.

Senator MENENDEZ. I would look forward to that.

Ms. TAVENNER. The same is true with the issue of essential health benefits. I think it would be helpful if I could come sit down in your office and walk through some of these concerns. I had not heard this specifically, so I would like to get some more information from your staff and follow up with you.

Senator MENENDEZ. Well, we would love to do that. I mean, it clearly was the intent of myself as the author, the broad support we received in the committee, and obviously in the final version of

the law, to have the inclusion of the benefits for behavioral health as part of the essential health benefits package, and to begin to water that down would clearly violate the intention of those of us who offered it.

Finally, in a New Jersey-specific context, our Governor has indicated that he has no intention of doing anything to assist HHS with the establishment of the New Jersey health insurance exchange. There is not a State-based exchange; there is going to be a Federal exchange.

Since many of the consumer protections and market reforms we instituted in health care reform require State regulators to enforce, I am concerned that people living in States like New Jersey where the State government is uncooperative it will not actually benefit from these protections.

What specific role will State insurance regulators have under a federally facilitated exchange, and are you going to provide vigorous oversight and reject State certification of exchange plans if they do not meet the standards for quality required under the Affordable Care Act?

Ms. TAVENNER. That is a great question as well, Senator. In most cases, States have continued to implement—if you remember, there was a certain section, if you will, of insurance reforms separate from the exchanges or the marketplace. We have had great cooperation with States, with insurance commissioners. We have also had the ability to work with the National Association of Insurance Commissioners.

Wherever possible, both in proposed rulemaking and in final rules, we have gotten their feedback. So what we are seeing inside States is, they have very active rate review programs. We do have the authority under the statute to step in and supervise and have more rigorous oversight. We may ultimately end up doing that in a couple of States, but right now States have been very much a part of that process.

In States where we are responsible for the exchange, we work with the issuers and with the State Insurance Office. The issuers will be submitting their plans. They will go through a series of reviews, first to make sure they fit, if you will, all of the 10 central categories, then to make sure that they are appropriate for services covered. So that process is actually under way even as we speak, and we handle that for any State that does not have a State-based exchange.

Senator MENENDEZ. Well, my time is up. I would love to get feedback from you, as we move forward to——

Ms. TAVENNER. Absolutely.

Senator MENENDEZ [continuing]. The specific New Jersey exchange, on how we are proceeding and whether we are getting the cooperation necessary.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator, very much.

Senator Grassley?

Senator GRASSLEY. I, too, join my colleagues in welcoming you, more importantly, for the work you have done thus far, and hopefully you will be able to continue. I particularly appreciated your coming to my office for some meetings, and I think it reinforces

what Senator Kaine said about you as you worked for him in that administration. I think you would make a fine Administrator, and I want to be able to support your confirmation.

I have just one issue that, in the scheme of things that you deal with might be a little issue, I want to bring up with you. It is something that maybe back in 2011 from another angle I wrote to you about. So I would like to know how you would deal with a problem that has recently come to my attention.

On Monday, April 1st, this year, at 3:42 p.m., Height Securities sent an advisory that told their clients of the CMS Medicare Advantage policy decision and that they supported related stocks. The consequences of a political intelligence firm having access to this information 18 minutes before the market closed is astonishing.

In the 18 minutes remaining, trading minutes, on April 1st, the volume of Humana, United Healthgroup, and Aetna stock was more than half a billion dollars. More stock in those companies was traded in those 18 minutes than throughout the rest of the day.

[The related *Wall Street Journal* article appears in the appendix on p. 44.]

Senator GRASSLEY. When information leaks from the administration that has the ability to cause significant market movement, it is wrong and quite possibly illegal.

I sent a letter last Thursday formally seeking information from you, and I hope you agree that ultimately you are responsible. What are you going to do to hold somebody accountable for this leak?

Ms. TAVENNER. Senator Grassley, let me start by saying I, too, have appreciated our meetings. Second, I do not consider this a small issue. I consider this a huge issue. CMS takes all of this seriously, and we did receive your letter. We have initiated an internal review. It will be extensive, and obviously we will give you feedback from that review.

But the second thing is, I have also asked that the Office of Inspector General be brought in on this issue as well, because we need a third impartial, if you will, review of this. CMS—I take a lot of pride in the staff at CMS, and this is not something that we want to happen ever, so we will do a thorough investigation, and we will give you feedback.

Senator GRASSLEY. All right. And I thank you for inviting in the Inspector General, because I was going to ask you if you were going to do that, and you are. I assume that that gives you the authority that your investigation needs to compel the production of information within CMS. Would that be fair to conclude that the Inspector General can get all this information out, and you do not have to worry about authority?

Ms. TAVENNER. Yes.

Senator GRASSLEY. All right.

I would be even more curious what authority your investigation has to compel the production of information beyond CMS—at HHS, OMB, or the White House. I assume that you are saying that that is the Inspector General who is going to do that. I hope that, if it is found that other agencies are involved, he has the authority to get that information out.

Ms. TAVENNER. I will follow up with that, Senator, because I do not want to give you incorrect information as to their authorities.

Senator GRASSLEY. Now, I obviously do not believe that you can get the folks at HHS or OMB or the White House without some help, so I am going to pursue this. So you inform them that, if this is beyond CMS, I expect action to be taken, and I am going to get to the bottom of it one way or the other. Thank you very much.

Ms. TAVENNER. Thank you.

Senator GRASSLEY. And I know you are very sincere in what you said, and I am going to be following up with the Inspector General as well.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Carper, you are next.

Senator CARPER. Thanks very much.

Welcome. Thank you for your service today and for your willingness to continue to serve. One of the things that we spoke about when you came to see us was legislation called the FAST Act* that Senator Coburn and I, joined by 36 of our colleagues in the last Congress, introduced.

CMS was good enough, your department was good enough, to adopt a number of those provisions without the legislation being passed. We will be reintroducing the legislation. I would invite my colleagues to join us in the idea that there can be better health care results for the same amount of money or less money by going after some of the fraud that we all know exists, some of the waste and inefficiencies that exist.

So I want to just thank you for the cooperation we have experienced thus far and invite the continued participation of your staff to help make the legislation better. And tell us what we need to do to enable you to do your jobs better on that front.

I also want to mention an issue called improper payments. A lot of people think improper payments are the same as fraud. They are not. Improper payments are mistakes. They are accounting mistakes, financial mistakes. They are just human mistakes, and they add up to a lot of money, as we know. In 2002, we passed legislation, signed by former President Bush, that said agencies must begin reporting improper payments.

In 2010, Senator Coburn and I introduced legislation, adopted and signed by President Obama, that said not only do they have to report improper payments, they have to stop making them, they have to begin to try to go out and recover money that has been improperly paid, and that we are going to hold accountable the folks who are running those agencies to make sure that they are adhering to the law.

We have seen, I think, in the last 2, maybe 3 years now—even though almost every agency is now reporting them—the amount of improper payments actually is dropping, which is a very, very good thing. Even though the amount of improper payments being reported has gone up, the number of improper payments has gone down, which is a real positive.

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*The Medicare and Medicaid Fighting Fraud and Abuse to Save Taxpayer Dollars Act (S. 1251).

Talk to us about your efforts to continue to drive down improper payments, not just do this pay-and-chase, where you actually pay a bill, a medical bill, and then find that it was wrong, and then we try to run the money down. What you are doing at the front end of the situation to stop the improper payments? Thank you.

Ms. TAVENNER. Thank you, Senator Carper.

Obviously, one of the first things we do has to do with training and education, not only for physicians and hospitals but also for their staffs and the individuals they work with. So we spend a great deal of time on what I will call the training and education piece on the front end.

The second thing that we do, in some areas where we have seen consistent fraud, if you will—and you are right, it is not fraud in the terms of deliberate fraud; it is documentation difficulties, it is failure to submit the required documentation, it is review of documentation after the fact.

One area where we had a tremendous amount of problems had to do with power mobility devices, the power wheelchairs. So we implemented a pilot in a prior authorization mode, which is somewhat more like private insurance tends to do. So now, since September of last year, for individuals who need power wheelchairs, there is actually a prior authorization process.

What we have seen happen there is, it controls some of the abuse, and also beneficiaries are still able to get their wheelchairs within a short period of time. We have a 10-day threshold that we hold ourselves to to get this reviewed and turned around and out. So it is those kind of models, I think, that help more on the front end.

We are seeing a reduction in improper payments, which is encouraging, but we also are looking at, are there other areas we need to look at? Are there things inside labs, or things inside DME that we can do on the front end? Obviously, some of the work around competitive bidding in DME had to do with some of the prevention on the front end. So we are open to new ideas. We enjoy working with you and your staff and supporting you.

Senator CARPER. All right. Thanks. Thanks very much. I have some numbers that you might find interesting. Improper payments in 2010, $121 billion—billion! In 2011, down to $115 billion. That is still a lot of money. In 2012, down to $108 billion. We are seeing drops in Medicaid improper payments of several billion dollars. Medicare numbers are actually flat across those years, and we want to do better in that regard.

The last thing. I spent some time this last week in Minnesota and visited Mayo, visited United Healthgroup. One of the things we talked about was, how do we move away from fee-for-service, how do we better collaborate delivery of health care, and what is the role that Medicare Advantage may play in that regard?

Previously we have overpaid Medicare Advantage. I think we have corrected that. Just talk to us about the role you see Medicare Advantage playing in the next several years in moving away from fee-for-service, please. Thank you.

Ms. TAVENNER. I think, as you are well-aware, the Medicare Advantage programs have grown and continue to grow. We have had great working relationships with some of their medical directors on

this issue of, how do we stop paying under a fee-for-service model? How do we look at, whether it is an Accountable Care Organization, if it is some type of coordinated approach—some of the folks whom you talked about are leaders in that area. So I think we are sharing ideas.

Some of the things that we have learned in the Innovation Center, they are adopting; we are adopting some of their ideas. So, I see that role continuing to grow. They are great partners with us. Beneficiaries like the programs. They do good quality reviews, so I see that partnership continuing.

Senator CARPER. Thanks. Mr. Chairman, I have just one last quick point just to share with my Republican colleagues. We have been a long time without a confirmed CMS Administrator. I think we have a good one here, and I would just hope that we can get her reported out of here, get her confirmed with great dispatch. She is a good candidate, an excellent candidate, and we are lucky that she is willing to serve. Thank you.

The CHAIRMAN. That is my plan: do it quickly.

Senator Enzi?

Senator ENZI. Thank you, Mr. Chairman. That was an impressive group of introductions, and I really appreciate that you listed out the stakeholders in your statement. I used to be in the shoe business, so I call those customers. That is a great thing to have recognized.

I am concerned about some recent reports that have identified some anti-competitive effects of excessive integration of hospital systems, including reductions in access and increases in costs for the consumer. What is CMS doing to ensure that the incentives that it is building into the Medicare program to better coordinate care or integrate services do not have an adverse effect on competition and the price of health care in the long run? Have you engaged the Department of Justice on this issue at all?

Ms. TAVENNER. Senator Enzi, thank you. This is something that we do work on with the Department of Justice, but in a different way. We tend to look at models through the Innovation Center. That tends to be where we are engaging the Department of Justice to make sure that we are not creating any anti-competitive work in the demonstration areas. I think engaging them more and having them be a partner is a good suggestion, and that is something that we could do.

Senator ENZI. In your answers to some of the questions, you mentioned your involvement with HCA. This one is a hospital issue, but I assume that your thing about it not being specifically about HCA precludes you from having to recuse yourself on that?

Ms. TAVENNER. Right.

Senator ENZI. All right.

Now, the Society of Actuaries recently released a report in which they estimated that health insurance premiums in the individual market will increase 32 percent on the average nationally and in Wyoming specifically. The National Association of Insurance Commissioners released a paper just in the last week that outlined steps States can take to mitigate expected rate increases due to the health care law.

In fact, the NAIC paper concludes that States "should begin evaluating these and other strategies immediately in order to mitigate the rate increases when the major market reforms take effect in 2014." What is CMS doing to address the risks identified by that report and other reports?

Ms. TAVENNER. Senator Enzi, first, I would say that we do not agree completely with the actuary report. I will give you some reasons why, but I will also remind this committee that, while I have great respect for actuaries and work with them daily, these are estimates or predictions about things that we do not know for certain.

I will take us back to Part D and some of the estimates around Part D where I think we ended up at less than 40 percent of the original estimates for the cost of Part D. So I would just caution us about taking the word or the reports of actuaries as more than just estimates or speculation.

But having said all that, there are some things in the Affordable Care Act that I think mitigate any type of insurance increases, and I will try to talk about those. But I will talk about them in three areas. The first area is, when individuals talk about premium increases, I think they would have you believe that that is the entire insurance market. I will remind you that what the Affordable Care Act is dealing with is the small market or the individual market, so less than 20 million max.

Large employers are fairly exempt from the requirements, and large employers have seen the most modest increases in the last 3 years that they have seen in some time, so I think our overall strategy, both in government and in the private sector, around controlling cost is bearing some fruit.

The second issue is, in addition to the size of the market, these studies do not take into account those pieces of the Affordable Care Act that actually work to decrease premiums. First of all, there is the issue of the tax credit, which is obviously applied to the premium. Second, there is a variety in plans, so you can have a bronze, or a silver, or platinum plan, which changes the premium. Third, there is the availability of catastrophic coverage for individuals up to 30. Fourth, there is the issue of dependent coverage where, thanks to you all and the work in the law, we are covering individuals up to the age of 26.

I could go on. There are issues around reinsurance. If you will remember, you put $10 billion into a reinsurance pool for the next 3 years with the idea of mitigating any type of premium increases. The rate bands that we have—there is a long list. I will not bore you with the entire list, although I am happy to give it to you; we have it.

The third area that I would mention is a reminder to folks, and I think we saw this in the *Time* magazine article: insurance is not necessarily insurance as we all tend to think of it, having worked for large employers and having pretty robust insurance policies.

Some of these, if you will, low-cost premiums were low-cost for a reason. They did not really offer robust insurance, as many folks found out the first time they had to be hospitalized or they were diagnosed with cancer or another disease that required a lot of

treatment. So, as you can tell, I feel pretty strongly about this, but I would not agree with the actuarial assumptions.

Senator ENZI. My time has expired, but I will have some specific follow-up questions, as the accountant.

Ms. TAVENNER. Right. Thank you.

Senator ENZI. And also some other questions that I hope you will answer.

Ms. TAVENNER. Thank you.

Senator ENZI. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

Ms. Tavenner, I also want to thank you for your public service and thank your family for their willingness to serve, because it is a family effort, and we appreciate that.

In your statement, you point out that you have many stakeholders, and that is true, but the most important stakeholders, as Chairman Baucus has pointed out, are taxpayers in this country and the families that depend upon the implementation of the Affordable Care Act, Medicare, Medicaid, and the CHIP program.

So I want to talk about one aspect of that, which is pediatric dental care. Jon Blum, when he was before our committee, the Director of Medicare, said it would be a mistake to silo oral healthcare and treat it separately as we once did mental healthcare. But I am worried that that is exactly how we are moving, in treating pediatric dental care as a secondary issue, even though it is an essential health benefit.

You have pointed out in a response to a letter from me that it is clear that the stand-alone policy, Congress wanted that, but, even though it is part of the essential health benefits, it is not a requirement for an individual to obtain pediatric oral health coverage. If their primary policy does not cover it, as it does not have to, then it looks like they do not have to take a stand-alone policy if they do not want to.

You also have gone through the deductibles and you started with $1,000 in those plans that you are administering. Now you are talking about $700 as a separate deductible for dental, oral health. You cite as one of the reasons to me the cost issue, even though the Millman report reflects that the difference between $700 and $270 is less than $2 a month.

So can you just assure me about how you are going to implement the Affordable Care Act to make sure that pediatric dental care does not become secondary coverage, that it is what Congress intended it to be—part of the essential health benefits—and how we are going to assure that all families have access to affordable pediatric dental care? We have made progress, and I acknowledge that, but I am concerned that this could be some backsliding. Please assure me that my fears are going to be alleviated.

Ms. TAVENNER. Thank you, Senator Cardin. As you know from our conversations, I am very much supportive of pediatric dental, and obviously you all have done a tremendous amount of work in the Medicaid program, and we have come a long way. Obviously the tragedy in Maryland had a lot to do with that.

But I hear you on this issue, and I will tell you that we will go back and take a look at it. We did mitigate some of the cost sharing, if you will, at your recommendation. But on the coordination of the two, we may have more work to do, and I am happy to take a look at it and work with you. But we would have to do it in future rulemakings, because we are pretty far along right now, and that is the part I wanted to——

Senator CARDIN. I understand that. I just urge you—Congress allowed you to have stand-alone policies, but I do not think we intended that families would not have coverage. Now it looks like, because of the combination that you are interpreting it as not being required and the fact that you have high deductibles, meaning that families would have to make a decision, am I really going to reach $700 per child, do I really want a policy, it looks like many families will go without coverage, which is certainly not what Congress intended. I would very much appreciate you following up on that.

Ms. TAVENNER. Will do. I would like to come meet with you and look at this report as well.

Senator CARDIN. Thank you.

Ms. TAVENNER. Thank you.

Senator CARDIN. I also contacted you about an experience we had in our State with a private Medicare plan, Bravo Health Plan, that gave notice of termination 1 week before the end of the open enrollment period. This plan included a large number of people under a federally qualified plan in East Baltimore, where the individuals are of modest income. It is very difficult for them to travel; many of them do not have automobiles, and it is just difficult. It is a pretty closed community.

As a result of the decision to terminate, they no longer have their primary care physician whom they had once before. They have been given information that they have to travel a long distance in order to get to a primary care physician. We asked for some relaxation of the open enrollment period in order to deal with this hardship. So far we have not heard anything positive about this. Can you look into this and perhaps find a way in which we can provide help to these individuals?

Ms. TAVENNER. I will do that, and I will get back to you.

Senator CARDIN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator.

On the list I have several Senators next in order, but I understand that Senator Roberts has a pressing engagement and is going to ask the indulgence of the Senators ahead of him. But that is up to Senator Roberts, as well as the Senators ahead of him. On the list I have Senator Isakson next, Senator Portman, and following him, Senator Bennet.

Senator ROBERTS. I have not asked Senator Isakson if that would be possible. I do have permission from my friend and colleague, Senator Portman, however. But I would ask the Senator's indulgence.

Senator ISAKSON. I will voluntarily indulge the Senator from Kansas. [Laughter.]

Senator ROBERTS. Ms. Tavenner, what do you want to be called? Do you want to be called Administrator? Madam Administrator? That does not sound very——

Ms. TAVENNER. I actually prefer Marilyn. [Laughter.]

Senator ROBERTS. Marilyn. I have a different name. Our State motto is, "To the stars through difficulty." I apply that to CMS, farmers in Montana—for that matter, anywhere. Hope always springs eternal. They would never put the seed in the ground unless they thought they were going to have a crop, regardless of 3 years of drought.

You have been endorsed by the Kansas Hospital Association, the Kansas Medical Society. You have the support of hospices, you have the support of ambulance drivers, you have the support of nurses and doctors, you have the support of home health care, and the list goes on—all of our providers.

There is a reason for that. That is because of everything that has been said about you. So I think I am going to dub you, at least for Kansas and the Dodge City area, as the new sheriff in town. You are going to wear a white hat. There are an awful lot of people in CMS who wear black hats, and that is just in the way that the rural health care delivery system has been treated. It is most unfortunate.

When you say "CMS," the line used by many of our providers is that there is a new acronym: "it's a mess." That is not a very nice thing to be saying about an agency that is supposed to be helping folks, but that is the way it is.

Now, you and I have talked about this, and I appreciate you coming in. You have been through those chairs, which is exceedingly important. I expressed my concerns with the current regulatory process. We discussed the deviation from the traditional regulatory process of notice and comment, the lack of stakeholder input, especially as it relates to shortened comment periods and through the use of something called sub-regulatory guidance—postings, e-mails, bulletins, guidance, and something called FAQs, frequently asked questions.

Unfortunately, nobody has any time to read this stuff or to be aware of this until somebody who has been contracted out knocks on the hospital door with a fine. That is not right.

So, during our discussions, you had mentioned that these are all issues that CMS is aware of and that you expect to be addressed. Specifically, I have received commitments that there would be no more IFRs, what we call the "gotchas," interim final rules, that stakeholders would be given more opportunity to participate in the regulatory process by allowing a 60-day comment period as has been done in the past; then, if enough suggestions have come in to tweak the proposed regulation or to change it, you could have another 60 days to get it right, and CMS would work with OMB to ensure the cost estimates included in the regulations are clear so that all of our health care providers can know what to expect as it relates to the costs associated with the regulatory actions. And you agreed with me, and I agreed with you in regards to your commitment.

But I was dismayed that, following our most recent conversation, an IFR was issued to implement something called Benefit and Payment Parameters. Understanding that you are on a tight time line, this is a completely unacceptable process, however, and I would hope that your previous commitments to return to the traditional

notice and comment period—i.e., transparency—and make it such that CMS is not considered in the rural health care areas as welcome as a plague of locusts, that you would work with me. I think you said "yes" at that particular time. I hope that we could continue on that basis. I think the answer is "yes," and I will yield back the balance of my time to Senator Portman or Senator Isakson.

Ms. TAVENNER. Senator Roberts, the answer is "yes." You did educate me about the four corners, and we will try to do our best to follow the regular process. There are obviously sometimes emergency situations where we do an IFR, so I do not want to leave you with the impression that we would never, ever consider an IFR, because I think——

Senator ROBERTS. I understand that.

Ms. TAVENNER. But yes, I think we are more into the regular order of business, and I appreciate your support.

Senator ROBERTS. Mr. Chairman, it is not often I give you 50 seconds back.

Senator ROCKEFELLER [presiding]. That is true.

Senator Isakson?

Senator ISAKSON. Thank you, Mr. Chairman.

The SGR. I was sworn in in February of 1999 to the U.S. House of Representatives, and, if I am correct, every year in December we had to, at the last minute, patch the SGR or physicians were going down the tubes on reimbursement. That still is the case now, and it is 2013.

CBO recently gave us a good score, or a much lower score, on the cost of fixing the SGR. Will you encourage the President, if you are confirmed—and I assume you will be confirmed because you have done a great job—to adopt that as a priority this year? We have a window of opportunity to do it, and I would like to see us fix the SGR.

Ms. TAVENNER. Yes, I will certainly work with the President and the President's team. We agree that SGR needs to be replaced, and we need a permanent solution.

Senator ISAKSON. Every doctor in America would agree with you as well.

Ms. TAVENNER. Yes.

Senator ISAKSON. The Georgia Department of Community Health has a Medicaid waiver application in to allow them to put foster children under Georgia's care in a managed care program. As you know, foster kids move around a lot; they go from home to home a lot. They have, many times, complex medical issues. A managed care type of approach allows them to get away from fee-for-service, do it all over again when they move locations, and instead have good quality of coordination on their care.

I work a lot with foster kids, and did when I was in the State legislature in Georgia. If you could check on that application and see if you could help expedite it, or help them expedite what they need to do, because foster kids are important people in our State's care, and I would love to see us do that.

Ms. TAVENNER. I can certainly do that.

Senator ISAKSON. One other question. In the House, we did a piece of legislation, probably 10 years ago now, on needle sticks. I

have been a member of the Diabetes Caucus for a number of years and am aware of the number of complications that come from needle sticks with diabetes.

I understand, from what I am told by my staff, that you have the flexibility with regard to diabetes to approve reimbursement for ancillary and related diabetes treatment and services. Needle stick devices, of which there are any number available right now, are an excellent way to avoid unwanted needle sticks and further complications and other problems.

I have a piece of legislation that I have introduced with Senator Coons to try to get CMS to approve a reimbursement for needle stick devices, but, if you can do it administratively, it would seem to be a big help. We have a study done by United Healthcare that estimated the savings to those who had a needle stick destruction device, and the savings that would bring to CMS and to United Healthcare because of the number of other ancillary problems it would reduce. Would you look into that for me?

Ms. TAVENNER. I certainly will.

Senator ISAKSON. And that is all of my questions. Thank you.

Ms. TAVENNER. Thank you, Senator Isakson.

Senator ROCKEFELLER. Senator Casey?

Senator CASEY. Mr. Chairman, thank you very much.

Ms. Tavenner, I wanted to commend you for your public service already, the work that you have done over a long period of time in a very difficult area of our government, and also the work you have done in the private sector.

I want to commend as well your family. I think the applause that we gave to your family earlier today was entirely appropriate, but not at all commensurate with the sacrifice that they have made, and we are grateful for that.

I wanted to focus—and I will try to be brief because I know we have a number of other questioners—on children in the context of health care as we implement a very difficult piece of legislation to implement and get right. Those of us who supported it had better be committed to getting it right, especially as it relates to children.

In our State, we have a little more than 900,000—at the last count about 919,300—children covered by Medicaid, about 45 percent of the total. As a lot of the experts tell us about children, when it comes to the kind of health care we have to provide to them, that children—these are not my words, but I try to remember them—are not small adults, they are different. Their health care needs are different. You know that from your experience better than I do.

I wanted to focus maybe on two or three areas. One would be—instead of asking a broad question, because we probably do not have time for that—some of the challenges that will arise when we begin to see the exchanges being implemented, in particular, where kids in the exchanges who normally would get, by way of Medicaid or some other way, but mostly by way of Medicaid, so-called wrap-around services if they have particularly difficult challenges.

If a child is covered in the exchange at some future time, how do you deal with that to make sure that, if the private coverage does not meet their needs, that there is going to be something comparable to or similar to wrap-around services? Can you address that?

Ms. TAVENNER. Yes, sir. Senator Casey, let me start by saying—and I think we heard this from Senator Kaine in the opening comments—that we are very much committed to helping children in the Medicaid program and in private insurance. I think we heard that in regards to the oral care, dental care. We have done work around the Strong Start, and I know your State has a project there, and we appreciate your support of that.

So there is a lot of work to be done around newborns and infant mortality, around childhood obesity, smoking, and so we have projects under way inside Medicaid, and I am happy to brief your staff on that.

But we are committed to working on this. What we are seeing is that we may have parents in the exchange, children in CHIP, and vice versa. We are working with them as a family unit. I am happy to come sit down with your staff and walk through how we will put those added protections in, because, if they are in Medicaid, they obviously are eligible for all of the wrap-around benefits and the added protections. Wherever possible, we try to sync up both Medicaid policy and, if you will, the essential health benefits, and we can kind of give you some more detail in that area.

Senator CASEY. That would be great. With all the changes, I just want to make sure we—meaning myself as well—meet these obligations.

One of the challenges we are facing as well is, as in some States like Pennsylvania, we may be confronting a situation where the State is not part of the exchange and may not embrace the changes as they relate to Medicaid. So, in two major areas of health care implementation, our State may be in a different position than a lot of other States. I know we will continue to talk about this, but do you have any suggestions or any insights as it relates to States that are in that position, either not part of the exchange or not part of the Medicaid elements?

Ms. TAVENNER. Yes, sir. Senator Casey, obviously Pennsylvania is one such State. We are actually meeting with the Pennsylvania team today. We are continuing to work with each State on the issue of Medicaid expansion to see if there are at least educational pieces we can give them, ways they can look at it, clarifying any questions they may have, and encouraging Medicaid expansion.

In the issue of the exchanges, you actually have a bit of an advantage in Pennsylvania in that we have a regional office there. But I will remind folks that we do have 10 regional offices throughout the country, and so, in States where States are not having a State-based exchange or partnership, we will be mobilizing our regional staff to work inside each State. We will also be doing a series of webinars and educational programs, traveling inside the State. There are several other things we will be rolling out through the summer to help.

Senator CASEY. Thank you very much.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. Thank you.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Ms. Tavenner, welcome. Thank you for your service and willingness to come up here and answer all these questions today.

I want to ask a couple of things, really quickly. I am interested in the physician supervision of outpatient therapeutic services and a 2009 Medicare Prospective Payment Systems final rule in which CMS issued a new policy regarding direct physician supervision of outpatient therapeutic services.

There are a lot of health care organizations that have recognized this as a burdensome and unnecessary policy change, but CMS characterized it as a clarification. It seems as if CMS retroactively interpreted the policy to require that a physician provide direct supervision instead of general supervision and be physically present in the same outpatient department at all times when outpatient therapeutic services are furnished.

I am concerned that the clarification is in fact instead a significant change in Medicare policy that would place considerable burden on hospitals, especially facilities in rural areas. So I know there has been a panel convened, but I am also concerned that that panel is not sufficiently considering the input from rural critical access hospitals. So I am wondering if you would agree to return to the pre-2009 interpretation of this policy for critical access hospitals.

Ms. TAVENNER. Senator Thune, I appreciate that question. After we talked yesterday, I thought there were a couple of things that we could do. First of all—and I think we discussed this with your staff yesterday—adding additional members representing the rural hospitals and critical access hospitals would be helpful so we would make sure we have a balanced dialogue about what direct supervision really means and what is required in these smaller hospitals in remote areas.

I will go back and take a look and then sit down with your team. I think we have made some progress, so I would want the opportunity to sit down with your team and walk through what has been done, but we are certainly willing to look at the original standards and see where we are different.

Senator THUNE. I guess my concern in all this—and I wish I had voiced it to you yesterday—is that there is not a sufficient avenue for rural voices to be heard in this process when the panel is predominantly from non-rural facilities, so I would appreciate any consideration that you could give for input from rural hospitals.

Ms. TAVENNER. I think that is an excellent suggestion.

Senator THUNE. The other question I wanted to raise with you is, I have been hearing from constituents in South Dakota about the impact of preferred pharmacy networks and the Part D program. For some seniors, they are not even aware of the preferred network until after open enrollment for Part D.

For some seniors, it means the drug plan that they have been using for several years has changed, and those changes increase copays to go to their regular pharmacy instead of the pharmacy in the new preferred network. For some pharmacies, this is having an adverse impact, as you might expect, on their client base.

I would like to know what is being done to ensure that seniors are aware of the impact of choosing a Part D drug plan with a preferred network and what that might mean in terms of them being able to access their pharmaceutical services from the pharmacy that they have been using previously.

Ms. TAVENNER. Senator Thune, after we talked about this one yesterday, I also went back and did a little homework last night in this area. I think we certainly try to educate beneficiaries about the plan they are in and what is involved, what pharmacies are in the network, but we need to do more in that area, obviously, if beneficiaries are still confused. So that is the first area.

The second area is—and I think based on your feedback yesterday—we need to take a look at the policy and see if there are changes that we can make in the policy in the future that might make it a little easier on this issue. So I appreciate that. I was not as aware of that issue until we talked, so we will follow up with it.

Senator THUNE. All right. Thank you. I appreciate your responses.

Mr. Chairman, thank you. I yield back the balance of my time.

The CHAIRMAN. Thank you, Senator.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

Thank you, Ms. Tavenner, for your willingness to step forward. Thank you for coming by the office. I enjoyed our conversation on some of the issues I will raise today. Also, I think your background is going to be very helpful as you move from Acting Administrator, assuming you are successfully confirmed—I think you will be—to being the Administrator.

I like your nursing background, I like your State background in Virginia, and I like your private sector background. You are going to have a huge job. A number of us are deeply concerned about how ACA is going to be implemented. We continue to have strong concerns about some of the policy decisions that were made here a couple of years ago, and yet, because our constituents are looking at huge changes, many of them, we want to be sure somebody is there who can help them work through that.

So one thing that I am very concerned about is wellness and prevention and what ACA might do or not do to help that. As I travel around Ohio, I am constantly amazed by the companies that are doing innovative, state-of-the-art things in terms of encouraging their employees to get involved in wellness and prevention. Some are self-insured, some are not.

I am very concerned about the regulations and the mandates that might actually take the country in the wrong direction in terms of what is starting to happen out there in the private sector. I would like to hear your comments on that and be sure you are sensitive to that.

Second, within the Federal programs themselves, I think there is great opportunity, and particularly with regard to Medicare, but also Medicaid. As you know, Senator Wyden and I introduced a bill called the Better Health Rewards last year. We are planning to reintroduce it soon.

It is really the only prevention and wellness idea I see out there on Medicare, but basically it says that people, as they go to their annual physicals that are paid for anyway, go through a process voluntarily, if they like, with six different criteria, including looking at diabetes, looking at smoking cessation, and so on, and then they get a reward if they go through the program.

So, could you comment on those two things? One, are you going to be sensitive to private sector initiatives in this area, and two, are you willing to look at more innovative programs within Medicare and Medicaid, in particular on wellness and prevention?

Ms. TAVENNER. Thank you, Senator Portman. First of all, I am very much aware of the wellness and prevention programs in the private sector, and I certainly think they are critical and very important. We actually have a demonstration inside Medicaid where we have actually adopted some of those ideas around wellness and prevention, more from the standpoint of encouraging Medicaid recipients, so it is more the reward than the punishment look, if you will. But yes, we are open to wellness and prevention opportunities.

As far as Medicare, I certainly would like to work with you on your legislation and offer assistance there. We have tried to look at that in a couple of ways, obviously as part of the Affordable Care Act, and this administration has been focused on covering more preventive services, because we think that it is key to preventing long-term, if you will expensive, illness. So, not only from a cost but from a quality perspective, it is a better place to be.

Second, in how we are looking at changes in payment, I think that sends a strong signal to physicians and other providers that it is not about the volume of services you provide, it is about, what is the outcome of the individual, and that outcome should be as much focused on prevention and having optimal health as opposed to waiting until after the fact and dealing with expensive and low-quality type outcomes.

Senator PORTMAN. Well, I appreciate those comments, and I hope that you will be willing to show respect for the private sector initiatives in this area, and, particularly with regard to the way regulations were formulated and mandates on coverage, that you are sensitive to that.

Another issue big in Ohio is durable medical equipment. You and I have talked about this. There are a lot of companies in Ohio involved in this and a lot of patients in Ohio who rely on durable medical equipment. The current program has nine bidding areas total, two are located in Ohio. This summer, the number of bidding areas will expand to an additional 91 areas, including another six in Ohio.

Again, access to durable medical equipment is critical to seniors, particularly in Ohio, but also around the country. They depend on it. Also, businesses that supply this equipment to our seniors are worried about the uncertainty. We all want to see savings, but we want to see it done in a smart way, and we certainly do not want to see it done at the expense of seniors' access to necessary equipment.

A number of constituents have contacted me, talking about how, once bidders win through this competition, they are not able to supply the necessary equipment for beneficiaries, because they come in with such a low bid. They get selected, and then they cannot complete the responsibilities.

CMS, in your role as Acting Administrator, has provided assurance you are strengthening this bid review process to ensure that low bids are sustainable for the suppliers. Can you describe for us quickly the measures you have already taken to strengthen this re-

view process and what you are going to do in the future before expanding this program, including what you are going to do before you expand it later this summer?

Ms. TAVENNER. Yes, sir. Senator Portman, let me start with, when Congress authorized the competitive bidding for DME—this was several years ago—we spent a long time in planning this effort, and obviously we rolled out the pilot a couple of years ago. The pilot was critical to determining and modifying the program, so I will give you some of the results from the pilot.

In the first areas that we have done, what we have seen is, actually there were no issues with access. We have obviously seen reduction in cost. In fact, we still have over 90 percent of the original folks who bid still in the market, still supplying. We also were careful that we did not allow individuals to take too much of the market, if you will.

We have kind of this informal cap, if you will, of about 20 percent so that we make sure we have at least five suppliers in an area providing a piece of equipment. We have ongoing, real-time evaluation with beneficiaries. We set up a separate call center. We have monitored their feedback.

The feedback has been great from the beneficiaries, but we also have been careful to look at, what is the trend? Where are we seeing drop-offs in supplies that would cause concerns? We actually saw drops in two areas. One area was the CPAP disposable monitor, if you will, the mouthpiece, and the second area was in diabetic testing strips. So we actually called beneficiaries and said, what is going on? Why are you not getting these? Because those are pretty critical things, particularly diabetics' testing strips.

In fact, most of them had several months' supply stored, so it was more of an inventory thing. They really did not need it, which is one of the issues that we were hoping to address in the competitive bidding, that we were getting folks what they needed but not more than they needed. So I think we have been comfortable. We will always continue to try to improve the program, but obviously we are getting ready to roll out the second portion very soon.

The CHAIRMAN. Thank you very much.

Senator Burr?

Senator BURR. Ms. Tavenner, welcome. I join my colleagues in urging the chairman for an expeditious confirmation. I have enjoyed my meetings, plural, with you, and I am sure we will have more in the future.

Ms. TAVENNER. Thank you, Senator.

Senator BURR. Let me just, in full disclosure, say that I am not that confident about the Affordable Care Act and its implementation being seamless and its costs being predictable. I do not believe it is the panacea that many people present, both from that table and in some of the public comments. The truth is that the cost of the Affordable Care Act is very questionable.

The most alarming thing to me today is, I cannot find anybody in the administration who has a Plan B. What if more people enroll in the State exchange, meaning there is an employer dump? What if 30 percent of those employees who are dumped qualify for a subsidy? What happens when we run out of money in a health care plan that has been designed based upon fees and taxes that are not

unlimited? What happens when there is not enough money to make the payments? These are all questions that have yet to be answered.

Now, you quickly pointed to Part D and Part D's success. Let me suggest to you, Part D is very different from what we have created with the Affordable Care Act. Part D was designed to generate fierce competition between suppliers.

Part D was not designed with subsidies, it was not designed with fees, and it certainly did not have the degree of mandates that you find in the Affordable Care Act. One thing that I have learned in health care is, for everything that you require, health care is going to have a reaction to that, and usually it is an increasing cost.

Let me ask you: you said that you are using CBO's projections for enrollment in the exchange. Is that 7 million, or is it 8 million since CBO's estimate was changed?

Ms. TAVENNER. We are using 7 million.

Senator BURR. You are using 7 million. What does CMS estimate it will cost to run the federally facilitated exchange?

Ms. TAVENNER. Senator, I can get you that information, but I do not have that today.

Senator BURR. Would you supply that for us? Would you also supply what the total budget for the exchanges is?

Ms. TAVENNER. Yes, sir.

Senator BURR. Thank you.

Now, you said earlier that there are going to be no premium increases, and you cited a number of reasons as to why there would not be. Let me ask you: the 3.5-percent user fee applies to insurers in the exchange and outside the exchange, correct?

Ms. TAVENNER. Yes, sir.

Senator BURR. So, if we are going to require insurers outside the exchange to pay a 3.5-percent additional fee, you do not believe that is going to have an impact on premium increases on people outside the exchange?

Ms. TAVENNER. I think some of the trends that we are seeing outside the exchange will offset some of those.

Senator BURR. Some of those, but there will be a premium increase. As a matter of fact, most of the averages from the industry looking at this are that there will be a $600-per-year increase on a family plan. Do you dispute that?

Ms. TAVENNER. I have not seen that, so I need to take a look at that.

Senator BURR. All right.

Let me suggest to you that to make the statement that subsidies do not allow premiums to go up is somewhat disingenuous. Subsidies mask the cost, so, when we put in a subsidy so that somebody does not feel the personal effects of it, we are masking the cost of that. I think one of the problems that we have with the Affordable Care Act is that nobody really understands what the costs, not just of implementation, but of running the Affordable Care Act, will be.

Now earlier, Senator Enzi talked about actuaries, and you expressed your concern over actuaries. Let me ask you, though, will you commit to providing the committee with a timely, detailed pre-

mium impact analysis for all title 1 reforms included in the health care law?

Ms. TAVENNER. Yes, sir. But, going back to Senator Grassley's comments earlier about Medicare Advantage and what happened last Monday, there is a point where we can go public with what the premiums are, but it will be later in the game, if you will, for the very reasons that we outlined. It is not until a premium is actually locked down that we would be able to share that, so I suspect that will be probably late August or September.

Senator BURR. All right. That is fine. But I hope you understand that it is important for us all to be looking at the same numbers. You may interpret the impact differently; you are entitled to do that. But, if we are working off of two different sets of numbers, it makes it impossible to try to analyze where we are and, more importantly, where we are headed.

Ms. TAVENNER. I understand. We will share those numbers.

Senator BURR. Thank you for your time today.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Schumer?

Senator SCHUMER. Just quickly—and thank you for your good work. I know we have worked together on many issues, and I appreciate your expertise, your concern, and your caring.

Two quick questions. One relates to a specific hospital called Samaritan Hospital Medical Center in Watertown, NY. It is less than 250 beds. It is a rural hospital that serves 120,000 New Yorkers in, actually, a growing area of our State, because of Ft. Drum. The medical residency program was supposed to be exempt by law from cuts, but Samaritan was inappropriately misclassified in the spring of 2011. They were notified the Medicare program was reducing graduate medical education funding by three slots.

The slots are important. This is a rural area. It uses NHS, the National Health Service, and all of that to get doctors. It is a very busy hospital. Now, here is the catch. CMS staff agreed that Samaritan was wrongly classified. There is no dispute that they should have been excluded, but they said there is no method of appeal for a wrong decision. That sounds more like Russia, Communist Russia, or Kafka-esque places, or whatever. So could you take a look at that for me, please?

Ms. TAVENNER. Certainly, Senator.

Senator SCHUMER. Great.

The second issue is also specific, and then I will be out of everyone's hair. Observation days. Senator Brown has introduced a bill; I have co-sponsored it. I do not know if he addressed it. Under current medical law, patients must be categorized as inpatient for 3 days before entering a nursing or rehabilitation facility if they want Medicare to cover their costs. However, if no operation or major procedure is performed, they are in there 3 days, but they are called under "observation" status.

Then if the hospital says, look, you do not need an operation but you need physical therapy, Medicare does not cover them. So you have, in my area, hundreds and hundreds of seniors—I am sure it is thousands across America—who, because of this catch-22 of observation days, end up having to pay $8,000, $10,000 for the reha-

bilitation that they need. Had the hospital done a procedure, it would have been fine, they would have been inpatient, but they are called "observation" patients.

So we have introduced legislation for this. The number of observation days is going way up. Could you take a look and see if there is a way, without legislation, that that can be rectified?

Ms. TAVENNER. Yes, sir. We are happy to work with your team on it.

Senator SCHUMER. Mr. Chairman, thank you.

The CHAIRMAN. Senator Rockefeller?

Senator ROCKEFELLER. Senator Schumer, I am working on a case in West Virginia which is precisely what you described—precisely. Then they are caught.

Senator SCHUMER. Yes.

Senator ROCKEFELLER. They cannot pay. Nobody pays.

First of all, I want to say that both you and the Secretary have been before us on a number of occasions, and I have been quite critical, sometimes in meetings in my office or in open or closed meetings with the Finance Committee, as have others.

But what has occurred to me is that both of you have sort of sat there all by yourselves and taken the questions and the hits. I am of the belief that the ACA is probably the most complex piece of legislation ever passed by the U.S. Congress.

Tax reform obviously is going to be huge too, but it means, up to this point, it is just beyond comprehensive and adds all kinds of requests and individual insults, and this, that, and the other thing. But I have to say that I very much admire the way both of you handle it, the way you are stoic about it, and I look forward to supporting your nomination.

A couple of questions. You approved for Arkansas—we began to talk about this before—premium assistance instead of expanding Medicaid as usual, which is in spite of the fact that even Arkansas admits that it is going to be 13 to 14 percent more expensive to do that.

I do not understand why that allowance was made, why that waiver was given. Now, the whole business of the giving of waivers by CMS to States is still something of a mystery to me. I am sure there are explanations for some, and I am sure there are not very good explanations for the others. I do not know really what was involved. But this is a very clear case of going to something which is clearly more expensive. Did Arkansas want to pay more money?

Ms. TAVENNER. So Arkansas—Senator Rockefeller, I think there has been a lot of confusion, and a lot of that generated by the press, about actually what is going on with Arkansas as it relates to premium assistance. They approached us with the idea of taking what has historically been done in premium assistance and trying to apply it to the Medicaid expansion, so we do not yet have a formal proposal from Arkansas, and we have not approved anything. So, let me start there.

Senator ROCKEFELLER. Oh.

Ms. TAVENNER. The second thing that is important to know, though, is we did put out some Q&A—I am glad I am not using Q&A right now in a bad way—some clarification around what premium assistance is and is not. One of the things that we have

stressed—we have a handful of States that are interested in this program. Arkansas is one of them.

So we have tried to spend our time educating them that these are still Medicaid beneficiaries with the same rights and protections of Medicaid. On the issue of cost effectiveness, which before has always been a requirement and waiver, we will look at, is there a band that we are willing to take a look at if in fact this would reduce the churn and the movement back and forth? But there have been no decisions made, and there has been no approval granted to Arkansas.

Senator ROCKEFELLER. Well, I am glad.

I worry also particularly about the level of health care, the quality of health care, for children under such a program.

Ms. TAVENNER. Yes.

Senator ROCKEFELLER. Medicaid does very well by children. What premium assistance does for children under a Medicaid expansion program, I know not.

Second, on the matter of Medicaid cost sharing, you put out a proposed rule, which means maybe you have not done it, which actually sort of goes up against what is authorized by the Affordable Care Act, and I am curious about that.

Medicare beneficiaries obviously do not have much money to spend, and any kind of a study has shown that you just tweak a little bit in this direction and you cause a whole lot of damage. So I am confused by it. Are you still studying it? Are you still thinking about it?

Ms. TAVENNER. It is still in a proposed rule, and we are accepting comments.

Senator ROCKEFELLER. When you come to making a decision, will they be able to opt out of that?

Ms. TAVENNER. I am happy to sit down and discuss this with you and your staff. Basically, if you will remember—you will remember well because you were very involved in it—below 100 percent of the poverty level, there is a very, very small cost sharing. In fact, it is in statute. In the 100- to 133-percent range, there is a little more openness, if you will, of cost sharing, a little higher percentage. So that is what we discussed in the proposed rule.

But there is no opting out if a State decides they want to go that route, but there are very small caps. They are like $4 or $5 a visit. That is something that was in the proposed rule, and we are happy to come sit down and go over that with the team.

Senator ROCKEFELLER. So individuals could not opt out?

Ms. TAVENNER. It would depend on what the State applied for, so we would have to look at it on a State-by-State basis. But this is in a proposed rule, and right now we are just getting comments back on, is this something that States are interested in, and, if so, what would they like to see?

Senator ROCKEFELLER. Mr. Chairman, just indulge me for a second. I get a lot of answers like that, that we are looking at it, when I thought something had been done because the word around the circle is that something has been done.

Ms. TAVENNER. I know.

Senator ROCKEFELLER. Then you say, let me get back to you on that, let me come talk with your staff on that—and we have had

very, very good staff meetings as a result. I mean, you have been very faithful and very good on that. But it worries me, because it is so complicated. If it is not done right the first time, it will simply get worse.

The bill has been voted on, so it is not a question of trying to get constituencies, like exempting the hospitals from IPAB until 2019. I mean, maybe that was necessary to get the American Hospital Association's support, I have no idea. I did not like it. But we are past that point now.

Ms. TAVENNER. Yes, sir.

Senator ROCKEFELLER. So a rulemaking should be made in terms of the best interests of the Affordable Care Act, of course taking the needs of the State into mind.

Ms. TAVENNER. Yes, sir.

Senator ROCKEFELLER. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

Ms. Tavenner, great to see you. Thank you for our previous conversations. You know I have been very concerned about the failure to implement the basic health plan by 2014. I recently received a letter from Secretary Sebelius saying that, no later than April 15, 2013, you would issue a time line for guidance but that the program would be implemented as the law states, as fully operational with States being able to receive 95 percent of the tax credit value in 2015.

So first I wanted to ask you—well, in general I wanted to ask you about your beliefs about the basic health plan, what you think is valuable about it and your commitment to that 2013, April 15th deadline.

Ms. TAVENNER. Yes. We are committed to the April 15th deadline, and I realize that is Monday. So we will have information to you then. We have started to work informally with the States on this issue. We certainly understand that the basic health plan is an important piece of the Affordable Care Act, and so you have our commitment to implement it by January.

Senator CANTWELL. What do you think is important about it?

Ms. TAVENNER. I think it gives States options for those States that want to try something innovative, and it is obviously a cost-effective strategy as well.

Senator CANTWELL. So you think it saves money?

Ms. TAVENNER. I think it certainly can, but I think that is not the only reason for doing it. But I think that is an important reason. I think it also can provide a coordinated approach and quality care to patients.

Senator CANTWELL. Managed care. Is that what you are saying? When you say "coordinated care" do you mean "managed care"?

Ms. TAVENNER. No, I mean coordinated care.

Senator CANTWELL. All right. Well, we will look forward to seeing those guidelines then by next Monday. Just to be clear, the basic health plan for individuals—let us take somebody who is making just over $17,000 a year who applies for this, they would save about, let us say, $1,161 in health care costs for an individual. So that, versus the exchange, is a huge savings for the individual.

The Urban Institute says that if all States implemented this—this is a report that they did in 2011—the Federal Government would save $1.3 billion a year. So there is obviously a lot at stake for the Federal Government in the savings, and individual States—for example, our State would save something like $173 million per year. This is the Urban Institute that has done this analysis.

So what we have accomplished here is to be able to bundle up that population that is just above the Medicaid rate, bundle them up and make them interesting, where insurers were not interested in them before. The success of that has been to get a better rate for individuals and to get a better, obviously, cost-effective rate, both for providers—and that is why they have participated—and a cost-effective rate for us, the taxpayer.

So I will certainly look forward to seeing that on Monday and certainly would love to support your nomination throughout the process, but definitely I want to see this information. So, thank you very much.

The CHAIRMAN. Thank you, Senator.

Just a couple of questions, Ms. Tavenner. Did you read the Steven Brill piece in *Time* magazine?

Ms. TAVENNER. I did.

The CHAIRMAN. Could you tell us what you think is most valid, the most valid criticisms about the American health care system, the most valid reasons in that article as to why we spend much more on our health care system in our country than we should? What were the best points there?

Ms. TAVENNER. Chairman Baucus, I would say I will start with three observations from that piece, which is obviously a lengthy piece, and very well done. The first one is that, obviously, the issue of hospital charges is a tremendous problem. It is a tremendous problem from the standpoint of consumers trying to figure it out, and it is a tremendous problem from the standpoint of hospitals trying to have charges be relevant to their cost.

The second take-away I had is it kind of highlighted, and I mentioned this earlier——

The CHAIRMAN. But that article basically stated and/or implied that the charge master was a set indication of prices which may or may not be relevant to what the costs actually were, and a lot of people did not know what the heck the charge master was.

Ms. TAVENNER. Correct. I agree.

The second piece is that, from the insurance perspective, going back to what I said earlier, I think a lot of people found out that they thought they had adequate insurance coverage, and then, when they got into a costly illness, they did not. So that was the second take-away.

The third take-away is really that I thought—and maybe I cannot be objective on this issue—that Medicare and the work that Congress and CMS have done around Medicare costs looked pretty strong in the article. So my take-away from that is that there is no relationship between charges and cost, and how do we educate the American public about that? It is difficult to be educated when, quite honestly, you have broken your arm and you are on your way to the emergency department. So we are actually looking at ways

we can get more transparency out to the public around the issue of hospital charges and costs.

The CHAIRMAN. But I also took away from that article the concern you mentioned, that it applies more to people who do not have insurance, or the individual market compared with employees who have insurance who work for a company.

Ms. TAVENNER. Right.

The CHAIRMAN. But even there, the difference between the actual costs and the charges is still quite significant.

Ms. TAVENNER. Yes.

The CHAIRMAN. Even with larger employers who provide health insurance for employees.

Ms. TAVENNER. And, obviously, the more we educate employers and beneficiaries about that, the more they will start to pay attention to it as well.

The CHAIRMAN. How much of this is education, though? This is such a complex subject. If someone gets a bill from the hospital, nobody can understand it.

Ms. TAVENNER. Right.

The CHAIRMAN. So is there more to it than just educating the public?

Ms. TAVENNER. And I think that is what we are looking at now, and we would like to work with you on that.

The CHAIRMAN. What might some of those things be?

Ms. TAVENNER. Well, I think initially for us, understanding what we think are within our authorities, we certainly have the ability to publish this information and do some comparison. We also have the ability to encourage States. Some States have more robust programs about the relationship between charges and costs, so those are a couple of areas that we could start on, working with States, working nationally, to get the information out.

The CHAIRMAN. Well, I urge you to be very aggressive in this area, because Medicare is such a large payer.

Ms. TAVENNER. Yes.

The CHAIRMAN. It can influence others in the private sector, that is, the commercial market.

Second, many of us met with some experts—at least we thought they were experts—in health care economics. They are experts. One suggested quite strongly—and I will not mention his name, but you would certainly know him if I were to mention his name—that CMS can do a better job and move much more quickly in moving from fee-for-service to reimbursement based on quality and outcomes.

So I asked the question of this person, what can be done? This person said, well, what CMS should do is just set a deadline. Like, 10 years from now, 90 percent of reimbursement will no longer be fee-for-service, but it will be based on quality, whether it is through the ACOs, bundled payments, or whatnot. But he felt very strongly that somebody needs to light a fire under CMS, that it is not moving fast enough.

Ms. TAVENNER. Chairman Baucus, that is interesting. I hear the opposite concern, needless to say, from consumers and the industries, that we are moving too fast. What we are trying to do is take a measured approach. We certainly have made more changes, and

the Affordable Care Act gave us a lot of that authority to do so, to get away from fee-for-service and move more to, whether it is payment for quality or avoiding the readmissions.

So I think a lot of work has gone on in the last 3 years, and I am proud of that work, but there is no question there is a lot more to do. We could probably move faster in some areas, particularly if you look at our current growth and spending. It has kind of moved some from the work that we have done around hospitals to more the outpatient sector, so there are some probably targeted things we could do in the outpatient sector that could move a little faster.

But I would be very nervous about setting an arbitrary target—and I think I know who the economist is who set that target, because I have heard these targets placed before—and then trying to back into a target. I would rather that we do an incremental, aggressive strategy moving forward.

The CHAIRMAN. I appreciate that, but sometimes you need to set deadlines and dates to make things happen. Even if you do not make the target, you can just ask yourself, well, why didn't we? Maybe the target was the wrong target. Maybe we did not do a good enough job. But if you do not set targets, you do not set dates, deadlines, and benchmarks, I would just submit you are going to not do as well as you otherwise would.

Ms. TAVENNER. Right. And we do set a lot of those each year, and I am happy to share those with you.

The CHAIRMAN. Yes. We are going to get to that. At some point we are going to ask you to share those so we can work together to get things done.

Ms. TAVENNER. All right.

The CHAIRMAN. All right.

Senator Wyden?

Senator WYDEN. Thank you very much, Mr. Chairman. I was chairing a hearing, and I appreciate your courtesy. I know you are trying to wrap up.

Ms. Tavenner, welcome. We have appreciated the discussions with you. As you know, I feel very strongly that it is time for the government to finally mobilize and take care of the millions and millions of seniors who could be taken care of at home, and we have not been able to reach them with good quality care, largely because, over the years, we have just studied and studied and studied.

It goes back to the days, I was telling my friend Senator Rockefeller, when I was director of the Gray Panthers. We were circulating petitions for Senator Rockefeller's efforts then to get more care for seniors at home. Now we finally got, with Chairman Baucus's support, the Independence at Home model into the Affordable Care Act. In effect, it is giving us a chance to really move like the VA has in order to get people better care where they want it and also to save substantial sums of money.

My understanding is that you all are beginning something called the Rapid Cycle Evaluation Group. That is kind of a mouthful, but I gather it is a fast way to really determine how to look at these care models, like Independence at Home, and, when they do show

that you can get better quality at less cost, they can be accelerated and serve to address the needs of more seniors.

Would you support including the Independence at Home program in this Rapid Cycle Evaluation Group? I hope I am using the right terminology.

Ms. TAVENNER. You are using the right term. And, yes, of course. Independence at Home has been a great project, and I too support more care in the home, in the proper setting. So, yes, we will use the same type of evaluation, and we should know something soon.

Senator WYDEN. Very good.

The other question I had deals with chronic care. As you know, Independence at Home is for the very sickest individuals, people who so often are home-bound. But there are millions of other seniors who essentially need chronic care. They may not face the same kind of challenges in terms of being home-bound, but they are walking around, for example, with high blood pressure, diabetes, a host of problems.

It seems to me that not enough has been done to address the needs of the chronic care population. Of course, this is about 70 percent of the Medicare dollar. So, when we find better ways to take care of the chronic care population with better quality and lower costs, to a great extent we fix Medicare. We are having a lot of debate about raising the age and all kinds of things. Here is a way to help people get better quality care at lower cost.

Have you all looked at trying to come up with a kind of health home option for States and Medicaid programs for the chronically ill beneficiary? Because it seems to me that this would be another way, using really existing authority, that we could step up our attack in terms of improving care for this population, as Senator Rockefeller started years and years ago.

Ms. TAVENNER. Yes, sir, we have. We actually have some Medicaid health home models that have started. They are small in number, but they are starting to catch on. We work with States to make that happen. Obviously in Medicare, some of the work we are doing in the Innovation Center is around the medical health home.

Senator WYDEN. The time for the vote is about to expire.

Would you look at extending this model? We are talking about for Medicaid to Medicare. Yes or no?

Ms. TAVENNER. Yes, I would look at it.

Senator WYDEN. Very good. Thank you. I am looking forward to supporting you, and I appreciate your help in the office.

Senator Rockefeller, thank you for the extra time.

Senator ROCKEFELLER [presiding]. Thank you very much, Ms. Tavenner, for your presence. I look forward to voting for you.

Ms. TAVENNER. Thank you, Senator Rockefeller.

Senator ROCKEFELLER. The hearing is adjourned.

[Whereupon, at 12:10 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.)
On the Nomination of Marilyn Tavenner to be the Administrator of the Centers for Medicare and Medicaid Services
As prepared for delivery

General Douglas MacArthur once said, "A true leader has the confidence to stand alone, the courage to make tough decisions, and the compassion to listen to the needs of others."

Testifying before us today is Marilyn Tavenner, nominated to be the administrator of the Centers for Medicare and Medicaid Services, or CMS. Ms. Tavenner, you are being asked to draw on years of extensive experience to lead this agency and administer programs upon which millions of Americans rely. You will surely need confidence, courage and compassion in this role.

The head of CMS has a great responsibility. CMS administers health coverage to roughly one in three Americans. This includes 50 million Medicare patients, 56 million Medicaid patients and more than 5.5 million children through the Children's Health Insurance Program.

Some 167,000 seniors and 8,300 military retirees in Montana rely on Medicare, the largest program you'll oversee at CMS. These Montanans are my bosses and they — as well as millions more across the nation — are your bosses as well, Ms. Tavenner. I encourage you never to forget that.

It's also important to remember who works for you. The administrator of CMS oversees 5,800 employees. If confirmed, you must demand from these employees the utmost efficiency. Spread throughout ten regional offices across the country, CMS employees are responsible for distributing more benefits than any other federal agency.

Benefit outlays for fiscal year 2012 totaled $819 billion. The agency's administrative costs made up just one-half of one percent of this amount. That is significantly less than most private health care payers spend, and this efficiency must continue. There can be no room for error – no wasted time, effort or taxpayer dollars.

Ms. Tavenner, you have spent your entire career providing care to people in need. You started as a nurse — in my opinion, one of the most important professions in the world. Then you rose up through the ranks to become a hospital administrator and then Virginia's secretary of Health and Human Resources. You joined CMS in 2010, and became the acting administrator the next year.

You have the knowledge. You have the real world experience. And I believe you have proven yourself to officially take the reins of CMS.

Some have pointed out that CMS has not had a confirmed administrator in several years. I am glad we are moving forward today to change that. With new Affordable Care Act programs coming online, it is a critical time to have someone with your knowledge in charge at CMS.

We need strong leadership for successful implementation of the health insurance marketplaces and other key provisions of the health law. As administrator, you will have to make sure these programs are ready to go on day one. And you need to ensure the health care law's programs work for the people they are intended to serve. There will be a lot of people watching you, myself included.

The Administration and CMS need to implement health care reform the way Congress intended. I was home in Montana the past two weeks and I heard from small businesses that they need more clarity about rules. They need more information and transparency. I will be holding the administration's feet to the fire to ensure this is all done correctly.

You will also need to make sure America's health care safety net is working. Medicaid is going through a period of significant transformation. The program is changing everything from how income is counted, how care is delivered, to how eligibility determinations are made. And millions of low-income Americans will have access to coverage for the first time starting next year. Medicaid needs strong, stable leadership overseeing these changes to ensure they go smoothly.

Health reform also vastly improved the way Medicare delivers and pays for care. Medicare continues to slow its spending by transforming from a system that pays for volume to one that rewards value. CMS needs a leader focused on payment reforms that incentivize providers to provide high quality care in a cost-effective manner.

One of the highest priorities for the Finance Committee — and a responsibility I take very seriously — is protecting the integrity of federal health care programs by fighting fraud, waste and abuse.

The Affordable Care Act included significant new authority and tools for CMS to protect Medicare and Medicaid and save taxpayer dollars. A confirmed administrator is necessary to oversee and use the new tools that will prevent and fight health care fraud.

Last April, this Committee held a hearing to examine what, at that time, was the biggest Medicare fraud takedown in history. Thanks to tools and increased resources from the Affordable Care Act, a joint HHS and Justice taskforce recovered $295 million. The fraud involved 70 individuals across six cities.

We held that hearing to learn lessons to apply to future cases. We learned that every dollar invested to fight fraud, waste and abuse, generates a 500 percent return. We need the next CMS administrator to continue making fighting fraud a top priority.

Your experience shows an ability to effectively administer health care programs, and also an appreciation for the crucial services they provide. You are known as a pragmatist with an understanding of the ins and outs of health care administration.

I recently read a profile of you in the Washington Post. The article detailed an incident in the 1980s. You were working as a nurse in the Intensive Care Unit at Johnston-Willis Hospital in Richmond, Virginia.

At 2:00 a.m. a young woman in her late twenties was brought to the hospital by a rescue squad. She had been in a horrific car accident and crashed through the windshield of her old VW bug.

Badly injured and having suffered massive blood loss, she was pronounced dead, but you and the doctors went to work anyway, trying to revive her.

The surgeon on call told reporters that, "Marilyn was very supportive in everything ... We came up with a game plan, and it was right on target. We used about 60 units of blood, but the patient ultimately walked out of the hospital."

Ms. Tavenner, it sounds like you are someone who doesn't give up. Your experience is real and varied, and it will serve you well in this position.

CMS faces a great task and it requires a leader with the qualities General MacArthur described: confidence, courage and compassion. Ms. Tavenner, I believe you have ably served as the acting administrator, and I look forward to our discussion today.

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SUBMITTED BY SENATOR GRASSLEY

From *The Wall Street Journal*

Tip on Policy Shift Jolted Health Shares

By Brody Mullins and Tom McGinty

April 3, 2013

WASHINGTON—Alerted by a private message about a potential coming change in government health-care policy, certain investors earlier this week sparked a frenzy of trading in some of the industry's largest companies.

The last-minute action, which drove the shares sharply higher before the close of trading, is throwing a spotlight on the controversial "political intelligence" industry, the subject of a report due Thursday by the investigative arm of Congress.

The instigator for Monday's rally was a report from a Washington-based investment-research firm that often ferrets out policy news and analysis for investors, according to industry experts and market data from that afternoon. About 15 minutes before markets closed, the firm correctly predicted the Obama administration would reverse course on big spending cuts that would have hit health insurers.

The resulting stock surge is one of the most dramatic examples in recent years of how tips and insights from Washington's burgeoning political-intelligence business can drive trading on Wall Street, potentially leading to big profits for those in the know.

Shares in several big insurers rose as much as 6% between the time the firm, Height Securities, made its prediction at 3:42 p.m. and when markets closed. Volume for those companies in those final minutes was higher than the rest of the trading day put together. The government announced its change in policy about 35 minutes after the emailed scoop, which was reviewed by The Wall Street Journal. Shares continued to rise after the opening bell the next day.

A Height executive acknowledged that the firm's alert led to the trading surge but said it did nothing wrong.

The activity came the same week the U.S. government is expected to release its first study of the political-intelligence business. The report by the Government Accountability Office is set for Thursday release and expected to signal the starting point for a congressional push to regulate the industry.

According to people familiar with it, the report finds it is often difficult to prove how market-moving information seeps from government insiders to stock traders.

According to people familiar with it, the report finds it is often difficult to prove how market-moving information seeps from government insiders to stock traders.

"When a political-intelligence firm is able to anticipate a move by the federal government and alert investors, that raises questions," said Sen. Charles Grassley (R., Iowa), one of the lawmakers who want such firms to disclose more information about their activities, referring to Monday's trading activity.

If political-intelligence firms are getting their information from the agency, Congress or the White House, "that's unfair to everyday investors," Mr. Grassley said in a written statement.

The business of "political intelligence" isn't illegal but has come under increasing scrutiny as it has grown rapidly. Last year, Congress came close to approving a provision that would require individuals who get paid to gather government information for investors to make public their names and clients.

That provision was eventually stripped from a related piece of legislation designed to limit the possibility of insider trading by lawmakers and their staffs. A measure requiring the GAO study was approved in its place.

The rules regarding the political-intelligence industry are murky. Under Congress's new insider-trading law, passed last year, it is now clear that government officials for the most part cannot intentionally pass along nonpublic, market-moving information to individuals if they know the information will be used to make stock trades. More broadly, securities laws generally prohibit trading on material nonpublic information about activities at federal agencies.

Little, however, prevents lobbyists and other Washington insiders from gathering information, testing a hypothesis with former government officials and making informed predictions about coming government actions. Regulators have never brought an insider-trading case against a political-intelligence firm, member of Congress or congressional aide.

Monday's before-the-close trading was related to the possibility of a change in how the government pays private insurers to run Medicare health plans for seniors and the disabled. Nearly one in three people on Medicare are on such plans, called Medicare Advantage.

Once a year, the agency that oversees Medicare, the Centers for Medicare and Medicaid Services, or CMS, adjusts the amount of money it plans to allocate for the plans for the following year. The agency surprised Congress and Wall Street earlier this year when it announced that it would likely cut rates steeply. One key payment metric was set to fall 2.2%.

Monday was the deadline for the agency to set final rates for 2014. Many health-care analysts didn't expect changes and health-insurance stocks were mostly flat during the day.

At 3:42 p.m., Height Securities sent a report to its Wall Street clients with a surprising development: CMS planned to reverse course—a major boon for insurers.

"We now believe that a deal has been hatched to protect Medicare Advantage rates," Height Securities wrote in the email. "This is a drastic change in historical policy aimed to smooth the confirmation" of a new head of CMS.

Height Securities is a broker dealer regulated by the Securities and Exchange Commission. One of its services to clients is providing research on macroeconomic and policy developments in Washington.

Andrew Parmentier, managing partner with Height Securities, said its health-care analyst had been following the issue for some time, and that no one at the firm did anything wrong. He acknowledged the firm appeared to be the source of the trading spike after it picked up a rumor that CMS would scratch the cuts.

"Height Securities has established specific procedures to reduce the risk that is inherent in gathering information from government employees for investment purposes," he said.

CMS didn't immediately respond to a request for comment.

After the email, trading surged in shares of health insurers. Three of the biggest gainers were Humana Inc., UnitedHealth Group Inc. and Aetna Inc., which rank among the biggest companies that provide Medicare Advantage plans.

Volume in the three stocks exploded after 3:43 p.m., according to a Journal analysis of trade data provided by Telvent DTN. In the final 17 minutes of trading, the value of trades in those three companies' shares totaled $662.8 million, more than the entire day up to that point.

About 30 minutes after the markets closed, CMS announced it had reversed the payment cuts it had previously proposed.

Insurance stocks rallied Tuesday, too. The three insurers each gained between 3.7% and 5.5%.

Humana shares closed with a two-day gain of 14.5%. UnitedHealth and Aetna were up 7.9% and 6.2%, respectively.

Humana and Aetna declined to comment. UnitedHealth said it doesn't comment on its stock movements.

—Jon Kamp contributed to this article


Intelligent Trading
Investors piled into health insurers Monday after a Washington broker-dealer correctly predicted a positive government decision on Medicare payments to those firms. These stocks saw additional runups of between 3.7% and 5.5% on Tuesday.
PERCENTAGE CHANGE FROM PREVIOUS CLOSE
10%
8
6
4
2
0
-2
Humana: ▲ 8.6%
UnitedHealth Group: ▲ 3.1%
Aetna: ▲ 2.4%
2 p.m.
3
4
TRADING VOLUME OF ALL THREE COMPANIES
$60 million
50
40
30
20
10
0
Final minutes of trading
$662.8 million
3:42 p.m.: Email from the Washington broker-dealer went out
2 p.m.
3
4
Source: WSJ analysis of trading data provided by Telvent DTN
The Wall Street Journal

STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER U.S. SENATE COMMITTEE ON FINANCE HEARING OF APRIL 9, 2013 NOMINATION OF MARILYN B. TAVENNER TO BE CMS ADMINISTRATOR

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, today delivered the following remarks during a Senate Finance Committee hearing considering the nomination of Marilyn Tavenner to serve as Administrator of the Centers for Medicare and Medicaid Services (CMS):

I want to thank Chairman Baucus for convening this hearing to consider the nomination of Marilyn Tavenner to serve as Administrator of the Centers for Medicare and Medicaid Services (CMS).

This is a critical agency that, for a number of reasons, has been without a confirmed Administrator since the fall of 2006.

I want to thank Ms. Tavenner for her willingness to serve in this capacity.

After serving as Deputy Administrator since 2010 and Acting Administrator for well over a year, you know full well the challenges involved with leading an agency as large as CMS and that this job is an unenviable and often thankless one.

CMS is the world's largest health insurer. It has a budget of nearly one trillion dollars and it processes over 1.2 billion claims a year for services provided to some of our nation's most vulnerable citizens receiving Medicare and Medicaid.

If confirmed, you will have a daunting challenge ahead of you.

While I believe you have the qualifications to do the job, there is still much that you will need to do in order to assure members of this committee that CMS is heading in the right direction and that your leadership will help steer the agency through the very turbulent times that lie ahead.

One of the greatest challenges facing CMS in the near future is implementation of the federal and state-based health insurance exchanges.

In a speech last June, you said that the health care exchanges "keep you up at night."

I can relate.

They keep me up at night too, but probably not for all the same reasons.

There are numerous obstacles and issues that will need to be addressed as CMS works to implement the exchanges and bring them online later this year.

To date, CMS has not been able to provide satisfactory answers to a number of questions posed by myself, the Chairman, and other members of Congress regarding the exchanges.

For example, we still know very little about how the exchanges will operate, what the key operational and implementation deadlines are, and how CMS is monitoring them to determine if things are on track or not.

And, we are still waiting to see a breakdown of the budget for the federally-facilitated exchange.

If you are confirmed, it is essential that you work with this committee to provide us with this level of detail so that we can assess the implementation of the exchanges and work with you to address issues as they arise.

The costs associated with the exchanges are of critical importance to this committee as we are already seeing evidence that health insurance premium costs are continuing to rise and are projected to be, on average, 32 percent higher in the individual market.

At the same time, the Congressional Budget Office has estimated that the number of people enrolled in the exchanges in 2014 will be one million lower than originally projected, and quotes from the Administration officials indicate that the number could be even lower.

This is a perfect storm of unanticipated consequences that are combining to make this part of the so-called Affordable Care Act seem more like what I prefer to call it: The Unaffordable Care Act.

In addition to overseeing this massive new expansion of benefits, you will also be charged with helping to ensure the longevity and solvency of the existing Medicare trust fund, which is projected to go bankrupt in 2024.

All told, between now and 2030, 76 million baby boomers will become eligible for Medicare.

Even factoring in deaths over that period, the program will grow from approximately 47 million beneficiaries today to roughly 80 million in 2030.

Maintaining the solvency of the Medicare program while continuing to provide care for an ever-increasing beneficiary base is going to require creative solutions and a skillful Administrator at the helm.

I hope that you will be up to the challenge. Overseeing the complex infrastructure of an agency like CMS is not a job for the faint of heart.

You will be expected to ensure that beneficiaries get the care they want from the providers they prefer all while making sure that the claims get paid on time, that administrative and overhead costs are kept low, and that Congressional mandates are fully implemented.

I wish you the best of luck as you work to address these challenges and as you continue going through the confirmation process. You will need it.

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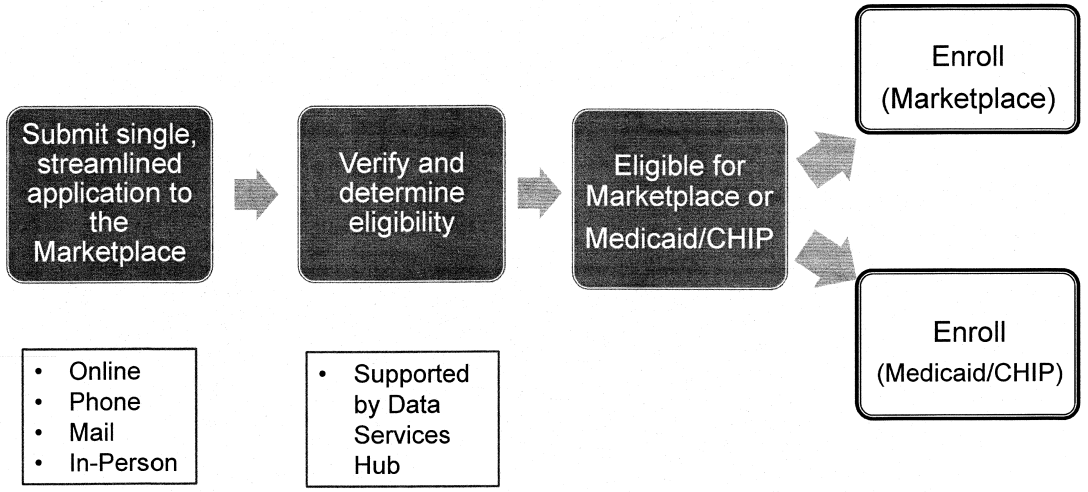
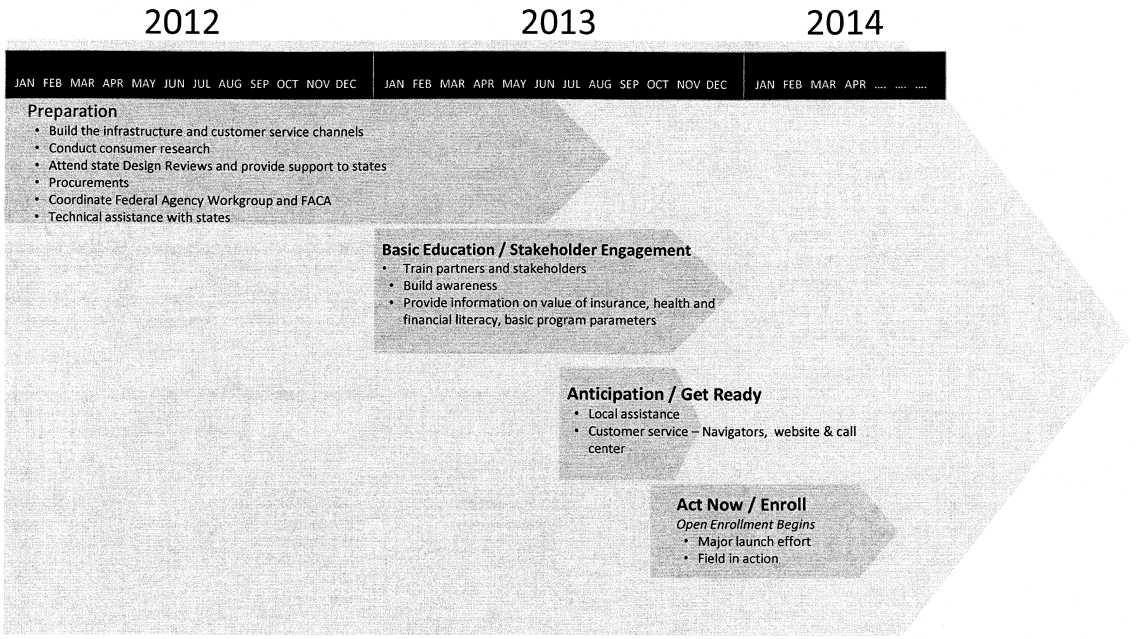
APPLICATION AND ELIGIBILITY



Consumer Outreach Timeline



The United States Senate

Committee on Finance

Opening Statement of Marilyn B. Tavenner of Virginia

Nominee to be Administrator of the Centers for Medicare and Medicaid Services

Department of Health and Human Services

April 9, 2013

Chairman Baucus, Ranking Member Hatch, and members of the Committee, thank you for holding this hearing today, and for the Committee's consideration of my nomination to be Administrator of the Centers for Medicare & Medicaid Services (CMS).

I'd like to start by acknowledging what we are all aware of – CMS is a large and complex agency; we have a large federal budget, and we provide services that are critical to our nation's healthcare. As such, this Committee and all of Congress have a strong interest in the management of our agency, as they should and as do I, and so I'd like to explain a little bit about myself and my background, why CMS is so important to me, how I've spent the past three years managing the agency, and my vision for moving us forward.

I'll begin with my mother, Ruby Martin; I just celebrated her 88th birthday with her down in the small rural town of Fieldale, Virginia where I grew up. As a strong woman who raised four children, she has been and continues to be a huge inspiration in everything I do – and she relies on Medicare. My youngest child, Sarah, was diagnosed with diabetes at the age of 11; she too has been a strong inspiration for what I do – and she relies on access to health insurance. I think that all of us know someone who relies on either the traditional programs we've been

administering at CMS, or the ones we are embarking on for 2014; that makes it personal for a lot of us and it underscores the fact that what we do at CMS directly affects the lives of so many.

I have been fortunate that my career path has given me a variety of perspectives on healthcare that I believe uniquely position me to lead CMS. I have a clinical perspective from my early days as a staff nurse, a business perspective from my days as a hospital CEO and Division President, and a government perspective both from my work as Virginia's Secretary for Health and Human Resources and the previous three years at CMS.

Simply put, CMS needs an Administrator, and one with strong operational skills. While it is important to have a vision for the agency, we have an $820 billion dollar business to run that a large amount of this country has a stake in, from beneficiaries to providers to hospitals to insurance companies to Congress to the administration to our CMS employees and contractors. Therefore, I consider it essential to my leadership role at CMS to be a partner to all of those stakeholders. And, I view my relationship with this Committee, and Congress as a whole, as a partnership. I have personally met with most of the members of this Committee and have appreciated the opportunity to engage with all of you in an open dialogue. While we may not always share the same views, we have worked together to resolve challenges and I'd like the chance to continue to do so.

My management style centers a lot around listening, pragmatism, and consistently trying to do what is right, even though it may not be the quickest and easiest path.

This style has led to many achievements over the past three years, and I would like to describe some of the accomplishments I am proud to have managed and led.

First, and most basic, is the daily operation of Medicare. Every workday, the fee-for-service Medicare program pays out more than $1 billion from some 4.64 million claims within the statutory requirement of 14 to 30 days.

The Medicare program and the coverage it provides is stronger and higher quality now than ever before. For example, more than one third of beneficiaries are enrolled in four or five star Medicare Advantage plans and 30 percent of stand-alone prescription drug plans available to beneficiaries received a star rating of four or higher. Thirty-four million Medicare beneficiaries now have increased coverage of preventive services and more than 6.3 million people with Medicare have saved over $6.1 billion on prescription drugs. Hospital readmissions in Medicare have fallen dramatically in the past year, resulting in an estimated 70,000 fewer patients returning to the hospital with dangerous and costly complications.

Additionally, over the course of the last few years, CMS has implemented new strategies to reduce waste, fraud, and abuse. For example, along with our partners, we were able to recover a record-high $4.2 billion from individuals trying to defraud health care programs in Fiscal Year (FY) 2012, and have reduced the Medicare fee-for-service payment error rate from 10.8 percent in FY 2009 to 8.5 percent in FY 2012.

CMS has also prioritized modernizing the administration of the Medicaid program. We are moving from the paper-driven, process-intensive approach to a more streamlined way of doing business with states. We are also supporting innovation and flexibility for states in both the Medicaid program and the state-based aspects of the Affordable Care Act.

We have improved our partnerships with the groups CMS does business with by streamlining regulations and improving data access. We have already finalized two regulations that will reduce regulatory burden – particularly on rural providers - under the President's Executive Order on Improving Regulation and Regulatory Rules. We believe that these rules combined will save at least $5 billion across the health care system over 5 years. Under my leadership, CMS is improving data access and sharing with strong privacy protections to develop new tools for policy and decision makers both within and outside CMS. CMS has already announced a data set that leverages almost five billion Medicare claims over a four-year period into an easy-to-use data resource, so that a variety of users can analyze the data to learn more about Medicare trends and geographic variation.

These past three years managing CMS have been a busy time, and I am proud of these examples and everything else we have been able to accomplish.

In closing, I want to share my vision and three primary focuses for moving this agency forward:

1. We need to operate CMS as a business and act like business partners. This means having an "open door policy" to work together and listen to the concerns of all the groups we

essentially do business with: beneficiaries, providers, hospitals, members of Congress, states, advocacy groups, insurance companies and our own employees and contractors.

2. We have a large responsibility in the months ahead to implement key pieces of legislation to ensure all Americans have access to affordable healthcare coverage, whether it is through the Health Insurance Marketplace, Medicaid, original Medicare, or Medicare Advantage.

3. We need to leverage the tools Congress has granted us to both reduce overall costs of care and improve the healthcare delivery system. These tools include new payment strategies connected to performance, innovative new models of care, and enhanced tools to combat fraud.

Lastly, I want to thank this Committee and staff for the respect and working relationships we've built over the past three years. And, I want to thank you, Mr. Chairman and Senator Hatch, for holding this hearing and giving me the opportunity to speak before the Committee and answer any questions.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)

   Marilyn Barbour Tavenner

2. Position to which nominated:

   Administrator, Centers for Medicare and Medicaid Services

3. Date of nomination:

   February 7, 2013

4. Address: (List current residence, office, and mailing addresses.)

   Permanent Residence:

   Office Address:

   Temporary Address: (During the week while working in DC, effective December 15, 2011)

5. Date and place of birth:

   May 31, 1951
   Martinsville, VA

6. Marital status: (Include maiden name of wife or husband's name.)

7. Names and ages of children:

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

Virginia Commonwealth University, Richmond, Virginia, 1983-1989
Masters in Health Administration (MHA),1989

Virginia Commonwealth University, Richmond, Virginia, 1981-1983
Bachelor of Science in Nursing (BSN),1983

Roanoke Memorial Hospital, Roanoke, Virginia, 1969-1972
Diploma in Nursing,1972

Fieldale-Collinsville High School, Collinsville, VA, 1964 - 1969
High School Diploma,1969

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

December 2011 – Present
April 2010 – July 2010
Acting Administrator
Centers for Medicare and Medicaid Services
(Washington, DC)

February 2010 – Present
Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
(Washington, DC)

January 2006 – January 2010
Secretary of Health and Human Resources for the Commonwealth of Virginia
(Richmond, VA)

December 2003 – December 2005
Group President of Outpatient Services
Hospital Corporation of America (HCA)
(Nashville, TN)

May 2001 – December 2003
President, HCA Central Atlantic Division
Hospital Corporation of America (HCA)
(Richmond, VA)

February 1996 – May 2001
Richmond Market President, HCA
Hospital Corporation of America (HCA)
(Richmond, VA)

March 1995 – February 1996
CEO, Chippenham Medical Center & Johnston-Willis Hospital
Hospital Corporation of America (HCA)
(Richmond, VA)

April 1993 – March 1995
CEO, Johnston-Willis Hospital
Hospital Corporation of America (HCA)
(Richmond, VA)

1986 – 1993
Director of Nursing
Johnston-Willis Hospital
(Richmond, VA)

1984 – 1986
Assistant Director of Nursing
Johnston-Willis Hospital
(Richmond, VA)

1981– 1984
Nursing Supervisor
Johnston-Willis Hospital
(Richmond, VA)

1978-1981
Nursing Supervisor
Community Memorial Hospital
(South Hill, VA)

1973-1978
Staff Nurse
Southside Regional Medical Center
(Petersburg, VA)

1972-1973
Staff Nurse
University of Virginia Medical Center
(Charlottesville, VA)

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

Appointed by Governor Mark Warner to serve on a committee to restore the Virginia Capitol (approximately 2004 – 2006).

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

- *Virginia Hospital Association, President and Board Member (approximately 1993-2005)*
- *United Way, Chairman, Health Section (during 1990s; approximately 1-3 years)*
- *American Hospital Association, Board Member (approximately 2003 – 2005)*
- *Chesterfield Business Council, Chairman, 1995 (Member 1993 until 2001)*
- *Hospital Corporation of America, Officer (approximately 2003-2005)*

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

- *St. Andrews Episcopal Church School, Board of Trustees Member (approximately 2009 – 2010)*
- *YMCA, Board of Directors(during 1990s; approximately 1-3 years)*
- *Meals on Wheels, Board of Directors(during 1990s; approximately 1-3 years)*
- *Science Museum, Board of Trustees Member (during 1990s; approximately 1-3 years)*
- *Midlothian Rotary, Lifetime Member (approximately 1993 until present)*
- *Salisbury Country Club, Member (1993-2009)*
- *Federation of American Hospitals, Member (1993-2005)*

13. Political affiliations and activities:

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

None.

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

None.

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

Eric Cantor (Cantor for Congress)

8/18/2003	*$500*
8/20/2003	*$775*
6/17/2004	*$500*
9/13/2004	*$250*
9/11/2011	*$250*

Ward Armstrong (Armstrong for Delegate of Virginia)

7/23/2011	*$500*

Democratic Party of Virginia

9/12/2006	*$500*
3/27/2007	*$2500*
10/2/2007	*$1000*
2/22/2008	*$2500*

Tim Kaine for Governor

2005	*$4350*

VA Hospital & Healthcare Association

Approx. early 2000s	*$2000*

John Watkins for Senate

Approx.early 2000s	*$1400*

Brian Moran for Governor

2009	*$1150*

Creigh Deeds for Governor

2009	*$1000*

Kaine Inaugural Committee

2006	*$800*

Jody Wagner for Lt. Governor

2009	*$500*

Tim Kaine for Lt. Governor

2001	*$450*

Jennifer McClellan for Delegate

2008	*$250*

ActBlue Virginia

Approx.2008	*$250*

Scott York for Loudoun County Board Chair

Approx. 2001	*$100*

James P. Moran, Jr. (Moran for Congress)

6/26/2007	*$1000*

Mark Warner (Friends of Mark Warner)

12/5/2007	*$500*
6/9/2008	*$250*
7/25/2008	*$500*
8/26/2008	*$500*

Forward Together PAC

5/10/2006	*$1000*

Federation of American Hospitals PAC

6/19/2001	*$1500*
5/24/2005	*$2500*
6/19/2003	*$1500*
5/4/2004	*$2500*

Tim Kaine (Kaine for Virginia)

5/7/2011	*$250*
8/28/2012	*$200*

George W. Bush (Bush-Cheney '04 (Primary) Inc.)

9/24/2003	*$1000*

The Committee for the Preservation of Capitalism

4/11/2005	*$1000*

American Hospital Association PAC

8/10/2004	*$1000*

Barack Obama (Obama for America)

9/11/2011	*$250*
9/18/2012	*$100*
9/25/2012	*$100*

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

- *Recipient, March of Dimes Citizen of the Year Award (2007)*
- *Honorary Doctor of Humane Letters, Virginia Commonwealth University(2008)*
- *American College of Healthcare Executives, Past Fellow (approximately 1995 – 2005)*
- *Star Award for Nursing, Virginia Commonwealth University (approximately 2005)*
- *YWCA, Outstanding Woman in Business(approximately 2003)*

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

- *2005 Award Winner*; Marilyn Tavenner, HCA President Outpatient Services Group; WomenWorthWatching.com; June 1, 2005
- *Governor's Plan Supports Abstinence Education*; By Marilyn Tavenner (Virginia Secretary of Health and Human Resources) Richmond Times-Dispatch Guest Columnist; December 3, 2007

- *Interview with Marilyn B. Tavenner, FACHE, Virginia Secretary of Health and Human Resources;* Health Administration Press, Foundation of the American College of Healthcare Executives; Volume 53, Number 1 January/February 2008

- *Should Virginia Raise its Cigarette Tax? YES or NO?;* By Marilyn Tavenner *(Virginia Secretary of Health & Human Resources)* and Frank Ruff, Richmond Times-Dispatch Guest Columnists; January 25, 2009

- *Connecting Care Through the Clinic and Community for a Healthier America*; By Howard Koh& Marilyn Tavenner, American Journal of Preventive Medicine, Volume 42, Issue 6, June 2012

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

April 16, 2010	*MedAxiom – Spring Member-Only Meeting*	*Washington, DC*
May 18, 2010	*National Institute for Health Care Management*	*Washington, DC*
June 10, 2010	*Blueskies& Brickwork Annual Summit*	*Washington, DC*
June 16, 2010	*FAH Annual Policy Conference*	*Baltimore, MD*
June 17, 2010	*Greater NY Hospital Association – Health Reform Implementation Meeting*	*New York, NY*
June 22, 2010	*Advisory Panel on Medicare Education - Meeting*	*Washington, DC*
July 15, 2010	*Health on Wednesday*	*Washington, DC*
Aug 5, 2010	*Health Affairs - Press Conference on MU*	*Washington, DC*
Aug 19, 2010	*HCA – Quarterly Meeting – panel presenter with other HHS staff*	*Washington, DC*
Sept 14, 2010	*NYS Public Employees Federation – Annual Convention*	*Washington, DC*
Sept 30, 2010	*University of Medicine & Dentistry, Newark – ACA informational event*	*Washington, DC*
Oct 26, 2010	*Geisinger Health System – Sr. Leadership Meeting*	*Danville, PA*
Nov 4, 2010	*C-SPAN – Washington Journal TV interview on Medicare Open Enrollment*	*Washington, DC*
March 22, 2011	*Nashville Health Care Council – Health Care Reform Policy Series*	*Nashville, TN*
March 29, 2011	*CQ Roll Call & Thomson Reuters – This Week in Health Care Forum*	*Washington, DC*
Sept 23, 2011	*CJW Annual Medical Society Meeting*	*Richmond, VA*

Oct 21, 2011	*Virginia Oral Health Coalition*	*Richmond, VA*
Oct 26, 2011	*East Coast Chief Medical Officers Summit*	*New York NY*
Nov 8, 2011	*National Association of State Medicaid Directors Conference*	*Washington, DC*
Dec 5, 2011	*Virginia Commonwealth University's Dept of Health Administration Students & Faculty*	*Richmond, VA*
Jan 4, 2012	*Leadership Council of Aging Organizations*	*Washington, DC*
Jan 24, 2012	*CMS' Innovation Advisors Kickoff Meeting*	*Baltimore, MD*
Jan 26, 2012	*Care Innovation Summit (Co-Hosted by HHS, CMS, West Wireless Health Institute, Health Affairs)*	*Washington, DC*
Jan 30, 2012	*CMS' Pioneer ACO Kickoff Meeting*	*Washington, DC*
Feb 7, 2012	*Advisory Panel on Outreach & Education*	*Washington, DC*
Feb 14, 2012	*American Medical Association National Advocacy Conference*	*Washington, DC*
Mar 6, 2012	*Federation of American Hospital's Public Policy Conference*	*Washington, DC*
Mar 16, 2012	*Virginia Telehealth Network*	*Charlottesville, VA*
April 30, 2012	*National Quality Forum /National Priorities Partnership Quarterly Meeting*	*Washington, DC*
May 1, 2012	*CMS' Comprehensive Primary Care Initiative Kickoff Meeting*	*Washington, DC*
May 7, 2012	*American Hospital Association Annual Membership Meeting*	*Washington, DC*
May 22, 2012	*American College of Emergency Physicians Annual Advocacy Meeting*	*Washington, DC*
May 22, 2012	*CMS' Health Insurance Marketplace (Exchanges) Grantee Conference*	*Washington, DC*
June 7, 2012	*3rd National ACO Summit hosted by: Engelberg Center for Health Care Reform at Brookings and the Dartmouth Institute for Health Policy and Clinical Practice*	*Washington, DC*
June 12, 2012	*Alliance for Health Reform*	*Washington, DC*
June 21, 2012	*Blue Cross Blue Shield Association*	*Washington, DC*
Sept 24, 2012	*Center for Excellence in Aging & Geriatric Health*	*Williamsburg, VA*

Oct 11, 2012	*American Academy of Nursing Annual Meeting*	*Washington, DC*
Oct 22, 2012	*Virginia Commonwealth University's Dept of Health Administration and School of Nursing Lecture*	*Richmond, VA*
Dec 13, 2012	*Annual QualityNet Conference*	*Baltimore, MD*
Jan 29, 2013	*Alliance of Community Health Plans*	*Washington, DC*

In addition, I gave several brief presentations and remarks to groups in my role as Virginia Secretary of Health and Human Resources from 2006 through 2009. I have not maintained and do not have access to records of those presentations or remarks.

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

I have served as the Principal Deputy Administrator of CMS since February 2010. From April 2010 through July 2010 and again from December 2011 to the present, I have also served as the Acting Administrator of CMS. My responsibilities in these roles include implementation of programs in Medicare, Medicaid, Program Integrity and overall agency operations.

Since the passage of the Affordable Care Act in March2010, my additional responsibilities have included expanding activities to combat fraud and abuse, establishing the Center for Innovation, creating the Medicare Medicaid Coordination Office, and working with the Center of Consumer Information and Insurance Oversight on health insurance marketplaces.

My twenty-five years at the Hospital Corporation of America (HCA) prepared me well for this role. Starting as a nurse, I went on to serve in hospital management and then in regional management of multiple hospitals/systems. My work at HCA culminated in the creation of a Senior Vice President position focused on outpatient services.

Those experiences taught me not only the importance of working closely with beneficiaries and their families but also how to manage complex financial institutions in the healthcare industry. My overall responsibilities during this period with HCA included insurance negotiations, recruitment of physicians and hospital personnel, developing and implementing quality programs, and building relationships in the community.

In 2006, I was appointed by Governor Tim Kaine as Secretary of Health and Human Resources for the Commonwealth of Virginia. In that role, I oversaw several state agencies: Medicaid, Mental Health, Aging, Disabilities, Public Health, Social Services, Children's Services, and Health Professions. Those four years gave me a great deal of experience in Medicare and Medicaid and in the effective and efficient use of state and federal funds to achieve agency goals.

My service as Principal Deputy Administrator and Acting Administrator for CMS for the past three years, combined with my four years in state government leadership, twenty-five years

managing multiple systems in the private sector healthcare industry, and my clinical background in nursing, have given me the solid background I will need, if confirmed, to move CMS forward in a manner that is fiscally responsible and improves the quality of healthcare.

B. FUTURE EMPLOYMENT RELATIONSHIPS

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

   No. I am currently employed by CMS.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

   No.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

   No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

   Yes.

C. POTENTIAL CONFLICTS OF INTEREST

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

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

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

   In connection with the nomination process, I have consulted with the Office of Government

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

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

   Since 2006, I have not engaged in any such activities outside of my state and federal government employment. Prior to 2006, while working at HCA, I occasionally met with members of state legislatures and Congress to discuss legislation related to HCA's work, including legislation related to the Virginia Certificate of Public Need program and payment reform. In order to conduct such discussions, I was registered as a lobbyist for HCA in the Commonwealth of Virginia through 2003.

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

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

5. Two copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

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

   N/A

D. LEGAL AND OTHER MATTERS

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

   No.

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

   No.

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

   With the exception of those listed below, I have not been personally involved in such proceedings or litigation. However, in my current and previous positions I have occasionally been named as a party to litigation involving my employer. None of these cases involved allegations of wrongdoing on my part, and I was not asked to provide testimony in any of these cases.

   I was the plaintiff in two divorce proceedings, in 1978 and 2008.

   It has also come to my attention that in December 2002, a case was filed relating to a property that my husband and I had purchased. My understanding is that this case was dismissed in 2003 and was related to some outstanding obligations of the prior owner. I was never served with any papers, nor was I aware of this case, until it was brought to my attention during this nomination process.

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

   No.

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

   None.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly

constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

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

Yes

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

Questions from Senator Baucus

Question 1
Arguably, the single most important provision of the ACA was the creation of health insurance Marketplaces (also known as Exchanges). These marketplaces, where individuals can compare and shop for health insurance, need to work seamlessly come 2014 if the law is to be considered a success. Consumer outreach and branding are essential to ensuring people are aware of their options and able to enroll in these new Marketplaces. How will CMS help businesses work in the Marketplaces? Can you describe the different types of outreach activities are CMS conducting to ensure consumers know about the Marketplaces?

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

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

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

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

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

Question 2

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

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

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

Question 3

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

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

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

Question 4

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

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

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

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

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

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

Question 5

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

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

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

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

Question 6

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

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

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

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

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

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

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

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

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

Question 7

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

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

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

Questions from Senator Hatch

Question 1

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

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

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

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

Question 2

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

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

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

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

Question 3

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

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

Question 4

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

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

Question 5

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

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

Question 6

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FFM includes the following functions and capabilities:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Question 8

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

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

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

- Administration of a SHOP Exchange.

Question 9

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

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

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

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

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

Question 10

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

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

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

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

Question 11

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

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

Question 12

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

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

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

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

Question 13

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

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

Question 14

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

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

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

Question 15

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

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

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

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

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

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

Question 16

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

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

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

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

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

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

Question 17

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

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

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

Question 18

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

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

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

Question 19

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

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

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

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

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

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

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

Question 20

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

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

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

Question 21

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

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

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

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

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

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

Question 22

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

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

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

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

Question 23

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

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

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

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

Question 24

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

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

Question 25

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

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

Question 26

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

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

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

Question 27

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

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

Question 28

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

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

Question 29

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

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

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

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

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

Question 30

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

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

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

Question 31

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

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

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

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

Question 32

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

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

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

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

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

Question 33

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

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

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

Question 34

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

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

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

Question 35

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

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

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

Question 36

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

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

Question 37

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

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

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

Question 38
Regarding Diagnostic Laboratory Payment Reform: The President's Budget has proposed additional cuts to the clinical lab fee schedule. Last year, CMS initiated re-pricing for several molecular diagnostics. Due to the antiquated nature of the fee schedule and the increased development of newer advanced diagnostics, the existing coverage and reimbursement platform used by CMS is in need of reform. What is CMS doing to modernize coverage and payment policies to appropriately reimburse for quality tests and create a stable foundation for encouraging the development of new technologies that improve quality and reduce costs? What new legislative authority or legislative guidelines does CMS need to achieve necessary reforms?

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

Question 39
Regarding Part B Drug Reimbursement: The reduction of reimbursement for physician-administered drugs that will occur due to sequestration has led to articles highlighting the cost of cancer drugs and the impact on community oncology practices. Market participants have suggested that many patients have been redirected from the clinic to the more expensive hospital outpatient setting. Does CMS have data available that will confirm that this transfer of patient care is occurring? If not, what is CMS prepared to do to make this data available to Congress?

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

government programs. That is why the Administration has indicated that we stand ready to work with Congress on balanced approaches to replace sequestration to avoid its adverse impacts. CMS is committed to preserving Medicare beneficiaries' access to quality health care. We will continue to monitor the impact of provider payment cuts mandated under the Budget Control Act to assess their impact on Medicare beneficiaries and we are happy to share our results.

Question 40

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

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

Question 41

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

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

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

Question 42

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

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

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

Question 43

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

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

Questions from Senator Rockefeller

Question 1

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

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

Question 2

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

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

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

Question 3

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

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

Question 4

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

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

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

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

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

Question 5

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

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

Question 6

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

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

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

Question 7

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

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

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

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

Questions from Senator Menendez

Question 1

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

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

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

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

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

Question 2

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Question 3

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

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

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

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

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

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

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

Questions from Senator Toomey

Question 1

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

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

Question 2

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

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

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

Question 3

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

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

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

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

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

Questions from Senator Nelson

Question 1

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

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

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

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

Question 2

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

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

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

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

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

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

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

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

Question 3

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

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

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

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

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

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

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

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

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

Question 4

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

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

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

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

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

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

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

Question 5

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

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

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

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

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

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

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

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

Question 6

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

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

Questions from Senator Casey

Question 1

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

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

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

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

Question 2

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

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

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

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

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

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

Question 3

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

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

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

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Question 4

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

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

Question 5

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

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

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

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

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

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

Question 6

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

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

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

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

Questions from Senator Grassley

Question 1

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

On April 4, 2013, the WSJ reported that Height Securities successfully predicted CMS's policy decision on MA plans. Height Securities sent out an alert to clients at 3:42 pm successfully predicting CMS's policy decision on MA. This had major consequences on the market.
You sent a letter on April 4, 2013, asking CMS who they told this information to prior to publicly releasing the information. This question follows up on your most recent letter to CMS.

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

On Monday, April 1, 2013, at 3:42 p.m., Height Securities sent an advisory that told their clients of the CMS Medicare Advantage policy decision and that they supported related stocks.
The consequence of a political intelligence firm having access to this information 18 minutes before the market closed was astonishing.

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

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

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

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

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

Question 2
IF TAVENNER SAYS THAT SHE DOES NOT KNOW WHO THE LEAK WAS AND THAT IT WASN'T CMS AND THEY ARE CONDUCTING THEIR OWN INVESTIGATION.

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

But how about his ... why don't we work together?
You can speak softly and I will bring a big stick.
I don't believe you can get to folks at HHS or OMB or the White House without help.
The sooner we figure out where the leak is, the sooner we can get you confirmed.

Question 3
Last year, CMS suspended implementation of the Quality Indicator Survey (QIS) for nursing homes. Why did CMS suspend implementation of the QIS? When will CMS resume implementation? How long do you expect it will take CMS to complete QIS training in every state? How do you plan to avoid similar complications or any other problems that would prevent a quick transition to the new survey system?

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

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

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

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

Question 4

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

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

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

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

Question 5

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

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

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

Questions from Senator Crapo

Question 1

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

Answer: We are aware that hospital acquisitions of other health care entities such as physician practices have been commonplace in the last few years. One of the ways that we are encouraging competition in hospital markets is through the operation of the Medicare accountable care organizations (ACOs). We believe that competition among ACOs will foster improvements in quality, innovation, and choice for Medicare beneficiaries. The antitrust agencies (Department of Justice and Federal Trade Commission) are monitoring the competitive effects of ACOs. These agencies issued guidance for providers seeking to become ACOs and established a voluntary expedited review process to give feedback to providers on potential anti-competitive activities.

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

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

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

Question 2

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

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

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

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

Question 3

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

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

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

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

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

Questions from Senator Isakson

Question 1

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

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

Question 2

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

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

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

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

Question 3

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

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

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

Question 4

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

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

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

Question 5

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

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

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

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

Question 6

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

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

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

Question 7

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

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

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

Question 8

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

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

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

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

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

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

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

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

Question 9

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

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

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

Question 10

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

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

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

Questions from Senator Enzi

Question 1

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

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

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

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

Question 2

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

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

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

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

Question 3

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

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

Question 4

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

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

Question 5

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

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

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

Question 6

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

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

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

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

Question 7

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

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

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

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

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

Questions from Senator Wyden

Question 1

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

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

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

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

Question 2

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

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

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

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

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

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

Question 3

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

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

Question 4

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

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

Questions from Senator Portman

Question 1

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

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

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

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

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

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

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

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

Question 2

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

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

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

Question 3

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

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

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

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

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

Question 4

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

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

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

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

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

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

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

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

Question 5

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

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

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

Questions from Senator Brown

Question 1

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

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

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

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

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

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

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

<u>Question 2</u>
Regarding Part D Preferred Provider Networks: I am concerned with the growing use of preferred pharmacy networks in the Medicare Part D program, and have heard concerns from small and medium-sized pharmacies in Ohio about being excluded from the networks. It seems the insurance companies are inviting only a few big box and other large pharmacies to participate. In the recently released Call Letter for the 2014 plan year, CMS itself identified concerns with the use of preferred pharmacy networks in the Medicare Part D program, particularly the potential for beneficiary disruption and travel costs, especially in rural areas. CMS also indicated concern that the structure of some preferred networks may actually be increasing costs for the Medicare program.

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

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

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

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

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

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

Question 3

Investment in Pediatric Innovations

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

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

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

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

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

Question 4

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

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

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

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

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

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

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

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

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

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

Question 5

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

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

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

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

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

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

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

Question 6

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

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

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

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

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

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

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

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

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

Question 7

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

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

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

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

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

Question 8

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

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

Answer: We are also concerned about the recent increases in the length of time that Medicare beneficiaries spend as an outpatient receiving observation services. This can affect beneficiaries' financial liability during the hospital stay and their ability to meet the 3-day qualifying inpatient hospital stay requirement for coverage of skilled nursing facility services. We solicited comments from stakeholders on a rule last year that would address this issue.
We heard from stakeholders that hospitals appear to be responding to the financial risk associated with admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting beneficiaries as inpatients. In

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

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

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

Question 9

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

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

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

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

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

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

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

Questions from Senator Cornyn

Question 1

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

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

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

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

Question 2

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

Answer:

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

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

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

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

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

Question 3

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

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

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

Question 4

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

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

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

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

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

Question 5

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

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

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

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

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

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

- CBO Recommendation: Gather timely data on the use of care, especially hospital admissions.
    - Innovation Center action: Health systems participating in the Pioneer ACO and ACO Shared Savings models will receive updates on care received by their patients within a few weeks of when it occurred, down from 6 months or more in previous demonstrations.

- CBO Recommendation: Focus on transitions in care settings.
    - Innovation Center action: The Community-Based Care Transitions Program will invest in organizations such as Area Agencies on Aging that help seniors as they leave the hospital, including through home visits. In addition, the Demonstration to Reduce Hospitalizations of Nursing Facility Residents will invest $134 million in providing additional care and supports to help reduce preventable hospitalizations among nursing home residents.

- CBO Recommendation: Use team-based care.
    - Innovation Center action: The Comprehensive Primary Care Initiative provides new supports from both Medicare and private health insurers to make sure that participating primary care practices have robust care teams – which could include nurses, pharmacists, and dieticians – available 7 days a week to coordinate care and avert visits to the emergency room.

- CBO Recommendation: Target interventions toward high-risk enrollees.
    - Innovation Center action: Along with the Medicare-Medicaid Coordination Office, the Innovation Center is empowering states to invest in new models targeted toward beneficiaries that are eligible for both Medicare and Medicaid, a group of beneficiaries at particularly high risk for having multiple chronic health conditions and high health care costs.

- CBO Recommendation: Limit the costs of intervention.
    - Innovation Center action: The Innovation Center is testing several new payment models, such as the Pioneer ACO Model and the Bundled Payments for Care Improvement, with no upfront payments to participating doctors and hospitals. Rather, these groups will be rewarded once their innovative approach is proven to have reduced costs and kept patients healthier.

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

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

Question 6

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

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

Question 7

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

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

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

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

Question 8

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

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

Question 9

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

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

Question 10

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

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

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

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

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

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

Question 11

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

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

Question 12

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

Answer: CMS is working to address diabetes and other chronic conditions in a number of ways, including through Medicare's annual wellness visit, which provides beneficiaries with personalized prevention plan services at no cost. Such visits are crucial to the early detection and successful management of chronic conditions like diabetes. For beneficiaries' ongoing care, accountable care organizations (ACOs) are a CMS initiative to better coordinate care, which is particularly important for patients with multiple chronic conditions. ACOs are designed to promote accountability for a patient population, coordinate items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. ACOs have the ability to redesign care to address their unique circumstances, patient populations and local community needs. Many ACOs have indicated that they plan to focus on chronic disease, patients transitioning care and high risk patient populations.

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

Question 13

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

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

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

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

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

Question 14

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

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

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

Question 15

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

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

improvements in quality, innovation, and choice for Medicare beneficiaries. The antitrust agencies (Department of Justice and Federal Trade Commission) are monitoring the competitive effects of ACOs. These agencies issued guidance for providers seeking to become ACOs and established a voluntary expedited review process to give feedback to providers on potential anti-competitive activities.

CMS is providing aggregate claims data to the antitrust agencies to assist them in ensuring ACO formation and implementation does not have a detrimental effect upon competition. The antitrust agencies have existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct. In addition, we believe the testing of the Advance Payment ACO model has led to increased participation by smaller organizations in the Medicare Shared Savings Program, thus increasing competition. I would be happy to work with you and your staff on how we can improve on these efforts.

Questions from Senator Carper

Question 1

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

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

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

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

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

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

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

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

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

Question 2

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

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

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

Question 3

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

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

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

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

Question 4

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

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

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

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

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

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

Question 5

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

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

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

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

Question 6

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

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

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

Question 7

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

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

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

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

Questions from Senator Roberts

Question 1

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

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

Question 2

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

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

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

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

Question 3

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

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

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

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

Question 4

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

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

Questions from Senator Bennet

Question 1

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

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

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

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

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

Question 2

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

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

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

Question 3

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

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

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

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

Question 4

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

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

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

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

Question 5

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

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

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

Question 6

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

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

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

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

Question 7

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

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

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

Question 8

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

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

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

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

Question 9

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

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

Questions from Senator Cardin

Question 1

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

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

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

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

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

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

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

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

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

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

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

Question 2

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

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

Question 3

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

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

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

Question 4

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

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

Question 5

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

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

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

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

Question 6

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

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

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

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

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

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

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

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

Question 7

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

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

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

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

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

Question 8

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

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

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

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

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

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

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February 28, 2013

The Honorable Max Baucus
Chairman
U.S. Senate Committee on Finance
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Orrin G. Hatch
Ranking Member
U.S. Senate Committee on Finance
104 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Baucus and Ranking Member Hatch,

On behalf of the American College of Physicians (ACP), I am writing to express our strong support for the nomination of Marilyn Tavenner as administrator of the Centers for Medicare and Medicaid Services (CMS). ACP members include 133,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

As acting administrator for CMS, Marilyn Tavenner has shown her dedication to improving our health care system, ensuring patients have access to high quality care, and reducing health care costs. During her time as acting administrator, Ms. Tavenner has supported the important work of the Center for Medicare and Medicaid Innovation (CMMI). The CMMI has developed and piloted important programs and initiatives to test new payment and delivery models, such as the Comprehensive Primary Care Initiative (CPCI). In addition, under her leadership, the CMMI continues to conduct research on best practices and engage a broad range of stakeholders to develop additional models for testing.

Ms. Tavenner's dedication to improving our delivery and payment systems, willingness to work with stakeholders, and test out new models was also demonstrated in the 2013 Medicare Physician Fee Schedule. Under her leadership, CMS included a new set of codes focused on transitional care management services (TCM). The new reimbursement policies for TCM services will allow physicians and other qualified health care providers to coordinate Medicare beneficiaries' transitions from facility to non-facility settings. This is an enormous step forward in ensuring that patients receive the care they need and recognizing the important cognitive and coordinated care physicians provide. In addition, ACP applauds CMS and Ms. Tavenner for including in the 2013 Medicare Physician Fee Schedule a recognition of the growing evidence behind higher quality care provided through an advanced primary care practice that has implemented a patient-centered medical home (PCMH).

As the acting administrator for CMS, Ms. Tavenner has proven to be an effective and thoughtful leader who is willing to work with stakeholders to achieve meaningful change in our health care

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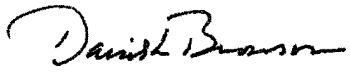
system. It is imperative that CMS continues to have a leader who understands our complex health care delivery system and is willing to work in partnership with stakeholders. The ACP is very pleased to support Marilyn Tavenner's nomination and looks forward to continuing to work with her on improving our health care system.

Sincerely,



David L. Bronson, MD, FACP
President, American College of Physicians

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