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STRENGTHENING MEDICARE AND MEDICAID: TAKING STEPS TO MODERNIZE AMERICA'S HEALTH CARE SYSTEM

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

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STRENGTHENING MEDICARE AND MEDICAID: TAKING STEPS TO MODERNIZE AMERICA'S HEALTH CARE SYSTEM

WEDNESDAY, NOVEMBER 17, 2010

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

The hearing was convened, pursuant to notice, at 10:04 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Rockefeller, Bingaman, Kerry, Wyden, Schumer, Stabenow, Cantwell, Nelson, Menendez, Carper, Grassley, Hatch, Snowe, Kyl, Bunning, Roberts, Ensign, and Enzi.

Also present: Democratic Staff: Bill Dauster, Deputy Staff Director and General Counsel; David Schwartz, Health Counsel; and Tony Clapsis, Associate. Republican Staff: Emilia DiSanto, Special Counsel and Chief Investigative Counsel; Andrew McKechnie, Health Policy Advisor; Susan Walden, Health Policy Counsel; and Rodney Whitlock, Health Policy Advisor.

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

The CHAIRMAN. The hearing will come to order.

Montesquieu said, "All people are born equal, but they cannot continue in this equality. They recover it only by the protection of the law."

When it comes to health care, the Affordable Care Act gives seniors, patients, and health care consumers historic protections under the law. The new law protects seniors by helping to ensure that they get the right care when they need it.

The old system, before health care reform, was failing too many seniors. Take Christine Brown. Christine's father had a blister on his toe. That blister became infected; it would not heal. Christine and her father tried everything. Every doctor they went to prescribed a different antibiotic. No one coordinated his care. There was no electronic record of his medications. After several months without anyone managing his care, it was too late. The infection had spread. The only way to save his life was to amputate the leg.

Christine's father is now confined to a wheelchair for the rest of his life, all because of a blister, all because no one coordinated his care. The new law protects patients like Christine's dad. The new law helps doctors coordinate and communicate with each other.

The old system, before health care reform, was failing too many seniors who get hospitalized. Yesterday, the HHS Inspector General released a report, and the IG found that nearly a quarter of seniors hospitalized suffer some form of adverse event in the hospital, and almost half of those are preventable. The new law helps protect patients from preventable adverse events.

Under the new law, Medicare and Medicaid will crack down on hospitals that do not prevent infections. Before reform, nearly one-fifth of seniors who were hospitalized were back at the hospital and readmitted. When patients leave the hospital, they clearly do not want to come back. They should receive the follow-up care that they need to stay well and to stay out of the hospital. The new law protects patients from needless readmissions. Medicare will protect seniors by penalizing hospitals that do not treat patients right the first time.

The old system, before health care reform, has been failing health insurance consumers. Far too frequently, insurance companies would drop coverage when patients get sick. The new law protects patients from this, and other, insurance company abuses. Far too frequently, insurance company executives would use premium dollars for lavish CEO bonuses instead of patient care. The new law requires health insurance companies to spend at least 80 percent of the premiums that they collect on providing health care. The new law puts a limit on funds for administrative costs, salaries, and CEO bonuses.

The old system, before health care reform, was failing the Medicare trust fund. Before health care reform, Medicare would have been bankrupt by the year 2017. Medicare would have gone broke in 6 years. The new law protects Medicare from going broke. The new law extends the life of Medicare by an additional 12 years.

In the old system, before health care reform, health care costs were out of control. In the last 8 years, average wages have increased just 20 percent, while the average cost of employer-sponsored health coverage has doubled. Family health insurance premiums have tripled. The new law will protect American families against these increasing costs. The new law transforms Medicare payments from paying for quantity to paying for the high-quality care that seniors deserve.

What does paying for quality mean? Paying for quality means protecting seniors from duplicative tests; it means protecting seniors from unnecessary procedures that waste time and money; it means empowering doctors with electronic medical records that put patients' information at their fingertips. Paying for quality means providing doctors with the latest evidence. That way, doctors and patients can make the best-informed decisions. Paying for quality means investing in primary care so that seniors have an advocate to help them navigate the health care system.

What does paying for quality not mean? Paying for quality does not mean cutting benefits that seniors are guaranteed. Paying for quality does not mean a one-size-fits-all Washington solution. Medicare and Medicaid must seize upon the innovations that work at the local level. Paying for quality does not mean interfering with the doctor/patient relationship. The doctor/patient relationship is sacred.

The old system, before health care reform, was failing to crack down on fraud and abuse. The new law protects the taxpayer by giving law enforcement officials new tools to combat fraud. The new law puts an end to wasteful overpayments to private insurance companies to participate in Medicare. These overpayments to Medicare Advantage plans used to cost the program tens of billions of dollars every year.

Under the new law, seniors on Medicare are protected. Seniors can feel confident that Medicare dollars will benefit the patients, not line the pockets of insurance companies. The new law slashes wasteful payments, and it does so without taking away a single guaranteed benefit under Medicare. I want to say that again, because it is important: health reform protects the Medicare program without taking away a single guaranteed benefit. In fact, the new law adds benefits, like lifetime free annual checkups and closing the donut hole.

The old system, before health care reform, was failing seniors, patients, and health care consumers. The new law gives them historic protections. Repealing the new law would return us to the failures of the old system. Repealing the new law would cause Medicare to go broke in just 6 years. Repealing the new law would increase the deficit by hundreds of billions of dollars. Repealing the new law would put insurance company bureaucrats back in charge of health care. Repealing the new law would threaten seniors' health with duplicative care and poor coordination.

Today we hear from the point man on the new law. We hear from the Administrator from the Centers for Medicare and Medicaid Services, Dr. Don Berwick. Under the new law, CMS is charged with strengthening Medicare and Medicaid, and he is in charge of making Medicare and Medicaid more efficient and modernizing them for the 21st century.

Dr. Berwick, the Affordable Care Act provides the protection of the law. We look forward to hearing how you will carry it out.

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

The CHAIRMAN. Senator Grassley?

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Thank you, Mr. Chairman.

I, and the members of this committee, take the importance of this committee and our constitutional role as the U.S. Senate very seriously. You, Dr. Berwick, were nominated by President Obama to serve as CMS Administrator on April 19. You and I personally met in my office to discuss—and we did this in June—your nomination. Despite repeated requests from me and my colleagues, we were never able to get a nomination hearing. Instead, you were appointed under recess powers July 7.

Dr. Berwick, I believe that that was incredibly unfortunate for you and for the position that you now hold. I think you should have had the opportunity to come before this committee and explain and defend yourself and make the case, in person, that you are the right person to be CMS Administrator. You were nominated 213 days ago and appointed 134 days ago, and yet this is our first

chance to get you before this committee to testify and answer questions. The phrase "better late than never" comes to mind.

Today, the Centers for Medicare and Medicaid Services have over 4,400 employees, not including thousands of outside contractors and an annual budget of over $700 billion. That is a bigger budget than even the Pentagon.

Through the Medicare, Medicaid, and CHIP programs, the Centers for Medicare and Medicaid Services provide health care coverage to about 1 in every 3 Americans, almost 100 million people. That is a lot of people, but that number is set to grow even more. The partisan health care overhaul will add about 16 million to Medicaid, with a price tag for the Federal Government of about $434 billion. This expansion will begin under your watch.

In addition to this massive coverage expansion, you have been given unprecedented authority to implement new payment and delivery models. Your decisions in this area will influence a significant amount of economic activity and determine how the new health care law affects health care coverage that millions of Americans rely on. We need to discuss your thoughts on the pending $500 billion of Medicare cuts and the massive Medicaid expansion that you are charged with implementing.

Now, the Office of the Actuary and providers across the country have expressed serious concerns that the deep Medicare cuts will hurt access to care and may hinder quality improvements. Both Republican and Democratic Governors are worried the Medicaid expansion will bankrupt State budgets. While some supporters of health care law may label these claims as partisan scare tactics or misinformation, we take these claims very seriously.

With all that is changing in the health care system and the sheer number of people who rely upon your agency for care, you have one of the most important jobs in government today. That is why it is so disappointing that you were recess-appointed without a hearing. It contradicts promises made by Candidate Obama about having the most open and transparent administration in history.

As I am sure you know, I take oversight and government transparency very seriously; I hope you share my enthusiasm. I hope you will show an even greater commitment to transparency and collaboration than any of your predecessors, but, based upon the number of letters that are still outstanding, I am concerned about the depth of that commitment. The American people deserve nothing less. I thank you, and I look forward to hearing your testimony.

The CHAIRMAN. Thank you, Senator.

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

The CHAIRMAN. Now I will introduce our witness, who is Dr. Don Berwick, the Administrator for the Centers for Medicare and Medicaid Services. Dr. Berwick, thank you very much for coming. It is good that you are here, because many Senators have many questions. I know you will answer them very forthrightly.

As is our usual practice, your written statement will be automatically included in the record, and I encourage you to speak—often we give witnesses about 5 minutes. If you want to take more than 5 minutes, go right ahead.

Dr. Berwick?

STATEMENT OF DR. DONALD BERWICK, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS), DEPARTMENT OF HEALTH AND HUMAN SERVICES, BALTIMORE, MD

Dr. BERWICK. Thank you very much, Mr. Chairman, Mr. Ranking Member, members of the committee. Thanks a lot for the chance to meet with you this morning. I feel very privileged to be here. My full testimony, as the chairman said, is submitted for the record.

I am a physician. I am the son of a general practitioner who practiced for 40 years in rural Connecticut. From my father, I learned the image of health care that I still cherish: responsive, imbedded in a community and connected to it, and focused on the needs of patients and families.

My father made house calls. He knew everybody's name in town. He did it all. He delivered babies. He took care of people through their whole lives. He rounded at the local hospital every single day before his afternoon, and sometimes evening, office hours. He took his own X-rays, and he read them.

In my own professional career, which is 40 years long so far, I also practice as a doctor. I am a pediatrician. But I practiced in a very different kind of health care world than my father started in, more interdependent, full of new and wonderful technologies, and much, much more complicated.

When everything goes well, that modern health care world can work miracles compared to what my father could do. My father watched children die of leukemia—that was always fatal. Most children with leukemia today are cured, and they live. He had little to offer people who had heart attacks, except oxygen or bed rest and hoping. Today, new treatments have cut heart attack death rates to less than half of what they were 30 years ago.

But with the miracles of modern health care have also come some major new challenges. Complex drugs and powerful treatments bring hazards with them, like medical errors and complications with treatment. From science, we know often the best way to treat disease, like diabetes or congestive heart failure, but then that poses us with a question: how can we make sure that that treatment, the best treatment, is within the reach of every single American?

We also need to address the rising cost of health care, cost that is stretching the Nation's public and private capacities, cost that by itself is a barrier to getting the right care to people and providing it.

These are not abstract problems. They affect real people. On my very first day in this new job, I was passing through a metal detector getting into the building on my way in, and I saw a rather intimidating-looking security guard on the other side of the metal detector staring at me, and he beckoned me to come over to him when I went through the detector. He said, "Can I talk to you?" I said, "Sure, you can talk to me. You have a gun." [Laughter.]

He said, "You're Don Berwick, aren't you?" And I was startled. I said, "Yes. Why do you want to know?" He said, "Well my name is John McCormick." He said, "My daughter was Taylor McCormick, and she died when she was 17 months old because of a medical error. I am devoting myself to making sure that doesn't happen

to other children," he said, "and I want to do anything I can possibly do to help you in your new job."

I do not know the particular error that cost little Taylor McCormick her life. I do know that she was not alone. As the chairman said, yesterday the Department of Health and Human Services Inspector General released a report showing, again, that far too many Medicare patients suffer, or even die, as a result of medical errors. For me, eliminating that harm is a top priority.

What I also know is that all over this Nation there are hospitals and clinics and offices that are making thrilling progress toward better, safer care. I have worked with these places for 20 years. There are hospitals that have reduced their infection rates to zero, that have reduced pressure sores by 90 percent, that have reduced waste, that have become truly, excitingly, patient-centered.

This has to do with cost, also. What is true in every other modern industry is true in health care: poor quality costs more than good quality does. Doing things right costs less than doing things wrong. Hospitals and clinics all over the country are discovering that and proving that.

Denver Health, for example, has reduced their costs by nearly $50 million simply by finding and removing waste, waste like asking nurses to fill out useless forms for hours instead of just using their time for what they want to do, which is taking care of patients. Better care leads to lower cost through improvement of care.

What I mean to say also is that improvement of care is not just possible, it is actual. It happens every day in this country. But that raises the question, again, how can it happen everywhere? How can we as a Nation take full advantage of everything we already know?

The biggest waste of all comes when we fail to meet the needs of patients and families who need us the most: the chronically ill. You probably know somebody who has cancer, heart disease, or lung disease. You know that they need health care that helps them through journeys, not fragments. They need us not to drop the ball. They need us not to forget their names, or the problem list, or what medications they are on.

I feel incredibly lucky to be able to join CMS at a historic time, a time of enormous promise for the future of our Nation's health care. I think we can, and we should, aim for three goals at once: better care for individuals; better health for the American people; and lower costs through improvement, through better care delivery; and I know that all of that is within our reach.

In the pursuit of that, the Affordable Care Act is a landmark. It is the best opportunity I think we have had in a generation or more to make progress toward the health care that our Nation wants and needs. We have already started. In the 9 months since the Affordable Care Act went into effect, millions of people have already seen benefits from it. Close to 2 million Medicare beneficiaries who have fallen into the donut hole have received checks to help them with their prescription drug costs.

Next year, the beneficiaries in the donut hole are going to see a 50-percent discount on brand-name drugs. The Act makes it easier for Medicare beneficiaries to get effective preventive care, like mammograms and colonoscopies, available free without any co-

payment at all. That will not just reduce their costs, that will keep them healthy.

We have turned up efforts to target criminals who are stealing from Medicare and violating the public trust. We are putting more boots on the ground, we are using better technology to detect them, we are empowering seniors to help us and report fraud when they see it. Through enforcement, we are getting millions and millions of dollars back into the trust fund. We have much better ways, new ways to measure and report on health care's performance so that beneficiaries can be better informed, so the care providers can learn from each other, and so we can reward the system for improving.

We have a marvelous new Center for Medicare and Medicaid Innovation, which we formally established yesterday, to help accelerate that learning and that invention. The new law strengthens our ability to measure quality and to use good market forces on behalf of beneficiaries to find them the best possible deals on health plans, on supplies, and medicines. As a result of that, for example, I am happy to report that Medicare Advantage premiums, on average, will go down next year.

When we raise the quality of care for Medicare beneficiaries, we raise the quality of care for all Americans. Every single day that I come into the CMS office now, I am thinking about the people we serve, those 100 million people, and thinking about Taylor McCormick. My brother Bob gave me a sign for my desk when I left for Washington, and the sign says, "How Will It Help the Patient?" That is the first thing you see when you visit me, and it is the first thing on my mind.

This is crucially important, but we—CMS, HHS, government—cannot possibly do this alone. We can help, and we will help, but the best roads to better care, the better health and lower costs through improvement, are locally built, they are built State-by-State and community-by-community.

This also has to be done in a very strong public/private partnership. Going it alone is not a good plan for CMS. I have been meeting with stakeholder groups of all sorts. They know that change is needed, and they all ask me the same questions. It is remarkable. They all say, "How can we help?" I think that is really good news, because that is the only way we can get this done—together.

Ever since I became a doctor, I have been trying to help make health care better, safer, more reliable, more patient-centered, more equitable. What I know is that all of that is possible, that improvement is possible, vast improvement is possible. I believe there is no better position in our Nation from which to help pursue those goals than the one I am now privileged to occupy, and there is not any better time than now when the Affordable Care Act has laid an unprecedented foundation for better patient care.

America needs three things from its health care now: better care, no more stories like Taylor McCormick's; better health so people can live full and happy lives, even with chronic illness; and lower cost through improvement of everything we do for patients, families, and communities. That is the root of quality, without harming a hair on anyone's head. I know all that is possible. I have seen it.

I am grateful for the privilege of working as your Administrator to make CMS a trustworthy partner and a constructive force for the improvement of health and health care for all Americans. Thank you very much for the privilege of being here, and I will be happy to answer questions.

The CHAIRMAN. Thank you, Dr. Berwick.

[The prepared statement of Dr. Berwick appears in the appendix.]

The CHAIRMAN. What are your priorities? You cannot do it all at once. You have costs, there are hospitals, delivery system reform, extending the life of the Medicare trust fund. There are lots of different areas from which you can work. Do you have a first, second, third, or fourth list?

Dr. BERWICK. Well, my overall top priorities are to protect the public trust, the trust fund, and ensure the longevity and viability of this system, but it is to protect the beneficiaries, 100 million people who depend on us to do as well as we possibly can for them. I have articulated four priorities in CMS at this stage: being a much more effective agency, working better with other agencies within government and the private sector; reducing waste within our own work; improving care of individuals—especially around issues like patient safety, Senator, such as you outlined in your opening remarks—moving swiftly toward better integrated, coordinated care, helping settings all over this country figure out and reach out for better ways to take care, especially, of chronically ill people, especially dual-eligibles; and then getting really serious about prevention upstream.

A lot of the illnesses that erode our well-being and erode the Treasury are avoidable. If we get very serious about working on prevention, problems like obesity and bad perinatal outcomes and avoidable heart disease, we can make a lot of progress. I am pushing hard in CMS for forward progress in all of those areas.

The CHAIRMAN. There is a lot of talk about the cost of chronic care. Could you just give us a little sense of how chronic care could be better addressed?

Dr. BERWICK. If you could imagine a Medicare beneficiary, Mrs. Jones. I heard from one. I was visiting regional offices, and I visited a senior center in Atlanta, and there was a woman there. I said, "What do you worry about?" She said, "Well, what I worry about is, I have five medicines, I see six doctors, I go to four different facilities. I am not sure these people are talking to each other. I need them to get together. I need a team."

What she was saying is what chronic disease care, coordinated seamless care, is. It is a net around the patient so we work well together. If we drop the ball, things get worse. If one doctor prescribes a medicine for Mrs. Jones that conflicts with the medicine that another doctor prescribed and they do not know it, she could end up bleeding, she could end up in a hospital and not at home where she wants to be. Better care for chronically ill people means coordinated care.

The CHAIRMAN. Right. We have all heard that. So how do we get there? How do we get better coordinated care?

Dr. BERWICK. You need to envision and reward it. Right now, we pay for health care in fragments. The new Affordable Care Act of-

fers us a tremendous range of possibilities for making it possible for clinicians to get together to do the kind of care they want—Accountable Care Organizations, medical health homes in Medicaid, and bundled payment. These are ways to support the system to come together to do the kind of work that the chronically ill really need them to do.

The CHAIRMAN. Could you tell us a little bit more about Accountable Care Organizations and how far along they are, and what you envision them doing, and in what parts of the country?

Dr. BERWICK. This is a really exciting part of the new law, the chance to encourage that kind of coordinated care, especially for chronically ill people. An Accountable Care Organization would be an entity able to take responsibility for the care of a group of patients with a primary care base, and then to coordinate services and to get rewarded for that so that there are bonus payments when things go well in the accountable care world. It operates on the fee-for-service side of Medicare. We are not talking about Medicare Advantage or managed care, this is in the natural state.

We are going to be writing the Notice of Proposed Rulemaking now that will be out at about the end of the year or so. Very important in that concept, though, is the one-size-does-not-fit-all theory. What accountable care is going to look like in a rural part of Montana or in inner city Manhattan, they are going to be different. We need to energize exploration toward that. That is one of the reasons the new Center for Medicare and Medicaid Innovation is so important. That will allow us additional possibilities to encourage local settings to devise the kind of accountable care that really will work for them.

The CHAIRMAN. My time is up. I think my clock was started too late.

Senator Grassley, you are next.

Senator GRASSLEY. Dr. Berwick, it is not your fault, or anybody's fault, what the schedule of the Senate is. But there is at least 70 minutes of questioning here, and we have votes starting at 11. So I was wondering if you would commit to appearing again before the committee after the Thanksgiving break so we would all have a chance to ask the questions we want to ask?

The CHAIRMAN. I think, Senator, that is really the prerogative of the chair as to whether to call hearings or not. It is interesting for you to get a commitment, but I cannot guarantee when we will or will not have another hearing. Although it is my intention to have a good number of hearings, because it is very important for this committee to hear from this Administrator about his plans.

Senator GRASSLEY. All right.

I will go on to the next point. Prior to your nomination, you led a group called the Institute of Healthcare Improvement, or IHI. It has numerous health care companies as both clients and donors, which gives rise to potential conflicts of interest in your new position.

To help shed some light on these potential conflicts during your initial confirmation process, my staff asked you to provide IHI's three most recent Form 990s, including Schedule B, which details donors and donation amounts. You agreed to comply with this request. Indeed, you even agreed to have my staff meet with your

IHI chief financial officer to ensure the financial information provided was accurate and complete.

It is now November, and the information still has not been provided. No chief financial officer has come to meet with my staff. Though your installment subverted the Senate's constitutional prerogative of advice and consent, it did not subvert its obligation of oversight. So I restated my request in an effort to ensure that there is transparency for your potential conflicts of interest and accountability at CMS.

So the question is, Dr. Berwick, you stated in an earlier letter that you planned on divesting any interest in companies you may oversee and that have interaction with CMS. Is this divestiture complete, and, if so, will you provide the committee with records documenting the divestiture?

Dr. BERWICK. Thank you, Senator. I recall that conversation. When you asked for that information, I intended to try to provide it. As it happened, it was not in my sole authority to provide that information and now, of course, I am recused from contact with IHI, so I cannot provide it on my own initiative.

What I can assure you is that all my past activities, my finances, were thoroughly reviewed by the appropriate ethics officers under congressional rules. Before I took office, I was given an ethics agreement to review and sign. I signed and agreed to every single condition of this agreement. I have complied with every single one. I am fully in compliance now with the conditions of that agreement, which were supplied to the committee.

Senator GRASSLEY. The waivers were not supplied to the committee. Could we have copies of the waivers?

Dr. BERWICK. I have requested no waivers yet, Senator. I am recused from contact. But because there are a couple of organizations from which I am recused that I think have important potential information for CMS, I requested and received the right to request a waiver when and if needed. I have not done so yet.

Senator GRASSLEY. All right. Then let me be specific. You also stated in an earlier letter that you were "seeking ethics waivers due to your connections with Kaiser Permanente and the Commonwealth Fund." Did you obtain these, or any other, waivers? That is what I would like to have provided for the committee.

Dr. BERWICK. I understand, Senator. Yes, those two organizations—I asked permission to seek a waiver, when necessary, for the conduct of my particular duties as CMS Administrator and not for particular party matters. I have not yet requested those waivers because that issue has not arisen.

Senator GRASSLEY. Dr. Berwick, health reform was supposed to improve the Medicare program, but these findings—which I am not going to take time to give now, but I made reference to them, particularly what the actuary said—indicate that some Medicaid cuts in the new health care law will move the program in an opposite direction by jeopardizing access for beneficiaries.

Dr. Berwick, would you agree with Rick Foster when he made those comments about the health care bill potentially jeopardizing health care for beneficiaries, whether these cuts will jeopardize access to Medicare Part A providers?

Dr. BERWICK. You say Medicare, not Medicaid?

Senator GRASSLEY. I am sorry if I said Medicaid. This is all Medicare.

Dr. BERWICK. Yes. The actuary's estimates are just that, they are estimates. They are based on his best judgment. What we can look at now is facts as they are developing. Our intention is to increase access to care for Medicare beneficiaries. We are strengthening Part A, Part B, and Parts C and D as we go, and I think those will be more and more attractive to beneficiaries. I think they will find themselves in better shape after implementation of this Act is fully engaged.

Senator GRASSLEY. I am done.

The CHAIRMAN. Thank you, Senator. I would like to, for the information of Senators, indicate the order. Next is Senator Rockefeller, then Senator Hatch, Senator Bingaman, Senator Bunning. Those are the next four.

Senator Rockefeller?

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Dr. Berwick, I would like to ask three quick questions in a row.

The CHAIRMAN. Senator Roberts would like to be recognized. He is not going to make a statement.

Senator ROBERTS. Did the chairman indicate to the ranking member that we will have an opportunity, we will try to have an opportunity, to talk to Dr. Berwick after Thanksgiving, or before Thanksgiving?

The CHAIRMAN. I did not. We should sometime, but I did not say when.

Senator ROBERTS. Sometime. All right.

The CHAIRMAN. In good faith, that would be reasonable.

Senator ROBERTS. Well, I think the obvious statement by the Senator from Iowa, and our ranking member, is that, in 5 minutes, obviously, I cannot do this because I have other obligations, and I have to leave, and I apologize for that. But I would hope we would have an opportunity to do that.

I would like, then, to ask unanimous consent to submit some questions for the record.

The CHAIRMAN. Without objection.

[The questions appear in the appendix.]

Senator ROBERTS. And thank you, Dr. Berwick, for coming.

Dr. BERWICK. Thank you, Senator Roberts.

The CHAIRMAN. Senator Rockefeller?

Senator ROCKEFELLER. Can the time be put back to the original?

The CHAIRMAN. Absolutely.

Senator ROCKEFELLER. Thank you.

Dr. Berwick, under health reform, the Federal Government is paying for the vast majority of the Medicaid expansion under the health care reform act. It averages about 95 percent on a nationwide basis, actually up to 100 percent in four or five States, between 2014 and 2019.

So the first question is, if States reject this funding and do not expand their Medicaid programs, where else could these vulnerable citizens get coverage? That is question number one.

Question number two is an interesting one, I think. I want to ask you about the practical impact of Medicare. When people are uninsured for 10 to 15 years before they sign up for the Medicare pro-

gram, as a physician, can you tell us what would happen to your efforts to improve quality and lower the cost of care if we do not move forward with covering 32 million uninsured Americans under health reform? And you see the link there.

The third question is, could you explain how this law gives States flexibility? Everybody says it is government-run. In fact, it is State-run—exchanges, et cetera. Could you explain how this law gives States flexibility in reforming health care delivery? You referred to that in your statement. Could you talk about how it gives health care providers the ability to innovate and improve health care for patients? Those are the three questions.

Dr. BERWICK. Thank you for them, Senator.

With respect to the first—the choices States make about their participation in Medicaid—my job is to make the Medicaid program ever stronger and more attractive and more viable for States. I understand that States are dealing with a lot of very serious financial issues right now, and they are very much on my mind. As you pointed out, the new law gives us the chance to help States with this transition to broader coverage for people who really need it.

The same things that are making the States suffer under the recession are hurting people of marginal income, and they will find themselves with no insurance and nowhere to go without the benefit of this new law in place. We are doing a 100-percent Federal match for the newly eligible Medicaid beneficiaries, and, as you say, over a multi-year period after that it goes down only to 90 percent and stays there.

We are reaching out to States with a 90/10 match, that is, 90 cents out of every dollar the States are going to spend to smooth their enrollment procedures across these new forms of enrollment, we are reaching out to States with that. We are helping them with waiver authority, and we are strengthening Medicaid every day. It is a much stronger program now than it has ever been before.

With respect to the practical impact on Medicare of failing to insure people in the pre-Medicare area, you are absolutely right. I mean, someone does not get chronic congestive heart failure on the day they become a Medicare beneficiary. Their diabetes does not suddenly occur at age 65 or 66—it has been there all along. When people, especially people with these underlying risks or chronic illness, cannot get access to health care, their care deteriorates. Their kidneys get damaged, their hearts get damaged, they lose their way. Then Medicare ends up, you are right, holding the bag for that.

But the States are paying for that anyway with the uninsured prior to that. That person who has undetected hypertension or diabetes that is hurting their kidneys will get worse, and eventually that care will be given, and in most States that means the States will pick up the tab a different way. So it is, you pay me now or you pay me later. The best way to provide care is to anticipate the needs of patients at all stages of life, not just in the Medicare group. You are absolutely right about that. It always is reflected in the care of the chronically ill.

An enormous burden on the States right now is the dual-eligible population. Nine million Americans in the dual-eligible population account for 40 percent of the costs in Medicaid, and that is one of

the reasons the States are having these terrible problems. The best thing to do for them is to help them heal, to get them better care, and that will reduce the burdens on States.

Flexibility is essential to the future. We do not have a one-size-fits-all solution here. State-by-State, there will be innovations that will surface. We can support that through waivers, through the demonstration projects that are now anticipated in the new law, and in preexisting legislation.

Now we have these new wonderful assets in the law, the Center for Medicare and Medicaid Innovation, and the Center for Dual-Eligibles, which will soon be established. These will be able to support States with inventive, locally designed ways to get better care to people who really need it.

Just yesterday, when we set up the Center for Dual-Eligibles, we announced the possibility for up to 15 States to get grants now of up to $1 million just to plan better care for dual-eligibles in those States.

Senator ROCKEFELLER. Physicians, others, would have initiative?

Dr. BERWICK. Imagination around this country is extraordinary. In my work prior to coming here I had the chance to work with thousands of clinicians all over the country, hundreds of hospitals. I can see the inventive energies out there. I have met with physician groups now since I have arrived, almost every major physician organization, and they are raring to go to help physicians discover new ways to better coordinate their care, to get involved in patient safety. We can support them also through the new Center for Medicare and Medicaid Innovation, and we can now make them more and more aware of what is possible.

The new law has in it the capacity for more transparency so we can see where high performance lies in this country among hospitals, among physicians. For hospitals, we can tie that to payment as well. That kind of transparency builds knowledge, and people can begin to learn from each other. That will help physicians as well.

The CHAIRMAN. Senator Hatch?

Senator ROCKEFELLER. Thank you, Dr. Berwick.

The CHAIRMAN. Thank you.

Senator HATCH. Well, thank you, Mr. Chairman. Welcome, Dr. Berwick. Happy to have you here.

Let me just make a brief observation before I ask a question or two. Today is simply the first of many opportunities for us to have an open and honest dialogue on the impact of the new health care law. Now, the Centers for Medicare and Medicaid Services, CMS, are in charge of the largest Federal health care programs, Medicare, Medicaid, and of course the Children's Health Insurance Program. This agency has a larger budget than the Pentagon, and its actions directly impact the lives of almost, or a little more, perhaps, than 100 million Americans.

Since the passage of this new health law, we have seen that the reality has failed to match the rhetoric, on everything from the promised cost reductions, to Americans keeping the coverage of their choice, et cetera. I fear that this is only the beginning of these impacts, and that it is essential that we fully understand the consequences of this new law.

On November 2, the American people issued a clarion call for more transparency and responsiveness out of Washington. It is our responsibility to listen and respond to their concerns. Obviously, asking us to cover all of our concerns in this hour-long hearing with only 5 minutes per person is like asking us to drain the Pacific Ocean with a thimble. This cannot simply be a check-the-box exercise.

Although this hearing has been a long time in coming, almost 8 months since the passage of the health law, I am glad you are finally here. I plan to make sure that my constituents and the American people are fully informed of all the important actions being undertaken at CMS. I sincerely hope that you and your staff will be willing and responsive partners in this exercise.

Keep in mind, usually the President makes a nomination, the nominee comes up and talks to members of this committee, we have a hearing, and then we have a mark-up. For this $800 million agency, the President just recess-appointed you without any of that. Now, I think many constituents are outraged. I have a high respect for you as a doctor.

Now, Dr. Berwick, as I was reading through your testimony I came across a claim on page 3 that the new health care law will actually increase Medicare Part A trust fund solvency by 12 years, to 2029. I have also found this claim to be very puzzling.

As you may already know, I sent a letter to the Medicare trustees on June 24 of this year, along with Senator Gregg, on the issue of double-counting Medicare savings in the new law. The health care law contains more than $500 billion in cuts to the Medicare program, which were claimed by the administration not only to improve Medicare solvency, but also to fund new entitlement spending at the same time.

Now, this is like claiming that the American families can use the same magical dollars to pay their mortgage and their grocery bills at the same time, and it is really nonsensical. Now, do not just take my word for it. Here is what the nonpartisan Congressional Budget Office said on December 23, 2009: "The key point is that savings to the Hospital Insurance Trust Fund under the health law will be received by the government only once so they cannot be set aside to pay for future Medicare spending, and at the same time pay for current spending on other parts of the legislation or on other programs."

In fact, your own actuary at CMS also agreed with this viewpoint in his memorandum on April 22, 2010, when he said the following: "In practice, the improved HI financing cannot be simultaneously used to finance other Federal outlays, such as coverage expansions under PPACA, and to extend the trust fund, despite the appearance of this result from the respective accounting conventions."

So my question is a pretty simple one: do you agree with your own actuary, whom I strongly believe was rightly telling us that you cannot use the same magical dollar to extend the solvency of the Medicare Part A trust fund, while also using it to pay for new Federal spending? Now, is this not budgetary gimmickry?

Dr. BERWICK. No, Senator. In estimating the effects on the trust fund, the actuary is following standard accounting principles. It

has been done correctly. It is not double-counting, as I understand it. The Congressional Budget Office——

Senator HATCH. It is.

Dr. BERWICK. My understanding is, we are following standard accounting principles, and that money will go into helping extend the life of the trust fund.

The Congressional Budget Office has also estimated, I think, $140 billion of savings over the first 10 years of this new law, below business as usual, and $1 trillion for the decade following that. We are seeing the results now. In a lot of the implementation of the new law, we can see some of the savings now beginning to accrue.

Prior to the law, you know we engaged a trial of competitive bidding for durable medical equipment. We saw costs of DME fall 32 percent just in that trial, returning something like $150 million, I think, back to beneficiaries in those nine trial areas. We are strengthening Medicare Advantage, resulting in lower costs there by working very hard with those plans in strong negotiations.

Senator HATCH. By cutting a lot of people out of Medicare Advantage, you are not strengthening Medicare Advantage. You have cut a lot of people out of Medicare Advantage, especially in rural America.

Dr. BERWICK. There is normal turnover, Senator, in Medicare Advantage.

Senator HATCH. It is not normal.

Dr. BERWICK. More than 99 percent of Medicare beneficiaries have access to Medicare Advantage plans under the new arrangements.

Senator HATCH. They are a lot more expensive. My time is up. Let me just say this. I have a lot of questions for you, but this hearing is not going to allow us time. Normally you can count on me supporting all administration officials if I can. I think the President won, and he ought to have the people he wants around him.

Now, I hope when we send you questions in writing, that this administration will permit you to answer our questions, because this is a doggone important committee, and we oversee 60 percent of the spending in this country. I want to know what is going on, and I want answers to my questions.

So I just hope that you will answer our questions when we send them in writing to you and take the courtesy to show them to you, because we clearly do not have time in this hearing, and we certainly have not had time, since you were recess-appointed, to even get down to some of these questions that are very important. I have no doubt that you will be able to answer some of them.

Thank you, Mr. Chairman. Sorry.

The CHAIRMAN. Thank you. I would just reinforce what you said, Senator. I do expect CMS, and those in the White House, and whatnot, to allow full response to questions. One of your first words were, do it right the first time. So do it right the first time and answer it fully the first time.

Senator HATCH. Mr. Chairman——

The CHAIRMAN. And there are other Senators who have to speak. I appreciate it. I am trying to help you out, Senator.

Senator HATCH. I agree with that. But let me just say that this is pathetic. I am not meaning to be critical, because we are in a recess period. But my gosh, we ought to have time to ask the most important man in America on health care, questions that are relevant and important.

The CHAIRMAN. We will have sufficient hearings.

Senator HATCH. All right.

The CHAIRMAN. Next on the list is Senator Bingaman.

Senator BINGAMAN. Thank you, Mr. Chairman.

Dr. Berwick, thanks for being here and thanks for your willingness to serve in this very important position.

I would like to go back to this Office of Inspector General report, that you referred to, on medical errors. I think the euphemism that the report uses is "adverse events" in hospitals. I guess what I am interested in hearing from you, if you could tell me, is your reaction to some of the recommendations.

One of the recommendations in the report is that CMS "should provide further incentives to hospitals to reduce the incidence of adverse events through its payment and oversight functions," and then further down it says, "CMS should look for opportunities to hold hospitals accountable for adoption of evidence-based practice guidelines." This is something you have spent the last several decades working on. I would be interested in your views as to what opportunities you think you have under this new law to make progress on this.

Dr. BERWICK. Thank you, Senator Bingaman. Yes, you are correct. Patient safety has been an object of my ongoing professional concern and work for well over 2 decades. Unfortunately, the Inspector General's report was not a surprise. We know that patients are injured in American health care far too often.

The good news is, we know those injuries are preventable. We can find hospitals and clinics all over this country that are reducing injury rates to extremely low levels, and there are all types of places, little tiny hospitals. I got a communication a while ago from a hospital in upstate New York, in Ogdensburg, I think, Claxton-Hepburn Hospital. It almost eliminated infections that I thought were inevitable. Sentara Norfolk Hospital near here has gone almost 5 years, I believe, without a central line infection.

So we can really make substantial progress, but we have to make it more possible for hospitals to do that, including making it more in their interest. The Affordable Care Act has tremendous opportunities for doing that. There is a lot of focus in that Act on health care-acquired conditions and hospital-acquired infections, that is, other names for adverse events. We now can make them more transparent, more public, measure them better, post those measurements on Hospital Compare so beneficiaries know about that, and tie payment to hospitals to their ability to reduce those avoidable forms of harm and injury.

I will tell you, I have reached out to the hospital community and talked with the hospital leadership, the hospital associations, a number of times since I have arrived. They are enthusiastic about this. There is not resistance. Everyone knows that we need to promise every single American the safest possible health care that anyone can find anywhere.

Senator BINGAMAN. Let me also ask about a related issue, and that is the measurement of outcomes. We made provision in this law for trying to accelerate the adoption of outcome measures for the health care industry, and I believe the way we have it, the way the law reads, the first set of acute and chronic measures are required to be released by CMS within 24 months of enactment; the first set of primary care and preventative care measures are due within 36 months. I would be interested in any views you have about the importance of these outcome measures and what you anticipate being able to do in that regard.

Dr. BERWICK. I am aware of your leadership on that issue, Senator. I am very grateful for it and excited by that provision of the Act.

In proper stewardship in any exchange, what needs to be measured, defined, and paid for is what you really want in health care. We do not really want fragments, we do not want pieces of care, we want what health care achieves, which is good health, long life, comfort, relief of anxiety. Those are outcomes. That is about what happens to the patient.

Maturing our measurement systems and linking that to payment, so we move more toward purchasing what we really want, will be better for patients, and all our beneficiaries—and not just beneficiaries, but all of America. That involves investment in the development and use of those outcome measures. They are hard to develop. We are well under way, though.

A lot of the work on hospital value-based purchasing, the Medicare Advantage star rating system, is having more and more outcome measurements, one of which, by the way, is what the beneficiary, the patient, reports about their own experience. That is an outcome, too.

This involves public/private partnership because, the more we can align those measures with what is happening on the private side in private plans and private delivery systems, it will rationalize and make more sensible to physicians and hospitals what we really expect of them. It involves work with the National Quality Forum and other consensus-based entities to help us develop these measures all together, and I have been meeting with all of these stakeholders since I have arrived. You are absolutely right: that is the direction to move measurement.

Senator BINGAMAN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Bunning?

Senator BUNNING. Yes. I would like to point out that the opening statements took almost 30 minutes. Although Senator Baucus will not make a commitment to bring you back to testify before the end of the year, I can assure you that you will not get special treatment next year. I suspect that you will be spending a lot of time testifying before the House of Representatives, partly because we in the Senate have been shut out.

Why did you decide to accept a recess appointment by President Obama in July? You certainly had a choice to say "no" and that you wanted the nomination to work. I have heard people argue that the nominations had stalled; however, that is clearly untrue. You were not nominated until April, a mere 4 months before your recess ap-

pointment, and the Finance Committee, which is run by a Democratic chairman, did not even hold a hearing on your nomination as of this day.

Senator Hatch brought out some things about some early statements about 12 years, and 2029, and how the bill has helped Medicare. But it also failed to mention that the biggest problem Medicare faces, the dramatic cuts to the physician payment rate, was not addressed in the health care bill and still is not fixed.

On December 1, doctors started getting a 23-percent cut when they see Medicare patients. The cost of fixing this formula is probably somewhere around $300 billion, which will require more cuts to Medicare, adding to the deficit for future generations.

According to the AMA press release, about 1 in 5 physicians overall, or nearly one-third of primary care physicians, are restricting the number of Medicare patients in their practice because of low reimbursement rates and the threat of future cuts. So, as I see it, Democrats were able to extend the solvency of Medicare by 18 years, but did not bother to fix one of the most expensive problems Medicare faces each year, which will require more cuts in the future and make it harder for seniors—seniors—to find doctors to treat them. To me, this is not success.

Dr. BERWICK. Thank you, Senator Bunning. You asked a number of questions. Let me begin with SGR, with the physician payment. The President has stood firmly behind a call for the SGR receiving a permanent fix. I completely agree with that. I believe the AMA has requested a 13-month extension of the SGR to give us time to work that out. I hope that Congress acts on that, and I support the President's——

Senator BUNNING. We have not had a bill before us.

Dr. BERWICK. It is not acceptable for physicians and beneficiaries to be facing a Sword of Damocles of a 23-percent cut on this. It just is not a good idea.

With respect to the recess appointment, the reason I accepted it, sir, is that the President asked me, and I want to serve this country. It is an immense privilege to be able to do this work. It was not my choice to be recess-appointed or not; when asked, I came because it is my duty to do that.

Senator BUNNING. But did you not know your recess appointment was very, very controversial?

Dr. BERWICK. What I know is that the President of the United States asked me to serve to help my country to get to the better health care system we all want and need. That is what my career has been devoted to. As long as Congress, in its wisdom, chooses to have me do this service, I feel just very privileged to do it. That is all I can say about that.

With respect to communication, as you and Senator Hatch said, I want to have dialogue with you and all the members of Congress. I tried, before my appointment, to visit with each of you, and many who wished to see me, I saw and spoke with. Since then, any request at an individual level to meet with any member of Congress that has come my way, I have said "yes" to and done it. I look forward to ongoing dialogue and exchange with this committee, and all members of Congress. It is my job to do that.

Senator BUNNING. I want to ask one more question before my time runs out. I was struck by the conclusion in your testimony where you promise that you and others at CMS "will continue to be as open and as transparent as possible." You have to realize that many people may be a little skeptical of this comment, particularly considering the administration that you work for. For starters, your recess appointment was an end-run around Congress, which clearly was not an open and transparent process. The health care reform debate was far from open and transparent.

Republicans got locked out of any negotiations, and Democrats ended up having to jam a reconciliation bill through Congress to get the final bill passed. In fact, I could not even get all members of this committee to support an amendment I proposed that said we needed to have final and complete CBO scores, just the scores, along with the legislative language, before the committee passed the Health Care Reform bill. So open and transparent, we have not been.

Dr. BERWICK. I look forward to any forms of dialogue that I can engage in with you, Senator.

Senator BUNNING. I will guarantee you this: you will get open and transparent, and it will be on the other side in the House. They will see to it that you are open and transparent because they are going to oversee CMS very closely. Thank you very much.

The CHAIRMAN. Thank you, Senator. I might just also say that we are working with your side of the aisle to make sure that doctors do not get suspended cuts in Medicare. We are working on that right now and hope to get that enacted this year so doctors do not face that cut. We will find a way.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. Berwick, you cannot find a more important issue in health care than end-of-life care. The approach that I have supported is the opposite of rationing. For example, right now, traditionally, patients had to give up the prospect of curative care in order to get the hospice benefit. I do not think that is right. I think they ought to have all the choices.

I wrote a provision that is in the bill that begins the program that, for the first time, we give patients the right to get both the hospice program and curative care. So we start with two principles, empowering patients to make choices, and making sure they have all the options: hospice care, curative care, all of the options. Are those the kinds of principles that you believe would really enhance quality of life in this area of end-of-life health care?

Dr. BERWICK. First, thanks for your leadership on that, Senator Wyden, and some of the other important issues. I am very grateful for it. My principle is that every person in America, certainly every beneficiary in Medicare and Medicaid, should be able to get all the care they want and need when and how they want and need it. If someone in hospice care also needs and wants curative care at the same time, I am completely in agreement with you. As a physician, I am. When I saw patients, my question always was, what does that patient want and need and how will I get it for them? In this particular case of being able to offer curative therapy to patients

who are also in hospice care, that sounds totally consistent with that idea.

Senator WYDEN. The second question I want to ask you about is, at page 13 you make some very commendable statements about how States ought to have a key role in making sure that there are a wide array of options for innovation in health care. This is something I feel very strongly about. I was involved in writing the provision empowering the States to innovate.

My new Governor, Dr. John Kitzhaber, and there are going to be others, very much wants to speed up the opportunity for the States to be innovative, to have a chance to champion approaches that ensure we do not have one-size-fits-all health care, that they have an opportunity for flexibility, more choice, and more competition.

Would you be open within the department, because it has to be a departmental effort, to start reaching out now with the Governors to start looking for ways to be encouraging of this approach that would give not just my State, but every State, as much flexibility as possible, as soon as possible, to be innovative?

Dr. BERWICK. Yes, Senator, I would. The cliché about States as the laboratories of democracy is not just a cliché, it is true in the diversity of approach that we are seeing emerge State by State. It has been there for a long time. I think we should be doing everything we can to converge it, consistent with protecting the trust fund and protecting the well-being of beneficiaries.

We have duties to discharge from the Federal level, but releasing this kind of State energy is an extraordinarily important thing to do. We are doing it. There are demonstration authorities. Just yesterday we announced the multi-payer demonstration project, which was originally intended for six States, and I expanded it to eight States so we can get multi-payer work going on organizing care for the chronically ill.

May I take the liberty of saying it is not just States, it is communities and localities also that need the same latitude and flexibility. We have seen tremendous examples at the community level.

Senator WYDEN. Let me see if I can get one other one in. But I appreciate your answer, because we do want to speed up the opportunity for Oregon, and every other State, to have a chance to be innovative.

On Medicare Advantage, it was pretty clear to us that not all Medicare Advantage was created equal.

Dr. BERWICK. Yes.

Senator WYDEN. That there were some programs of very exceptional quality, and there were some others that, frankly, some of the CEOs ought to be put in jail, some of the hearings that Chairman Baucus had. So we created in the legislation an opportunity for bonus payments for high-quality plans based on these star ratings in the department. The whole point of this is to drive quality. How do you see bonus payments making Medicare Advantage more choice-oriented and more competitive by focusing on quality?

The CHAIRMAN. If I might, too, a vote has started. I want to give as many Senators as possible a chance to ask questions, so, if you could just answer that question, because time has expired, in about 15 seconds.

Dr. BERWICK. The law gives us the opportunity to measure and rate the quality of these plans and to attach payment to it. The star rating system is a strong step in which we reward plans as they improve their quality. It is only logical, and it will help plans and beneficiaries both.

The CHAIRMAN. Thank you, Senator.

Senator WYDEN. Thank you.

The CHAIRMAN. Thank you, Dr. Berwick.

Senator Roberts is next, and he is not here. I have, next, Senator Stabenow and Senator Ensign.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman. Welcome, Dr. Berwick. I very much appreciate your leadership and your experience. I think you are in the right place at the right time, and we are fortunate to have you.

I did want to first just comment. As you know, the Keystone Initiative put forward by the Michigan Hospital Association has been a real driver in terms of quality initiatives dealing with hospital-borne infections, reducing costs by saving lives, and focusing on quality. I know that this model is a part of, as you move forward, the way you are looking at improving care. Also, just for my colleagues, there was a comment made that we had not tried to fix, for doctors, the SGR. In fact, my legislation, S. 1776, we did put forward—thank you for the administration's support—and we could not get past a filibuster, unfortunately. But we are going to keep working on that.

I have a few just quick items I would like to speak to specifically about what repealing the new law on services would mean to seniors, to families, to moms, and children. We have now a new prescription drug benefit that, first of all, this year provides a $250 rebate or help to seniors. I know many are very grateful for having that help if they fall in the donut hole. Next year, half of the cost of folks who fall in the gap in prescription drug coverage for their brand name prescription drugs will be reduced, so a 50-percent reduction.

Could you speak, Dr. Berwick, about what would happen, in your judgment, to seniors in terms of higher prescription drug prices if this were repealed?

Dr. BERWICK. I cannot think of a worse plan than repealing this law, Senator, on that and so many other counts. It means seniors would not be getting the 50-percent discount on prescription drugs in the donut hole. We would ask them to return 1.8 million $250 rebate checks that they are getting this year. We tell them they look forward to the donut hole not closing, so they will not be able to afford lifesaving medicines.

We tell them we are not going to improve their access to preventive services, like colonoscopy and mammography, with first-dollar coverage, that we will not work on the safer care that I have been asked about, that we are not going to study and improve health care-acquired conditions, or work on unnecessary readmissions, that we are not going to improve chronic illness care the way the new Accountable Care Organizations and medical homes would allow us to do, that we are not going to be more transparent about performance.

There are all sorts of things in this new law that let beneficiaries know the performance of the health care that they are getting. That we are not going to work hard on fraud and abuse and criminal behavior with respect to stealing from the public trust fund, or that we are not going to extend the trust fund's life by 12 years, and it is just over in 2017—it would be a terrible plan.

Senator STABENOW. So prescription drug costs for seniors will go up next year if this provision is repealed, is that your judgment?

Dr. BERWICK. If it were repealed, their 50-percent discount on their drugs would be gone.

Senator STABENOW. We have also looked at coordinating mental health and primary care. One of the things that is very important in this new law, which was something very important to me, was to look at total health. I know that early-warning signs of Alzheimer's and dementia are often missed, and so having the ability to see the doctor to be able to get the screenings at no cost, to be able to look broadly at mental health and physical health, if that is taken away, if that is repealed and seniors are more at risk for these conditions, do you think that we are going to see more cases of undiagnosed Alzheimer's and dementia for seniors and their families?

Dr. BERWICK. Sure, Senator. I was delighted to see the attention to behavioral health and mental health issues in the law. The annual wellness physical, which this law now provides and will not be provided without it, includes important steps toward really responsible screening for these conditions. Detected early, we can intervene early and save a lot of damage.

Senator STABENOW. And then one final area, because there are so many ways in which, unfortunately, taking away services is really not in the interest of families and seniors, and taking away tax cuts for small businesses, and so on in the bill.

But we know that about 60 percent of the policies in the individual insurance market offered up to this point have not included maternity care. One of the things I am proudest about—and I know some folks have called you a baby doctor—is the fact that, going forward, moms and babies will be covered. I wondered if you might just speak to what happens to women and their unborn children if in fact health care reform is repealed.

Dr. BERWICK. Well, thanks for your leadership on that. I thank you as a pediatrician and as the CMS Administrator.

The CHAIRMAN. Again, Doctor, very briefly.

Dr. BERWICK. Yes. The new law allows extension of more services in perinatal care and coverage of children. I think something like 2.6 million children are already covered, and the Secretary has declared her intention to lead national efforts to get the 5 million remaining kids covered who are eligible for CHIP but not in that program.

The CHAIRMAN. Thank you.

Senator Ensign?

Senator STABENOW. Thank you.

Senator ENSIGN. Thank you, Mr. Chairman.

A provision that Senator Carper and I worked on dealing with healthy behaviors in the Health Care Reform bill—we are having difficulty. It is not your role, but we are having difficulty getting

answers from HHS. But dealing with the whole healthy behaviors issue, do you see—because the healthy behaviors issue does not apply to the Medicaid or Medicare populations—ways that we could implement this idea of encouraging healthier behaviors to Medicare or Medicaid patients?

Dr. BERWICK. Oh, definitely, Senator. And by the way, if you are having trouble with a response to an issue as important as that, please, let us deal with that afterward. I would be happy to look into it further and work with you on it.

Senator ENSIGN. I appreciate that.

Dr. BERWICK. Yes. Prevention is such a crucial area. So much of the morbidity we deal with comes out of the behaviors that we choose or the conditions of the environment that we can alter. And yes, it does affect elders substantially. So working with the Medicare and Medicaid beneficiaries both on choices that they make, helping them discover better patterns of nutrition, and the choices they make about the substances that they use, that is very important.

The extension in the Affordable Care Act of wellness visits for seniors will allow physicians and seniors to get together now to talk about how to stay healthy for as long as possible. The extension of coverage for children under Medicaid through CHIP and getting some of the single adults into that system, although it is not accomplished through CMS, is an important step forward to what you want.

Senator ENSIGN. But the incentive is financial incentives for healthy behaviors. That is just not preventative services. We have tried preventative services, and those do not save nearly the money. As a matter of fact, when you look at CBO, they say preventative services actually cost money. But rewarding healthier behaviors, we know saves money. I mean, Safeway has a pretty good model on this, and that is the reason that we were able to get that part in the bill. That is what I am talking about.

Do you see ways for financial incentives within the Medicare or Medicaid program to be applied so that we change people's behaviors? Because, if we do not change people's behaviors, the cost of health care in this country is going to continue to skyrocket.

Dr. BERWICK. I think helping people understand their self-interest when it comes to healthy behaviors is crucial. It is an interesting area that you are exploring, and I would be happy to talk with you more about it, Senator.

Senator ENSIGN. All right.

Lastly, one of the other things that Safeway did is, they provided—and because Medicare and Medicaid have this information that can be applied to the private sector, Safeway is a large enough organization to be able to put together enough data for transparency to help their employees shop, to basically become shoppers in the marketplace, for health care. An example: around the San Francisco area, because they are self-insured for the first 25,000, they pay for things like colonoscopies.

Well, they just paid, and they looked at 1-year data, and they paid as little as around $800 for a colonoscopy and as much as $8,400 for a colonoscopy in the same year. That kind of informa-

tion, if you could provide cost and quality transparency in the marketplace, you could get more market forces.

Is that something that you could foresee that Medicare and Medicaid could provide, just as information? Obviously we are protecting privacy, but I am talking about just with outcomes, with costs, so that more people could actually shop, and market forces could play more of a role in the health care field.

Dr. BERWICK. Senator, I remember you mentioning that to me when we met in your office. That is a very interesting area. I think in general the whole idea of empowering beneficiaries with more information about what is available to them, about their options, and about where they can find the care they need, to use that power of the beneficiaries' decision-making to help drive quality up across the board, is a very important principle, and I agree with you on the importance of exploring that everywhere we can.

Senator ENSIGN. I guess, can I get a commitment from you that you will, within your agency, work to try to figure out ways that you can make this kind of information public?

Dr. BERWICK. Making more and more information available from the Medicare data——

Senator ENSIGN. No. I am talking about cost and quality. I am talking about cost and quality across the board. Like, what hospitals charge for a total hip replacement, all of those things. Not just what Medicare pays, but what doctors charge and things like that. If we had more of that information available, I just think we could have a lot better shoppers in America on health care.

Dr. BERWICK. Yes, Senator. I share with you an interest in that information.

The CHAIRMAN. Thank you.

Dr. BERWICK. Let us certainly explore it further.

The CHAIRMAN. Thank you very much.

Senator Cantwell, you are next. You are in charge, so, when you are finished, you can adjourn the hearing.

Senator CANTWELL. Well, thank you, Mr. Chairman. I think I could go on forever, because I think this is an important hearing, and I think, Mr. Chairman, you stated at the beginning with your opening comments that this is about legislation that is estimated to save, you said, hundreds of billions of dollars in the reform of our Medicare system. Some people are saying, oh, let us do vouchers instead, or privatize it, or do something else.

But the truth is, this legislation has very powerful tools for reducing the cost of Medicare moving forward. If we get rid of them somehow, we are going to be in a world of hurt. So I just wanted to get your commitment on some of those provisions.

One, the rebalancing away from nursing home care to community-based care. Our State has saved about $243 million in about a 10-year time period by shifting away from nursing home care, and so I think the estimates are that it could save $10 billion federally over 5 years. How integral do you think that shift is?

Obviously, there is also a provision in this legislation that allows people in community-based care to hold on to their assets, so it really is going to have more people staying at home and having the benefit of getting home-based service.

The value index, moving away from fee-for-service to a cost efficiency model, we think that could save anywhere up to $100 billion for our health care system, moving that 30 percent of waste, fraud, and abuse in the system to a model that is based on quality care. So I am curious as to how essential you think that is to the success of Medicare moving forward.

The basic health plan. Another tool to give States the ability to negotiate on rates, for lower insurance rates for their consumers. Is CMS going to give technical assistance to States on how to implement that and obviously not penalize States who have already gone down that road?

The Pharmacy Benefit Managers transparency provision, we think, is probably another provision that could save as much as 10 percent on brand-name drugs by giving the aggregate types of rebates and price concessions to CMS so that we really understand that. So all of those are tools that we put in this legislation. How critical do you think they are? How will you work to implement them, and how can we get your guarantee that these are the critical frameworks for cost controls?

Dr. BERWICK. I agree with you, these are all important levers for doing what I said in my opening statement we can do: making care better and more affordable at the same time. Take the rebalancing work and the work we are progressing on now on home- and community-based services. People do not want to be in institutions, they do not want to be in hospitals, so a way to get them into communities, with the proper supports, it is better for them, it is better for their families and loved ones, and it will in general lower costs substantially. It is a very important example of progressive work. And yes, there is new authority in this law and in older legislation to help States try out their forms of home- and community-based services. I am totally in favor of that.

Integrating care through Accountable Care Organizations and medical homes will save money. Using the value index idea. The idea there is that we should pay for what we want. We want quality, we want better outcomes, we want satisfaction on the part of beneficiaries. Why would we pay for fragments, little piece by little piece, instead of understanding where the value really lies? In order to do that, we have to have tools like the value index.

Senator CANTWELL. And how big of a component do you think that is for the success of Medicare in reducing Medicare costs moving forward, a small piece or a very large piece?

Dr. BERWICK. A large piece. Measuring what we want and attaching incentives and rewards for going there is logical and powerful.

Senator CANTWELL. Great. Well, we have a vote on. I am sure we will have a chance to talk to you again about these. But I think it is very important that we understand that the tools are here. They are already law. We now have to get about implementing them. The more people talk about delaying them, the more we are going to delay cost controls. The public will greatly benefit by this. So, I thank you.

Dr. BERWICK. Thank you, Senator Cantwell.

Senator CANTWELL. The hearing is adjourned.

[Whereupon, at 11:23 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.)
Regarding New Patient Protections to Strengthen Medicare and Medicaid

Montesquieu said:

"All [people] are born equal, but they cannot continue in this equality. . . . [T]hey recover it only by the protection of the law."

When it comes to health care, the Affordable Care Act gives seniors, patients and health care consumers historic protections in the law.

The new law protects seniors by helping to ensure that they get the right care, when they need it.

The old system, before health care reform, was failing too many seniors.

Take Christine Brown. Christine's father had a blister on his toe that became infected. It would not heal.

Christine and her father tried everything. Every doctor they went to prescribed a different antibiotic.

No one coordinated his care. There was no electronic record of his medications.

After several months without anyone managing his care, it was too late.

The infection had spread. The only way to save his life was to amputate his leg.

Christine's father is now confined to a wheelchair, for the rest of his life — all because of a blister — all because no one coordinated his care.

The new law protects patients like Christine's dad. The new law helps doctors coordinate and communicate with each other.

The old system, before health care reform, was failing too many seniors who get hospitalized.

Yesterday, the HHS Inspector General released a report. The I.G. found that nearly a quarter of seniors hospitalized suffer some form of adverse event in the hospital. And almost half of those are preventable.

The new law helps protect patients from preventable adverse events. Under the new law, Medicare and Medicaid will crack down on hospitals that don't prevent infections.

Before reform, nearly a fifth of hospitalized seniors were back at the hospital and re-admitted. When patients leave the hospital, they don't want to come back. They should receive the follow-up care that they need to stay well, and to stay out of the hospital.

The new law protects patients from needless readmissions. Medicare will protect seniors by penalizing hospitals that don't treat patients right the first time.

The old system, before health care reform, has been failing health insurance consumers.

Far too frequently, insurance companies would drop coverage when patients get sick.

The new law protects patients from this and other insurance company abuses.

Far too frequently, insurance company executives would use premium dollars for lavish CEO bonuses, instead of patient care.

The new law requires health insurance companies to spend at least 80 percent of the premiums that they collect on providing health care. And the new law puts a limit on funds for administrative costs, salaries and CEO bonuses.

The old system, before health care reform, was failing the Medicare trust fund. Before health care reform, Medicare would have been bankrupt by 2017. Medicare would have gone broke in six years.

The new law protects Medicare from going broke. The new law extends the life of Medicare by an additional 12 years.

In the old system, before health care reform, health care costs were out of control.

In the last eight years, average wages have increased just 20 percent. But the average cost of employer-sponsored health coverage has doubled. Family health insurance premiums have tripled.

The new law will protect American families against these increasing costs.

The new law transforms Medicare payment from paying for quantity to paying for the high quality care that seniors deserve.

What does paying for quality mean?

Paying for quality means protecting seniors from duplicative tests. It means protecting seniors from unnecessary procedures that waste time and money. It means empowering doctors with electronic medical records that put patients' information at their fingertips.

Paying for quality means providing doctors with the latest evidence. That way, doctors and patients can make the best-informed decisions.

Paying for quality means investing in primary care, so that seniors have an advocate to help them navigate the health care system.

What does paying for quality not mean?

Paying for quality does not mean cutting benefits that seniors are guaranteed.

Paying for quality does not mean a one-size-fits-all Washington solution. Medicare and Medicaid must seize upon the innovations that work at the local level.

And paying for quality does not mean interfering with the doctor-patient relationship. The doctor-patient relationship is sacred.

The old system, before health care reform, was failing to crack down on fraud and abuse.

The new law protects the taxpayer, by giving law enforcement officials new tools to combat fraud.

The new law puts an end to wasteful overpayments to private insurance companies that participate in Medicare.

These overpayments to Medicare Advantage plans used to cost the program tens of billions of dollars every year.

Under the new law, seniors in Medicare are protected. Seniors can feel confident that Medicare dollars will benefit patients, not line the pockets of insurance companies.

The new law slashes wasteful payments.

And it does so without taking away a single guaranteed benefit under Medicare.

I want to say that again, because it's important.

Health reform protects the Medicare program, without taking away a single guaranteed benefit.

In fact, the new law adds benefits like a lifetime of free annual checkups and closing the donut hole.

The old system, before health care reform, was failing seniors, patients, and health care consumers.

The new law gives them historic protections.

Repealing the new law would return us to the failures of the old system.

Repealing the new law would cause Medicare to go broke in just six years.

Repealing the new law would increase the deficit by hundreds of billions of dollars.

Repealing the new law would put insurance company bureaucrats back in charge of health care.

And repealing the new law would threaten seniors' health with duplicative care and poor coordination.

Today, we hear from the point man on the new law. We hear from the Administrator of the Centers for Medicare and Medicaid Services, Dr. Don Berwick.

Under the new law, CMS is charged with strengthening Medicare and Medicaid. He's in charge of making Medicare and Medicaid more efficient, and modernizing them for the 21st century.

Dr. Berwick, the Affordable Care Act provides the protection of the law. We look forward to hearing how you'll carry it out.

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STATEMENT OF

DONALD M. BERWICK, M.D., M.P.P.

ADMINISTRATOR,
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

STRENGTHENING MEDICARE AND MEDICAID: TAKING STEPS TO MODERNIZE AMERICA'S HEALTH CARE SYSTEM

BEFORE THE

U.S. SENATE COMMITTEE ON FINANCE

NOVEMBER 17, 2010

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

U.S. Senate Committee on Finance
Hearing on Strengthening Medicare and Medicaid:
Taking Steps to Modernize America's Health Care System
November 17, 2010

Chairman Baucus, Ranking Member Grassley, and Members of the Committee; thank you for the opportunity to appear before you to discuss ways to strengthen Medicare and Medicaid and modernize America's health care delivery system. The Affordable Care Act, passed by Congress and signed into law by President Obama in March of this year, is landmark health care legislation that is bringing comprehensive insurance reforms, expanded coverage, and enhanced quality of health care to all Americans. Millions of people across the country are already benefiting from this law, including the more than 100 million people enrolled in Medicare, Medicaid and the Children's Health Insurance Program (CHIP). Because of the Affordable Care Act, the fiscal future of Medicare is stronger, new tools to fight Medicare and Medicaid fraud are returning money to the Trust Funds and the Treasury, Medicare beneficiaries have new benefits and lower costs, and State Medicaid programs have additional resources and options to expand coverage, which is especially important in these challenging economic times.

As a pediatrician, I have witnessed both the best and the worst of the American health care system. I had the opportunity to practice pediatrics for 20 years in an organization that promoted integrated care, and saw firsthand the enormous difference that a doctor, nurse, and patient working together can make in health care outcomes. I have devoted my career to the belief that all patients deserve access to high quality health care, regardless of who they are or whether they live in a large city or a small rural community. High quality health care does not necessarily mean the most expensive health care. It means safe care, free from medical injuries, errors and infections; it means reliable care, based on the best available science; and it means person-centered care, in which each patient is treated with dignity and respect for his or her own unique preferences.

These core beliefs will continue to shape my work at the Centers for Medicare & Medicaid Services (CMS). As Administrator, protecting and strengthening Medicare, Medicaid, and CHIP is my top priority. And the Affordable Care Act has provided a number of important tools to

help achieve this goal. It explicitly protects the guaranteed Medicare benefits on which so many seniors and individuals with disabilities rely. It will not cut these guaranteed benefits, nor will it ration care. The Affordable Care Act does not prescribe a "one size fits all" approach to health care, because health care is first and foremost about caring for unique individuals. The Affordable Care Act incentivizes hospitals to improve the quality of care and prevent unnecessary readmissions, which are often harmful to patients.

CMS can help lead health care improvement in many ways. With new provisions in the Affordable Care Act, you have presented CMS with additional opportunities to work with others both in the public and private sector to make real improvements in the nation's health care delivery systems.

CMS can and should be a major force and a trustworthy partner for the continual improvement of health and health care in this country. We all agree that we want the highest quality health care system possible, a system that coordinates and integrates care, eliminates waste, and encourages prevention of illness. With over 100 million beneficiaries depending on us each day, CMS has an important role to play in improving our nation's health care delivery system. We are striving to meet this challenge, while attending diligently to the crucial, day-to-day work of our operations and preserving and enhancing the integrity of our payments, our programs, and the Trust Funds.

Immediate Benefits for People with Medicare

It has been only eight months since the passage of the Affordable Care Act, but already Americans are seeing changes and benefits from the law, including millions of people with Medicare and their families. Moreover, Medicare's long-term sustainability is stronger than ever as a result of efficiencies, new tools, resources to reduce waste and fraud, and slower growth in Medicare costs.

Here are just a few examples:

- **Helping Medicare beneficiaries maintain access to life-saving medicines:** As a result of new provisions in the Affordable Care Act, people with Medicare are receiving immediate relief from the cost of their prescription medications. To date, 1.8 million seniors and people with disabilities who have incurred high prescription drug costs have received immediate help through a tax-free $250 rebate check to help reimburse them for out-of-pocket costs in the Part D prescription drug coverage gap known as the "donut hole." In addition, every year, people with Medicare Part D will pay less for their prescription drug costs in the coverage gap. Beginning in 2011, eligible Medicare beneficiaries will get a 50 percent discount on brand name prescription drugs in the coverage gap. By 2020, we will have closed the donut hole.

- **Making Medicare strong:** The Affordable Care Act contains many cost-saving provisions that will make the Medicare program more accountable and efficient, protect the program from waste, and slow the growth in cost of the Medicare program. These important changes put Medicare on a path toward long-term sustainability and produce savings for the taxpayers by prolonging the life of the Medicare Hospital Insurance Trust Fund for an additional 12 years to 2029. These important changes will also benefit people with Medicare by keeping their premiums and cost sharing low.

- **New tools and authorities to fight fraud:** New authorities in the Affordable Care Act offer additional front-end protections to keep those who commit fraud out of Federal health care programs, as well as new tools for deterring wasteful and fiscally abusive practices, promptly identifying and addressing fraudulent payment issues, and ensuring the integrity of the Medicare and Medicaid programs. CMS is pursuing an aggressive program integrity strategy that will prevent fraudulent transactions from occurring, rather than simply tracking down fraudulent providers and pursuing fake claims. CMS also now has the flexibility needed to tailor resources and activities in previously unavailable ways, which we believe will greatly support the effectiveness of our work.

  The Affordable Care Act provides CMS with additional tools to help the Agency tailor interventions to address areas of the most significant risk. Enhanced screening requirements for providers and suppliers to enroll in Medicare, along with oversight

controls such as a temporary enrollment moratorium and pre-payment review of claims in high risk areas, will allow the Agency to better focus its resources on addressing the areas of greatest concern and highest dollar impact.

Further, through the Health Care Fraud Prevention and Enforcement Action Team, or "Project HEAT," CMS has joined forces with our law-enforcement partners at the Department of Justice and the HHS Office of Inspector General to collaborate and streamline our efforts to prevent, identify, and prosecute health care fraud.

- **Reducing improper payments:** While continuing to be vigilant in detecting and pursuing problems when they occur, we are also pursuing prevention of improper payments before they occur. We are reexamining our claims and enrollment systems to enhance our ability to prevent improper payments while still promptly compensating honest, hard-working providers. Due to prompt pay requirements in Medicare, our claims processing systems were built to quickly process and pay claims. CMS pays 4.8 million Medicare claims each day, approximately 1.2 billion Medicare claims each year. Nevertheless, with the new tools provided to CMS under the Affordable Care Act, we are steadily working to better incorporate fraud and improper payment prevention activities into our claims payment and provider enrollment processes where appropriate so we can prevent paying improper claims in the first place.

- **Reducing payment error rates in Medicare, Medicaid, and CHIP:** This Administration is strongly committed to minimizing waste, fraud, and abuse in Federal health care programs. We are keenly focused on the President's ambitious goal of reducing the Medicare fee-for-service error rate in half by 2012.

- **High quality, low-cost Medicare Advantage benefits:** This year CMS has improved its oversight and management of the Medicare Advantage (MA) program. The results for 2011, announced this fall, show that when CMS negotiates on behalf of beneficiaries and strengthens our oversight and management of MA plans, seniors and people living with disabilities will have clearer plan choices offering better benefits. In 2011, premiums are

lower and enrollment is projected to be higher than ever before. As part of CMS' national strategy for implementing quality improvement in health care, CMS is also instituting quality bonus payments for MA plans, providing an incentive for all plans to improve the care they offer to Medicare beneficiaries.

- **Improved customer service for people with Medicare:** I am proud of the hard work of CMS' staff to implement the provisions of the Affordable Care Act on time. Nevertheless, I also recognize that much work remains in the coming days to administer our Federal health care programs and to implement new changes in the law. CMS can set an example for improving the health care system by working to improve ourselves as an Agency. We need to continually simplify and streamline our operations and work to reduce waste, both internally and externally. Diligence, agility, teamwork, and creativity should infuse CMS' day-to-day actions as we remain mindful of the people we serve: public and private sector leaders, clinicians, hospitals, health centers, care organizations, and most importantly, the people who rely on our programs.

- **Reorganizing and streamlining CMS to prioritize coordinated program administration, innovation and fiscal responsibility:** Importantly, CMS underwent an internal realignment in April 2010, before I arrived, which consolidated Medicare operations in the Center for Medicare, as well as brought the bulk of Medicare and Medicaid program integrity activities under a new CMS Center for Program Integrity. Research and policy development functions have also been consolidated in a new Center for Strategic Planning. Because of this streamlining of operations, CMS is now able to pursue a more strategic and broader approach to program operations and program integrity functions at the Agency.

The Affordable Care Act

We can all agree that we want a high quality health care system. However, the problems of American health care lie in the design of the care systems in which the people who give care work. These systems need to be reformed in order to deliver the higher levels of reliability,

safety, and person-centeredness that we owe to ourselves and our neighbors. Instead, our care is often fragmented and of inconsistent quality, without enough focus on prevention of disease. Historically, we have focused health care efforts on treating diseases after they occur, paying too little attention upstream to preventing and mitigating the underlying causes of diseases.

We can address and solve these problems through sensible and effective changes in the systems through which we deliver health care. Merely trying harder in the current system is not likely to get us very far; any doctor will admit that he or she is already trying as hard as he or she can. Better integration of care, better designed services for our beneficiaries, better measurement tools, and a focus on continual improvement can all help bring us closer to the health care system that we want and the American people deserve.

Congress, led by many members of this Committee, recognized the need to improve health care quality in this country with the passage of the Affordable Care Act. The legislation, which this Committee worked so hard to fashion, has already begun to help bring better quality care to the American people.

The Affordable Care Act includes unprecedented new tools that will enable us to reinvigorate our nation's focus on the quality, value, and outcomes of care, and help the public and the private sector produce a new system that is better for patients, families, communities, and the health care workforce. These innovative provisions will enable CMS to work with our partners in the private sector to improve care coordination, increase patient safety, offer beneficiaries more information and more control over their care, and achieve better outcomes. The Act allows us to better align incentives for quality care and move towards seamless, integrated care. This will help health care providers and patients better tackle the problems of fragmentation and unreliability in care, which can erode health and satisfaction and add cost to taxpayers without adding anything of value to patients.

To me, improving health care delivery has three major, overarching goals: first, providing better care for individuals – care that is more effective, more patient-centered, timelier, and more equitable; second, assuring better health for populations by addressing underlying causes of poor

health, like physical inactivity, behavioral risk factors, and poor nutrition; and third, reducing costs by improving care, eliminating waste and needless hassles, reducing preventable complications in care, and coordinating care for patients who are journeying through the system. To be absolutely clear, I am talking about reducing costs while improving the quality of care individuals receive.

1. Improving Care for Individuals

It has been almost a decade since the Institute of Medicine published their seminal reports on medical errors and quality in our health care system, outlining the six aims for improvement. We are still trying to get there. I strongly believe that every single American can and should always receive the highest quality of care, no matter where they live or happen to seek care.
I want CMS to continue its role as a leader and partner in encouraging safer and better care in hospitals, clinics, physician offices, and long-term care settings. I know we can get there, because I have seen throughout our nation example after example of bold and exciting progress. CMS is working to make the "best care" in America the norm in health care, for everyone.

Several Affordable Care Act provisions will help CMS move in this direction. Here are a few examples:

- Value-Based Purchasing: Allows us to measure and reward excellence in hospitals, physician offices, and elsewhere.

- Specific focus on Hospital-Acquired Conditions (HACs): These conditions consist of complications that patients acquire from the care that is supposed to help them. Not all HACs are preventable, but a great number can be avoided. For example, the Centers for Disease Control and Prevention has estimated that each year, almost 100,000 Americans die and millions suffer from hospital-acquired infections alone. In addition to pain, suffering, and, sometimes death, these complications also add as much as $45 billion to hospital costs paid each year by taxpayers, insurers, and consumers. We know of hospitals in this country that, through improvements in their health care processes, have virtually eliminated some forms of infections that other hospitals still think are inevitable.

To create incentives for hospitals to prevent such infections, the Affordable Care Act includes a Medicare payment reduction for hospitals that have a hospital acquired condition rate that is much higher than average, beginning in fiscal year 2015. Prior to each fiscal year, affected hospitals will receive confidential reports regarding HACs during the applicable period. In addition, the Secretary will publicly report the measures used for the payment adjustments on the Hospital Compare website,[1] after giving hospitals the opportunity to review and submit corrections to such information. The Affordable Care Act also requires that Medicaid regulations incorporate State practices that prohibit payment for Health Care-Acquired Conditions and directs CMS to apply certain Medicare HAC payment policies to Medicaid when appropriate.

- Helping to reduce unnecessary hospital readmissions: We know that about one in every five Medicare beneficiaries who leave the hospital will be re-admitted within 30 days of discharge. The Medicare Payment Advisory Commission (MedPAC) estimates that Medicare spends $12 billion annually on potentially preventable readmissions (based on 2005 data).[2] Half or more of these readmissions could be prevented with proper attention to care transitions, coordination, outreach, and patient education and support, allowing these patients to recover at home where they would prefer to be, rather than reentering the hospital with complications. The Affordable Care Act sets a course for hospitals to focus on reducing preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes. Readmission rate information for all patients for each hospital participating in the program will be publicly available on the CMS website.

- Adult health quality measures: The Affordable Care Act establishes a process for the development of a set of core health care quality measures specific to Medicaid-eligible adults; these new quality measures will be finalized by 2012 and we expect routine reporting will take place on the quality of services measured in the core set. These

[1] http://www.hospitalcompare.hhs.gov/
[2] Medicare Payment Advisory Commission (MedPAC) Report to the Congress, June 2007.

efforts complement those to develop child health quality measures as directed under the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

- Quality bonus payments in Medicare Advantage: Beginning in 2012, the Affordable Care Act introduces quality bonus payments into the MA program as part of the national strategy for implementing quality improvement in health care. MA plans will be paid a quality bonus payment (QBP) based on their rating using CMS' 5-star quality rating system. To provide a strong incentive for MA plans to improve performance, CMS will pursue a national demonstration project running from 2012 to 2014 that rewards all the plans receiving three stars or higher with progressively larger QBPs. The demonstration will test whether providing scaled bonuses will lead to more rapid and larger year-to-year quality improvements in MA program quality scores, compared to the current law approach to computation of QBPs.

2. Better Integration of Care

"Integrated care" is the care we need when we have a chronic disease, or are journeying through the health care system from place to place or doctor to doctor. We want seamlessness. We want coordination. We do not want to keep having to tell our story over and over again to multiple providers, or to be afraid that one doctor will not know what medications another doctor has already given us. We know for sure that integrated care is better care – safer, more likely to get us to the treatments we really need, less likely to confuse us, and, overall, less costly than the opposite – disintegrated, fragmented care. The problem is that our fragmented care system has a lot of trouble offering us integrated care when we need and want it.

We need to help integrated care thrive in America. Too often, health care takes place in series of fragments or episodes. We need to make it possible for entirely new levels of seamlessness, coordination, and cooperation to emerge among the people and the entities that provide health care, so as to smooth the journeys of patients and families – especially those coping with chronic illness – through their care over time and place.

The transition from a fragmented system to an integrated person-centered delivery system will not be an easy one. The new system that we can imagine together is not a "one size fits all" model or the *status quo* repackaged; many different approaches will be needed to match the enormous diversity of settings, communities, and histories in this textured nation. We will need to ensure the space and time for these many, adaptive forms of integrated care to succeed.

The Affordable Care Act, thanks to many members of this Committee, contains important new opportunities to encourage and foster seamless, coordinated care. Here are a few important examples:

- Medical Homes: We must examine approaches to promote effective "home bases" for patients, rooted in primary care, to help patients navigate and understand the complex health care system that they may rely on, and to help them be more proactive with prevention and detecting potential complications before they do their damage.

- Health Homes: For Medicaid beneficiaries, we will work with States to establish coordinated services for individuals with chronic conditions that not only make health care seamless, but that effectively bridge to home and community-based services. The Affordable Care Act also requires States participating in the health home option to monitor avoidable hospital readmissions, linking better integration with quality improvement priorities.

- Accountable Care Organizations (ACOs): The Affordable Care Act directs CMS to establish a shared savings program that promotes coordination of services under the Medicare program and accountability for a patient population through ACOs by January 2012. ACOs should not be thought of only as a financing mechanism, but as a care delivery organization. Eligible ACOs are groups of providers and suppliers that meet the requirements for participation in the shared savings program, which include having an established mechanism for joint decision making. The program will encourage ACOs to make investments in infrastructure and redesigned care processes for high quality and efficient service delivery.

- Federal Coordinated Health Care Office: Dual eligibles are uniquely at risk for duplicative and uncoordinated care as a result of their enrollment in both Medicare and Medicaid, which function as distinct programs with different program structures. The Affordable Care Act establishes an office whose sole focus is better coordinating the care and needs of this medically needy population.

- Building infrastructure to help with integration: As part of our commitment to assist States in the implementation of the Affordable Care Act, CMS has proposed to increase the current 50 percent Federal match to a 90 percent Federal match for investments that States make through December 31, 2015 to streamline and upgrade their Medicaid eligibility systems. CMS has also provided States with guidance on how to establish IT systems to enroll individuals who qualify for Medicaid or CHIP, premium tax credits or cost-sharing reductions in the Exchanges available through the Affordable Care Act. These efficient technology investments will support a coordinated, consumer-oriented system for individuals, families and businesses to sign up for the health insurance plan that they choose. Providing States with early guidance and funding assistance will allow them to reduce barriers and duplication as they develop new systems.

3. Better Health for Populations

Our system is often faulted for its focus on health care for the sick, instead of promoting better health for all. CMS is implementing a variety of initiatives that will encourage prevention and move towards the goal of improving the health of the entire population. CMS can meaningfully contribute to improving prevention of a variety of health problems, including obesity, cardiovascular disease, and improving perinatal outcomes. In addition to expanding health insurance coverage, the Affordable Care Act provides meaningful and affordable coverage of preventive health services.

- Annual Wellness Visit: While Medicare already covers a comprehensive package of preventive benefits as well as a one-time "Welcome to Medicare" exam for new

beneficiaries, before the enactment of the Affordable Care Act, Medicare did not cover annual check-ups for beneficiaries. Beginning in 2011, Medicare will cover an annual "wellness visit" at no cost to the beneficiary, so beneficiaries can work with their physicians to develop and update a personalized prevention plan. This new benefit will provide an ongoing focus on prevention that can be adapted as a beneficiary's health needs change over time.

- Removing financial barriers to prevention services: While Medicare covers a range of screening and preventive benefits, many of these services have been underutilized, in part because out-of-pocket costs have presented a financial barrier for beneficiaries. Beginning in 2011, all preventive benefits covered by Medicare that are recommended with an A or B rating by the U.S. Preventive Services Task Force will be available to beneficiaries free of charge (without having to pay coinsurance or apply the Part B deductible). These important benefits include tests and procedures that may either prevent illnesses or detect them at an early stage when treatment is likely to work best, such as screenings for breast, cervical, and colorectal cancers, and screenings for cardiovascular disease, diabetes, and osteoporosis.

- More prevention in Federally Qualified Health Centers (FQHCs): Beginning in 2011, the scope of Medicare-covered preventive services furnished in Federally Qualified Health Centers will expand significantly. FQHCs provide primary care services for all age groups in medically underserved areas or medically underserved populations across the nation.

- Promoting tobacco cessation in Medicaid: Under the Affordable Care Act, States must provide pregnant women with Medicaid coverage of tobacco cessation services, including counseling and pharmacotherapy, as recommended by the 2008 Public Health Service (PHS) Clinical Practice Guidelines. States are not permitted to charge any form of cost sharing for these services. We are also encouraging States to provide tobacco cessation services for Medicaid enrollees who are not pregnant. Beginning in 2014, the

Affordable Care Act removes tobacco cessation drugs from Medicaid's excluded drug list.

Thanks largely to the Affordable Care Act, CMS has a new cross-cutting resource to test change and accelerate progress in pursuing the goals of better care, better health, and lower cost through improvement of care, focusing on individuals, integration of care, and prevention: the Center for Medicare and Medicaid Innovation. This Innovation Center will test and study the most promising innovative payment and service delivery models. The Innovation Center will work with relevant Federal agencies and clinical and analytical experts, as well as local, national and regional providers, States and beneficiary organizations to identify and promote systems changes that can improve quality and outcomes for patients while containing costs.

An Essential Component: Collaboration with the Public and Private Sectors

Building an improved health care delivery system has to be a collaborative effort. CMS cannot do this alone, and neither can government as a whole. Achieving a high quality of care will require participation and leadership from all: from Congress, States, insurers, employers, health professionals, organizations, associations, patients, families and communities. CMS should partner extensively with all health care stakeholders in pursuit of our common goals for improving care.

As a trustworthy partner, CMS will collaborate with private insurers, State health officials, Federal health programs, consumers, beneficiaries, researchers, and other stakeholders to help improve the quality of health care for people who benefit from our programs. CMS can participate by incentivizing quality and efficiency in our reimbursement payments for Federal health care programs and by assuring sound and useful measurements of progress to maximize the value of Medicare spending and promote improvement in health outcomes.

States will have an integral role to play in the implementation of delivery system changes and other Affordable Care Act provisions. CMS is committed to ensuring that States have the tools they need to succeed at addressing these challenges. To that end, CMS has already conducted a number of outreach sessions and meetings with State stakeholders to discuss topics such as

Medicaid payment practices, health homes, and primary care practice support. CMS will also rely on input from States as we design guidance and implement other changes and improvements.

Health care providers who are directly interacting with patients each day are a crucial partner in this reform effort. They need stable and predictable payments in order to be able to play their key roles as foundations of delivery system reform. To ensure that Medicare beneficiaries continue to have appropriate access to necessary physician services, the Administration supports a permanent revision to the Sustainable Growth Rate methodology payment system for physicians.

In addition, CMS is entering into a public-private collaboration with the Multi-payer Advanced Primary Care Practice Demonstration (MAPCP). This demonstration marks the first time that Medicare, Medicaid and private insurers will join in a partnership with States to transform health care delivery. Advanced primary care practices, often referred to as patient-centered medical homes, utilize a team approach to health care, with the patient at the center. Under this demonstration program, Medicare will participate in existing State multi-payer health reform initiatives that include participation from both Medicaid and private health plans. Implementing a common payment method across different payers will reduce administrative burdens, align incentives, and provide participating practices with the resources needed to function as advanced primary care practices. This type of collaboration, involving CMS, private insurers, States and local practices, is essential as we work to build new systems.

Conclusion

Strengthening Medicare and Medicaid must be a step-by-step, community-by-community effort. All of us share the goal of improving the quality of health care in this country and helping to make care more affordable and accessible for America's seniors, families, and children.

Many of the programs, new authorities, and unprecedented innovations that CMS is implementing and pursuing as a result of the provisions of the Affordable Care Act are ideas that had their genesis in this Committee. I know that you and your staff spent many months working

collaboratively to transform America's health care system. While the Affordable Care Act is now the law of the land, the work is not done. We still need your help.

I know that many members of this Committee—on both sides of the aisle—have criticized CMS for not being transparent enough or for being overly rigid in the applications of its rules. While the Agency is filled with wonderful staff who work extremely hard to ensure that Medicare, Medicaid, and CHIP beneficiaries receive the highest quality services, I know we must rise to this Committee's expectations. I pledge to each and every member that I, the senior CMS leaders, and all members of the staff will continue to be as open and transparent as possible, to be as responsive as we can to your suggestions, questions, and concerns, and to try to understand the perspectives of your constituents. We may not always agree, but we will always listen.

Making a better health care system a reality – a system truly capable of major improvements in health care, health and cost – will require that we work well and continually together. I look forward to working with all stakeholders, and with members of this Committee, as CMS joins your effort to improve our nation's health care delivery system.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Baucus:

Questions for the Witness:

Delivery System Reform

The Affordable Care Act (ACA) includes a slate of new Medicare and Medicaid payment policies that seek to move the health care delivery system toward higher quality and value. For example: primary care medical homes, Accountable Care Organizations, and reduction of readmissions and hospital-acquired infections. Health reform also gives new tools and resources to CMS to test and expand innovative ways to pay providers based on quality and efficiency.

1. **Dr. Berwick, you have practiced medicine in a variety of settings. In your experience, how is the current health care system unsustainable for patients?**

Answer: Our current health care system does not provide patients and their families with the high quality, affordable care that we all expect. The problems do not lie in any failure of good will, benign intentions, or skills of our doctors, nurses, health care managers, or staffs. The problems lie in the design of the care systems in which they work, systems never built for the levels of reliability, safety, patient-centeredness, efficiency, or equity that we owe to ourselves and our neighbors. Care is often delivered in fragments and is not integrated. One doctor does not always know what medication another doctor has prescribed. Patients do not always know if they are receiving the best care, or whether another facility or provider could offer a better option. This system, and the waste and duplication it generates, often provides inadequate care at higher costs that are unsustainable for patients.

2. **How will a more modern health care system treat patients and their families differently than today's system?**

Answer: To me, improving health care delivery has three major, overarching goals that will reduce costs while improving quality: first, providing better care for individuals – care that is more effective, more patient-centered, timelier, and more equitable; second, assuring better health for populations by addressing underlying causes of poor health, like physical inactivity, behavioral risk factors, and poor nutrition; and third, reducing costs by improving care, eliminating waste and needless hassles, reducing preventable complications in care, and coordinating care for patients who are journeying through the system. A more modern health care system will ensure that every American receives the highest quality of care, no matter where

they live or happen to seek care. This means avoiding preventable errors, infections, and avoidable hospital readmissions. A modern health care system must do a much better job of preventing disease and illness. Our system too often focuses on health care for the sick, instead of better health for all. The Affordable Care Act takes important steps in this direction, by ensuring that Medicare beneficiaries receive needed preventive screenings and tests, as well as an Annual Wellness Benefit with no copayments.

Finally, we must move away from a fragmented system to an integrated person-centered delivery system. Through the Center for Medicare and Medicaid Innovation (Innovation Center), CMS will be testing a variety of new models to better deliver care. The Affordable Care Act also establishes a new Federal Coordinated Health Care office to better coordinate the care for those enrolled in both Medicare and Medicaid. These tools will give CMS an important opportunity to contribute to the development of a more modern health care system that provides the high quality, integrated care that all patients want and expect.

3. **How does CMS plan to improve the quality and safety of care that seniors and low-income families receive under Medicare and Medicaid?**

Answer: I strongly believe that every single American can and should always receive the highest quality of care, no matter where they live or happen to seek care. I want CMS to continue its role as a leader and partner in encouraging safer and better care in hospitals, clinics, physician offices, and long-term care settings. I know we can get there, because I have seen throughout our nation example after example of bold and exciting progress. CMS is working to make the "best care" in America the norm in health care, for everyone.

CMS is implementing several Affordable Care Act provisions designed to improve the quality of care for those enrolled in our programs. The Affordable Care Act contains provisions designed to help avoid preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes. It also requires CMS and providers to focus on the prevention of infections, conditions, and other complications that patients acquire from the care that is supposed to help them. To create incentives for hospitals to prevent such infections, the Affordable Care Act includes both Medicare and Medicaid payment adjustments for providers that fail to prevent healthcare or hospital acquired conditions.

To better measure the quality of health care provided, the Affordable Care Act establishes a process for the development of a set of core health care quality measures specific to adults enrolled in Medicaid. These efforts complement those to develop child health quality measures as directed under the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

Extending the Life of Medicare

According to the independent actuary at CMS, the ACA is estimated to extend the solvency of the Hospital Insurance Trust Fund by 12 years (until 2029).

4. **How will CMS ensure that the Medicare program achieves this critically important protection for our nation's seniors?**

Answer: The Affordable Care Act will allow CMS to better align incentives for quality care and move towards seamless, integrated care. This will help health care providers and patients better tackle the problems of fragmentation and unreliability in care, which can erode health and satisfaction and add cost to taxpayers without adding anything of value to patients. For example, the Medicare Payment Advisory Commission (MedPAC) estimates that Medicare spends $12 billion annually on potentially preventable readmissions. Half or more of these readmissions could be prevented with proper attention to care transitions, coordination, outreach, and patient education and support.

The Affordable Care Act also establishes an Independent Payment Advisory Board (IPAB) to develop and submit proposals to Congress aimed at extending the solvency of Medicare, slowing Medicare cost growth, and improving the quality of care delivered to Medicare beneficiaries. CBO estimated that the Independent Payment Advisory Board would save $15.5 billion over ten years. More significantly, CBO based its projected longer-term savings for the legislation on the assumption *"that the Independent Payment Advisory Board established by H.R. 3590 would be fairly effective in reducing costs beyond the reductions that would be achieved by other aspects of the legislation."*

Ending Waste in the Medicare System

The Health and Human Services Office of Inspector General (OIG) released a report that found one in seven Medicare beneficiaries experienced unnecessary harm or even death while receiving care in a hospital. An additional one in seven beneficiaries experienced temporary harm. That means almost a quarter of Medicare beneficiaries are receiving inadequate care – almost half of which could be prevented, according to the OIG. The OIG estimates this costs the Medicare program up to $4.4 billion in additional reimbursement in 2009. Medicare loses additional money by paying for care for patients that have to get readmitted to the hospital.

5. **Can you discuss the ways in which the ACA can help CMS incentivize providers to get the job right the first time?**

Answer: The Affordable Care Act contains a number of provisions that will incentivize providers to give high quality health care, which will help CMS to build on a number of efforts already underway in the Agency to improve the quality of health care. To create incentives for hospitals to prevent hospital-acquired infections, the Affordable Care Act includes a Medicare payment reduction for hospitals that have a hospital-acquired condition rate that is much higher than average, beginning in FY 2015. Additionally, the Affordable Care Act sets a course for hospitals to focus on reducing preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes.

Other Agency efforts that will help providers increase quality include the electronic prescribing (e-Prescribing) incentive program that can reduce drug errors and adverse drug interactions. E-prescribing can also reduce Medicare spending by identifying less expensive alternatives to certain prescribed drugs. In addition, CMS is implementing new payment provisions that will reward hospitals and physicians for adopting qualifying electronic health records (EHRs). All of these initiatives help CMS incentivize providers to eliminate preventable errors and get the job done right the first time.

6. **According to the Medicare Payment Advisory Commission, insurance companies pocketed $14 billion in wasteful overpayments from Medicare in 2009 alone. In fact, from 2006 to 2009, Medicare accounted for nearly 75 percent of the increase in profits among the largest plans in the industry. Dr. Berwick, if these wasteful payments to insurers are reinstated, what would be the impact on seniors?**

Answer: Reinstating previous payment policies would not be the best use of health care dollars for Medicare beneficiaries. These well-documented excess payments would enrich large insurance companies without regard to the quality of care or level of service they provide to Medicare beneficiaries. CMS is working to improve its oversight and management of the Medicare Advantage (MA) program; the results for 2011, announced this fall, show that when CMS negotiates on behalf of beneficiaries and strengthens our oversight and management of MA plans, seniors and people living with disabilities will have clearer plan choices offering better benefits. In 2011, MA premiums are lower and enrollment is projected to be higher than ever before.

As part of our national strategy for implementing quality improvement in health care, CMS is also instituting quality bonus payments for MA plans, providing an incentive for all plans to improve the care they offer to Medicare beneficiaries. MA plans will be paid a quality bonus payment (QBP) based on their rating using CMS' five-star quality rating system. To provide a strong incentive for all MA plans to improve performance, CMS will pursue a national demonstration project running from 2012 to 2014 that rewards plans receiving three stars or higher with progressively larger QBPs. The demonstration will test whether providing scaled bonuses will lead to more rapid and larger year-to-year quality improvements in MA program, compared to the current law approach to computation of QBPs.

CMS Innovation Center

The ACA provides a new Center for Medicare and Medicaid Innovation with new authority and funding ($10 billion every ten years) to test and expand innovative provider payment models that increase quality and reduce cost growth. Models that are proven to be successful during the testing phase can be expanded nationally without further Congressional approval if the Secretary attests that quality of care will improve and the independent CMS Actuary certifies that spending will be the same or lower. CBO scored this proposal as a net savings of $1.4 billion over ten years.

7. **Dr. Berwick, can you tell us how you can turn Medicare and Medicaid into 21st century programs with the Innovation Center?**

Answer: The Center for Medicare & Medicaid Innovation (Innovation Center) will identify, validate and disseminate information on innovative payment and service delivery models that promote the goals of better care, better health and lower costs. The Innovation Center has the funding and flexibility to aggressively pursue new care and payment models that will improve and sustain the Medicare, Medicaid, and CHIP programs for our beneficiaries. The Center for Innovation has the opportunity to transform our system to one that delivers patient-centered, coordinated, seamless care with better health outcomes for individuals and communities at sustainable costs.

We have identified an initial set of payment and care models to evaluate beginning in FY 2011 that show promise in enhancing care quality, coordination, and efficiency. This initial set of models includes working with Accountable Care Organizations, medical homes, testing bundled payments, and integrating care for the Medicare-Medicaid dual-eligible population.

In keeping with the parameters of the Innovation Center's authorization, we will set metrics for each innovation project to evaluate success. We plan to engage in the testing of models and to aim for continuous improvement, working with providers, systems, and communities to adjust models as necessary to achieve optimal results. Some projects may involve testing the expansion of existing models that are already achieving results on a small scale but that are relatively unknown. Models will be evaluated for their large-scale viability and potential for promoting coordinated, seamless, and person-centered care that can improve care, improve health and lower costs.

Health Care Waste, Fraud and Abuse

Health reform contained an unprecedented number of new policies aimed at preventing health care fraud. The law transitions the fight against fraud from a system that pays fraudulent claims then attempts to chase down and find the criminals to a system that focuses on preventing fraudulent claims from occurring in the first place. Policies put in place by health reform to achieve this "prevention-first" approach include: 1) stricter screening requirements for providers that wish to participate in Medicare and Medicaid, 2) new authority to suspend payment of claims that are under a credible suspicion of fraud, 3) a new requirement that Medicaid terminate providers if the same provider has been terminated in Medicare or another state's Medicaid program, and 4) increased funding to enhance fraud fighting activities.

8. **Can you explain how CMS is utilizing these tools and how CMS intends to measure its success?**

Answer: CMS has taken several initial steps to implement and utilize the new authorities provided by the Affordable Care Act. For example, CMS now requires all suppliers and providers that qualify for a National Provider Identifier (NPI) to include their NPI on all enrollment applications and on all claims for payment submitted under Medicare and Medicaid. Additionally, CMS issued a proposed rule in September to implement the provider and supplier screening and payment suspension authorities in the Affordable Care Act. CMS looks forward

to working with providers and suppliers and other key stakeholders as we review the comments submitted and finalize the rule in early 2011.

The $350 million in additional funding for the Health Care Fraud and Abuse Control account for fiscal years 2011 through 2020, along with the CPI-U adjustment to the base funds beginning in FY 2011, that Congress provided in the Affordable Care Act will allow HHS and CMS to implement and exercise the new authorities in the Affordable Care Act that strengthen the Medicare, Medicaid and CHIP programs through a demonstrable shift toward preventive activities, stricter provider and supplier enrollment requirements, and expanded oversight controls, such as pre-payment review of claims for high-risk items and services.

9. Has CMS undertaken a comprehensive evaluation of the amount of fraudulent payments being paid by Medicare, Medicaid and CHIP on an annual basis?

Answer: Fighting fraud, eliminating waste, and strengthening program integrity is a top priority for the President, the Secretary and me. While fraud against Medicare and Medicaid has received the most attention, the reality is that health care fraud affects all private and public health care programs alike.

CMS does not calculate a "fraud rate;" instead, it measures the amount of improper payments that occur in Federal health care programs and reports these error rates on an annual basis as part of the U.S. Department of Health and Human Services (HHS) Agency Financial Report. Improper payments include both overpayments and underpayments, but only a subset of these payments is likely to be fraudulent. While improper payment rates are not necessarily an indicator of fraud in Medicare, Medicaid or CHIP, they do provide HHS, CMS, and States with a more complete assessment of how many errors need to be fixed.

CMS is committed to meeting the President's goal to cut the Medicare error rate in half by 2012 and is on track to meet this goal. We are steadily working to reduce error rates in all Federal health care programs and ensure that appropriate payments are made.

10. Has CMS established any new criteria or measurement tools in order to quantify the level of improvement in preventing fraudulent claims? If so, what progress has been made in preventing fraudulent claims during 2010?

Answer: Under our existing authority, we are exploring the use of predictive analytics to identify improper claims or transactions and stop fraudulent claims from being paid. As we work to combat fraud on the front-end, we are ever mindful of our responsibility to ensure that millions of beneficiaries continue to have access to the medical care they need. The risk of an automated system generating "false positives," which could result in improper denials of care or services, is one of the reasons why CMS is first evaluating predictive analytics through a series of demonstrations (some of which are described below in question 11) to help us identify the most appropriate way to use predictive analytics and to get the highest return on investment.

11. With the new authority provided under the ACA, CMS has said it will be able to utilize new and innovative technologies to detect, prevent, and fight health care

fraud. Can you please identify and describe the use of such technology, both in demonstration projects and normal operations, and detail its effectiveness?

Answer: The Affordable Care Act provides for enhanced data integration across CMS programs and data sharing among Federal entities to monitor and assess high-risk program areas and better identify potential sources of fraud. CMS is already using its authority to examine new technological concepts through several exploratory pilots that will utilize a combination of behavioral analysis, network analysis, and predictive analysis to identify fraud prepayment (or pre-enrollment). The pilots test various approaches, seek to develop models that will not return false positives, and will identify subjects for further investigation. Examples of pilots already underway at CMS include:

- **Predictive Analysis Based on Identity Theft (Compromised Numbers):** Through this pilot, we are isolating billing patterns using compromised numbers (along with other data) to identify providers that may be fraudulent. The analysis has already identified suspicious cases that have been transferred to Medicare contractors for further investigation.

- **Swipe Card Pilot:** In this initiative, magnetic cards, similar to credit cards, will be issued for ordering and receiving DME supplies. Each time an item is ordered (e.g. by the physician) and distributed (e.g. by the supplier), the card will be swiped using existing credit card terminals. CMS intends to compare the information collected through the card swipes with the claims submitted. If successful, automated swipe cards may be a method to assist beneficiaries and providers who have had their Medicare numbers compromised by putting in place an additional safeguard that protects Medicare from fraud while ensuring that beneficiaries maintain appropriate access to DME supplies.

- **Complaints Analysis: We are developing and testing models that use consolidated complaints history (through 1-800-MEDICARE) to evaluate complaint trends and identify leads for further investigation.**

As required by the Affordable Care Act, CMS is expanding its Integrated Data Repository (IDR) to include claims and payment data, and intends to enter into data sharing and matching agreements with the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential waste, fraud, and abuse throughout Federal health programs. Also, the Affordable Care Act requires State Medicaid programs to report an expanded set of data elements to the Medicaid Management Information System that will strengthen CMS' program integrity work within State Medicaid programs.

<u>Electronic Medical Records</u>

The American Recovery and Reinvestment Act of 2009 invested $30 billion in health information technology. The law required HHS to develop and publish standards for system functionality and interoperability by January 1, 2010. It also requires CMS, beginning in 2011, to provide Medicare and Medicaid bonus payments to hospitals and doctors that are

"meaningful users" of qualified health IT systems. Starting in 2014, hospitals and doctors who are NOT meaningful users will face Medicare payment penalties.
The pay-for-quality reforms in the ACA provide further incentives for the use of health IT. As more and more providers are paid based on outcomes, they will find that electronic records are necessary to provide better care to their patients. And health IT systems will allow doctors and hospitals to connect with one another to support coordinated care across the health care spectrum. This will facilitate the creation of Accountable Care Organizations and other integrated delivery models.

12. Now that providers will have financial support in adopting health IT, how do you think the reforms included in the ACA will impact the use of electronic records?

Answer: CMS incentive programs to promote electronic prescribing (e-prescribing) and electronic health records (EHRs) are providing the infrastructure that will facilitate many Affordable Care Act provisions and goals. In 2009, as authorized by the Medicare Improvements for Patients and Providers Act (MIPPA), we implemented the e-prescribing incentive program that is designed to reduce drug errors from poor handwriting and adverse drug interactions. The American Recovery and Reinvestment Act (Recovery Act) granted further authority for CMS to establish the Medicare and Medicaid EHR incentive programs to reward hospitals and physicians for adopting EHRs. Taken together, these tools will help hospitals and physicians provide more integrated care and reduce waste through reductions of duplicated services and avoidance of preventable medical errors.

The meaningful use of EHRs will be further encouraged by the Affordable Care Act through provisions in the law that pays providers based on outcomes and value-based purchasing. The use of EHRs will further enable integrated delivery models by allowing providers and Accountable Care Organizations to use clinical data to support process improvements.

Part D Donut Hole $250 Rebates

Medicare Part D provides outpatient prescription drugs to Medicare beneficiaries. Part D pays for 75% of the first $2,840 worth of purchased drugs (after a $310 deductible is paid). For drugs purchased beyond the $2,840 threshold, but before the beneficiary reaches the catastrophic limit (purchases beyond $6,447.50 worth of drugs), there is no coverage provided by Part D. This gap in coverage is often referred to as the donut hole. As part of health reform, seniors who purchase drugs within the donut hole will receive a $250 rebate check. From 2011 to 2019, Part D will begin to phase in coverage of drugs in the donut hole, so that by 2020, beneficiaries will pay only 25% of the costs of drugs until they reach the catastrophic limit (where they will then pay only 5% of the cost of drugs).

13. Dr. Berwick, how many seniors have received the $250 check so far this year?

Answer: To date, more than 2 million checks have been mailed to Medicare beneficiaries.

14. What steps is CMS taking to begin to close the donut hole starting next year?

Answer: For 2011, CMS is initiating the phase-in of provisions to provide coverage for seniors in the coverage gap. The Secretary has entered into agreements with drug manufacturers to provide a 50 percent discount on brand name drugs and biologics purchased in the Part D coverage gap by Medicare beneficiaries enrolled in Part D who do not receive the low-income subsidy. Manufacturers of 99.9 percent of brand-name Part D drugs utilized by Medicare beneficiaries are participating in the program for 2011.

Additionally, we are beginning to phase-in coverage of drugs in the coverage gap. The coverage for drugs in the gap will increase incrementally each year until 2020. In 2020, beneficiaries will pay only 25 percent of the costs of brand name and generic drugs until they reach the catastrophic limit (where they will then pay only the greater of a small copayment or 5 percent of the cost of drugs). Coverage in the donut hole on brand name drugs will be 75 percent when combined with the manufacturer discount, and Part D coverage on generic drugs will be 75 percent.

Care Coordination between Medicare and Medicaid

The ACA created a new office at CMS called the Coordinated Health Care Office. This office is known as the "office of the duals" because it was created to coordinate the administration of Medicare and Medicaid for beneficiaries enrolled in both programs. Prior to ACA, the Medicare side of CMS and the Medicaid side of CMS could blame each other for the lack of coordination between the two programs, but now one office is in charge. The office of the duals is expected to propose changes to some Medicare and Medicaid regulations to make them work better together and to work the Center for Medicare and Medicaid Innovation to test new ideas to improve care delivery.

15. Please discuss what you've done thus far and what is planned for this office.

Answer: One of the top priorities of the Federal Coordinated Health Care Office (FCHCO) is improving the relationship and coordination between States and the Federal government with regard to individuals eligible for both Medicare and Medicaid. We will do that by focusing on administrative (e.g., conflicting policies, procedures, and regulations) and financial (e.g., disincentives and cost shifting) changes that will align incentives to reward improved coordination of care and services.

Demonstrations specific to the dual eligible population will be part of the Center for Medicare and Medicaid Innovation (the Innovation Center) portfolio of delivery system and payment demonstrations. We intend to have an ongoing dialogue with stakeholders, including States, providers, and beneficiary advocates, to get their best ideas and suggestions for ways to improve care for this population and determine which demonstrations would help inform the Agency's efforts to improve integration of care, better care coordination, and other quality of care improvements.

Medicaid Eligibility and Enrollment Simplification

Medicaid is a joint federal-state partnership, but the administration of the program is almost entirely state-based, operating within broad parameters established by the federal government. This means that the eligibility and enrollment processes are different from state-to-state, making Medicaid unnecessarily complicated. In ACA, these processes have been streamlined to avoid gaps in eligibility and coverage between Medicaid and state exchanges. This has the added bonus of making Medicaid more uniform from state-to-state as well, but the transition will be difficult.

16. How is CMS approaching these issues and how will you help states to make the transition as smooth as possible?

Answer: The Affordable Care Act creates a "no wrong door" approach to health insurance coverage to facilitate enrollment into the right program, regardless of where an individual applies. To accomplish this goal, Medicaid, the Children's Health Insurance Program (CHIP), and the Exchange will use a simplified income determination methodology for most populations, replacing the more complicated income disregards that Medicaid currently uses. To help streamline eligibility, the Affordable Care Act requires the establishment of a simplified enrollment system using various data sources, which would allow eligibility to be determined at one time for Medicaid, CHIP, premium assistance and cost-sharing subsidies in the Exchange, as well as enrollment in a health plan. We anticipate that individuals will be able to apply for coverage using a single enrollment form, which will be used to determine appropriate eligibility for Medicaid, CHIP or the state Exchanges. State programs will, to the maximum extent possible, establish, verify, and update eligibility for participation in the programs using data matching with other existing data sources. CMS, in coordination with the Office of Consumer Information and Insurance Oversight, as well as the Department of Treasury, will be issuing guidance to help States prepare for 2014.

We recognize that many States will have to upgrade their eligibility systems to accommodate the Medicaid expansion and to achieve the Affordable Care Act's requirements for seamless enrollment procedures between Medicaid and the new State Exchanges. Working with the new Office of Consumer Information and Insurance Oversight, CMS issued guidance to help States design and implement the information technology (IT) needed to establish Exchanges. To assist in these activities, CMS released a proposed rule that would provide enhanced Federal matching funds to States to design, develop, and install enhanced Medicaid eligibility determination systems. As proposed, the 90 percent matching rate will be available for eligibility systems until December 31, 2015, and the 75 percent match will be available for maintenance and operations of such systems. Additionally, on October 29, 2010, OCIIO announced a competitive funding opportunity for States to design and implement the IT infrastructure to operate Exchanges. Two-year grants will be awarded to up to five States or coalitions of States that have ambitious yet achievable proposals that can yield IT models and best practices that will benefit all States. This support, along with the generous matching rates described above, will help ease the burden on States as they implement the Medicaid expansion provisions of the Affordable Care Act.

Medicaid and the Juvenile Justice System

Youth involved with the justice system have a lot of things to worry about, but health care should not be one of them. Medicaid does not pay for care while youth are inmates, but it seems we can improve care coordination between the two systems overall. Some states maintain Medicaid eligibility for longer than others, and some states do a better job of re-enrolling youth once they return to the community, but a lot of opportunities to improve remain.

17. Dr. Berwick, what can states do to improve care coordination between Medicaid and the Juvenile Justice System?

Answer: Care coordination is an important goal for this Administration. CMS staff is participating in workgroups both within HHS and with other Federal agencies to consider issues pertaining to the re-entry of incarcerated individuals, with a specific focus on juvenile justice issues. CMS has twice issued guidance to State Medicaid Directors to clarify that while Federal Medicaid matching funds are not available to pay for the health care of incarcerated individuals, including juveniles, Medicaid *eligibility* is not precluded during an incarceration if appropriate eligibility criteria are met. States are encouraged to "suspend" and not "terminate" Medicaid eligibility for individuals who are held involuntarily in secure custody of a public institution. Individuals who meet Medicaid eligibility requirements may be enrolled in the program before, during, and after the time in which they are incarcerated. Additionally, once discharge from the facility is anticipated, States can improve care coordination by making arrangements to ensure that an eligible individual is either placed in payment status or initially enrolled in Medicaid so that he or she can begin receiving Medicaid-covered services immediately upon leaving the facility.

Given the high incidence of substance abuse, mental illness, and physical illness among those who have been incarcerated or otherwise held in involuntary custody, CMS continues to encourage States to take this action to ensure that eligible individuals receive appropriate medical services. Ultimately, though, this is a State issue and success will depend on how well the Medicaid, social service, and Juvenile Justice systems work together within the State. CMS can certainly help facilitate opportunities for States with a proven track record of managing transitions to share their experience and expertise with other States.

18. What can we – in Congress – do to make these systems work better together?

Answer: The Administration has not taken a position on any legislative solutions. However, I am aware that the House-passed health reform bill included a provision to help improve care coordination for incarcerated youth. The provision in the bill would have prohibited State Medicaid programs from terminating eligibility for beneficiaries under age 19 who are incarcerated in a public institution during the period of incarceration and would have required States, on or before the date of release, to ensure that eligible youth are enrolled in Medicaid.

I look forward to working with you, with our federal juvenile justice counterparts, and with our State partners to address this issue and think about ways to better coordinate care for all populations.

19. Dr. Berwick, under current law isn't it true that states can suspend, as opposed to terminate, Medicaid benefits for youth inmates making re-enrollment an easier process?

Answer: That is correct. CMS guidance has consistently indicated that States can suspend rather than terminate Medicaid benefits for inmates, including youth inmates, to ensure timely access to services upon release to help provide continuity of care.

<u>Medicaid Prescription Drugs</u>

Medicaid gets a good price for prescription drugs through the rebate program, and traditionally, Medicaid beneficiaries have had good access to prescription drugs through retail pharmacies. In 2005, there was an effort to limit Medicaid payments to pharmacists that went too far. The underlying policy and the regulations that followed were too sweeping and would have jeopardized the success of the Medicaid prescription drug benefit. In health reform, we replaced that policy with a reimbursement system that is fair – striking a good balance to provide adequate pharmacy reimbursement.

20. Dr. Berwick, How can you assure Congress and pharmacists across the country that this policy will be implemented in a fair and timely way?

Answer: Assuring adequate pharmacy reimbursement is an essential element of assuring access to medication for Medicaid beneficiaries. Since 2007 CMS has been unable to implement some of the changes made to the Medicaid Drug Program by the Deficit Reduction Act of 2005 (DRA). On November 15, 2010, CMS issued a final rule that withdraws the determination of the Average Manufacturer Price (AMP) and the Federal upper limits provision of the 2007 AMP final rule that implemented portions of the DRA. The November 15, 2010 final rule became effective on December 15, 2010.

We are committed to implementing changes made by the Affordable Care Act to the Medicaid Drug Program. Timely and fair implementation will ensure the best interest of our beneficiaries and to the fiscal integrity of the Medicaid Program. We believe that the November 15, 2010 final rule was a necessary step in implementing the Affordable Care Act requirements and we will continue to work with stakeholders to ensure that the provisions are implemented fairly.

<u>Medicare Advantage – Enrollment in 2011</u>

Medicare Advantage allows Medicare beneficiaries to enroll in private insurance plans to receive Medicare benefits. On average, the federal government pays private plans more than it costs traditional Medicare to pay for these benefits. These extra payments are generally used to offer extra, supplemental benefits. Health reform begins to phase down these payments to insurance companies, beginning in 2011 with a freeze in payments at

2010 levels. Health reform also, for the first time, rewards plans with a payment bonus that receive a high rating on CMS's quality rating system.

21. For several years, the federal government has made payments to private insurance companies to provide health benefits to Medicare beneficiaries. In fact, last year these private plans received payments that were, on average, 13 percent greater than the cost of traditional Medicare. Because payment plans are the same as they were last year, are we seeing a change in the availability of MA plans this year?

Answer: Beneficiaries' access to a wide variety of Medicare Advantage (MA) plans remains virtually unchanged, and 99.7 percent of beneficiaries will have access to a Medicare Advantage plan in 2011. CMS successfully eliminated many low-enrollment and duplicative plan options, providing clearer distinctions between plans for beneficiaries, while at the same time maintaining robust access. While the total number of MA plans has decreased by 16 percent in 2011, on average, there are 26 MA plans available in every county.

Ultimately, whether certain MA plans decide to leave a particular marketplace comes down to business decisions made by MA Organizations, which has been true since the beginning of the Part C program. Cost-sharing charged by plans and the supplemental benefits offered by plans change from year to year and result from business decisions made by each MA Organization. As they do every year, beneficiaries need to reassess their options and pick a plan the best meets their needs balancing their financial capacity with desired benefit packages.

22. What effect has this freeze had on MA enrollment, the premiums of these plans, and the benefits offered by these plans?

Answer: Despite a payment freeze for 2011, MA enrollment will increase 5 percent, according to MA plans' bids. In addition, CMS' efforts and the Affordable Care Act are making MA plans stronger – beneficiaries will have lower premiums and more comprehensive benefits in their MA plan in 2011.

For example:

- The weighted average for all MA premiums will be 1 percent lower in 2011 than premiums this year – compared to a 15 percent premium increase between 2009 and 2010.
- 98.4 percent of beneficiaries will have access to an MA plan with no premium in 2011.
- Virtually all (99.7 percent) beneficiaries will have access to a MA plan that waives cost-sharing for preventive benefits in 2011.
- All MA plans will offer mandatory maximum out-of-pocket limits for all Part A and Part B services.
- All MA plans are required to meet or exceed published cost sharing standards similar to Original Medicare in service categories such as inpatient care, Part B drugs, durable medical equipment (DME), and mental health services. All MA plans must provide cost-sharing for skilled nursing, chemotherapy, and renal dialysis at or below Original Medicare levels, per the Affordable Care Act.

Children's Health Insurance Program Outreach and Enrollment

In 2009, CHIP covered approximately 7.8 million children nationwide and nearly 19,000 kids in Montana. However, many kids who are eligible for CHIP are not enrolled. For every ten uninsured kids, seven are eligible for Medicaid or CHIP. The Children's Health Insurance Program Reauthorization Act of 2009 expanded funding for outreach programs and incentivized states to increase enrollment of eligible kids. CMS plays an important role in helping states to find and enroll eligible kids.

23. How can we put an end to the "eligible but un-enrolled" problem once and for all?

Answer: We agree that no child should be uninsured and that every child who is eligible for Medicaid and the Children's Health Insurance Program (CHIP) should be enrolled. Enrolling all eligible children is a high priority for Secretary Sebelius and also for me. In February 2010, the Secretary issued the "Connecting Kids to Coverage" challenge to States to enroll all 5 million uninsured children who are currently eligible for Medicaid or CHIP over the next 5 years, and she has been personally engaged in various Federal, State and local efforts to reach this goal. To date, organizations across the country as diverse as the March of Dimes, the National Council of La Raza, the American Academy of Pediatrics, United Way Worldwide, the National Association of Community Health Centers, and the Philadelphia Eagles, as well as Governors and other elected officials, have taken up the Secretary's challenge.

The Children's Health Insurance Program Reauthorization Act (CHIPRA) has helped States make great strides in covering eligible children. CHIPRA gave States a number of new tools and incentives to enroll eligible children in Medicaid and CHIP and we are already seeing progress. During FY 2009, 2.6 million additional children were enrolled in Medicaid and CHIP.

To assure progress, CMS is holding conferences, encouraging best practices, convening monthly technical assistance calls with States, and using the CHIPRA Performance Bonuses to reward qualifying States that significantly increase enrollment and improve outreach and enrollment procedures through adoption of an array of enrollment and retention simplifications. We also have been using the outreach and enrollment funds from CHIPRA and the Affordable Care Act to partner with community organizations, tribal organizations, and States on campaigns to find and enroll more eligible children. We have also updated and improved the Insure Kids Now Website (www.insurekidsnow.gov) to make it a more user-friendly focal point of the enrollment effort.

Building on the important steps CMS is taking now to end the "eligible but unenrolled" problem, new coverage and simplification provisions included in the Affordable Care Act, effective January 2014, will strengthen our current efforts to ensure that no child has to miss out on needed care due to lack of health insurance.

Health Care Quality

The ACA includes a series of provisions to help improve the health system's focus on quality. Previously, quality had been moving forward on a piecemeal basis spread over a

number of federal agencies. The ACA codifies discrete quality initiatives and directs HHS to coordinate them into a broader quality improvement strategy. It also tries to leverage those quality goals across Medicare and private payers. Lastly, it also includes value based purchasing for hospitals, and sets other providers on a path to value-based purchasing.

24. Dr. Berwick, can you discuss how CMS can use the reforms included in the ACA to ensure that we get the right care to the right patient at the right time?

Answer: The Affordable Care Act includes unprecedented new tools that will enable us to reinvigorate our nation's focus on the quality, value, and outcomes of care, and help the public and the private sector produce a new system that is better for patients, families, communities, and the health care workforce. These innovative provisions will enable CMS to work with our partners in the private sector to improve care coordination, increase patient safety, offer beneficiaries more information and more control over their care, and achieve better outcomes. The Act allows us to better align incentives for quality care and move towards seamless, integrated care. This will help health care providers and patients better tackle the problems of fragmentation and unreliability in care, which can erode health and add cost to taxpayers without adding anything of value to patients.

Improved quality will allow the right care to get to the right patient at the right time which will improve outcomes and reduce cost. Better integration of care, better designed services for our beneficiaries, better measurement tools, and a focus on continual improvement can all help bring us closer to the health care system that we want and the American people deserve.

CMS is implementing several Affordable Care Act provisions designed to improve the quality of care for those enrolled in our programs. The Affordable Care Act contains provisions designed to help avoid preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes. It also requires CMS and providers to focus on the prevention of infections, conditions, and other complications that patients acquire from the care that is supposed to help them. To create incentives for hospitals to prevent such infections, the Affordable Care Act includes both Medicare and Medicaid payment adjustments for providers that fail to prevent healthcare or hospital acquired conditions.

<u>Medication Therapy Management Benefit</u>

When Congress created the Medicare Part D prescription drug program, it included a medication therapy management (MTM) benefit. The concept behind MTM is that it is important for Medicare beneficiaries who have chronic conditions and take numerous prescriptions to have the opportunity to meet with a pharmacist or other health care provider to make sure they were taking their prescription drugs appropriately. The health care reform law codified those MTM improvements at Section 10328. In addition, Section 3503 of the law creates a grant program for medication management services in the treatment of chronic diseases. The law also includes other provisions to promote MTM as one important way to help improve outcomes and the coordination of health care delivery.

25. Can you provide us with the number of Medicare beneficiaries that is currently eligible for MTM in Part D, and discuss what additional steps is CMS taking to ensure broader access to this important service?

Answer: There were 2.8 million Medicare beneficiaries in Part D eligible for medication therapy management (MTM) in 2009. Information on eligibility for MTM for 2010 will be reported by the Part D plans in February 2011, and these data will be reflective of several of the enhancements beginning in 2010 to increase access to MTM in Part D.

CMS is committed to ensuring that all targeted beneficiaries have access to MTM services. To that end, CMS issued a final rule in April 2010 (CMS-4085-F) containing policy and technical changes under the Part C and D programs, including changes that improved access to the MTM benefit as well as the services received under that benefit. Specifically, the final rule sets parameters for the eligibility thresholds Part D plans establish for the MTM benefit. Consistent with requirements in the Affordable Care Act, the final rule also requires Part D plans to use an "opt-out" method of enrollment in the MTM benefit, to target beneficiaries for enrollment on at least a quarterly basis, and to conduct annual comprehensive medication reviews with written summaries.

Additionally, CMS issued a proposed rule in November 2010 (CMS-4144-P) that established telehealth as an option for delivery of comprehensive medication reviews. This new capability would improve access for beneficiaries unable to travel to the provider's location or who live in remote locales. The proposed rule would also require Part D plans to contract with long-term care facilities where their members reside to provide MTM services in coordination with the monthly medication reviews and assessments performed by the facilities' consultant pharmacists.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Grassley:

Questions for the Witness:

CHIPRA Performance Bonus

Dr. Berwick, as you know, legislation reauthorizing the State Children's Health Insurance Program (SCHIP) was enacted early last year. CHIPRA 09 included a provision that provided incentives for states to increase enrollment in Medicaid for low income children. According to a December 09 press release however, only 9 states were awarded a performance bonus.

1. **Can you provide an explanation on why so few states have improved their performance?**

Answer: Ultimately, ten States received 2009 Performance Bonuses totaling more than $75 million. Although we would like to see more States implement outreach and enrollment procedures that qualify for Performance Bonuses, we think Congress rightly set the bar for States to qualify for bonuses. States must implement five of eight outreach improvements and eligibility simplifications, and it can take States time to implement such changes. We were pleased that ten States were able to do so despite having less than a full year to meet the requirements. Over the last year, we have provided technical assistance to help States learn about the bonus requirements and help them qualify, or come closer to qualifying, in future cycles. CMS will announce the 2010 Performance Bonuses later this year.

Eligibility Determination

2. **Dr. Berwick, can you report on the efforts underway to comply with Section 1413 of PPACA which requires the Secretary to establish a system whereby an individual who is applying to an exchange that is found to be eligible for Medicaid or CHIP becomes enrolled in Medicaid or CHIP as applicable.**

Answer: The new Office of Consumer Information and Insurance Oversight (OCIIO) in HHS has primary responsibility for implementing section 1413 of the Affordable Care Act. CMS staff is working very closely with them to assure that forthcoming guidance will give States clear instructions about how to comply with the enrollment coordination and simplification provisions in the Affordable Care Act. Our overarching goal is to work with States to eliminate the red tape that people often experience today when they are looking for coverage. We will provide

guidance to States to support their efforts to create a system of coverage that will be less complicated for individuals seeking coverage, and more efficient for States to administer.

The Affordable Care Act creates a "no wrong door" approach to health insurance coverage to facilitate enrollment into the right program, regardless of where an individual applies. To accomplish this goal, Medicaid, the Children's Health Insurance Program (CHIP), and the Exchange will use a simplified income determination methodology for most populations, replacing the more complicated income disregards that Medicaid currently uses. To help streamline eligibility, the Affordable Care Act requires the establishment of a simplified enrollment system using various data sources, which would allow eligibility to be determined at one time for Medicaid, CHIP, premium assistance and cost-sharing subsidies in the Exchange, as well as enrollment in a health plan. The Affordable Care Act requires the Department to provide a model single form so that individuals will be able to apply for health benefits coverage – through Medicaid, CHIP or the state Exchanges - without needing to complete several different forms. We anticipate that CMS will work closely with the OCIIO in developing the model and establishing standards for States that will wish to develop and use their own streamlined form.

State programs will, to the maximum extent possible, establish, verify, and update eligibility for participation in the programs using data matching with other existing data sources. CMS, in coordination with OCIIO, as well as the Department of Treasury, will be issuing guidance to help States prepare for 2014.

CMS recognizes that many States will have to upgrade their eligibility systems to provide this type of seamless enrollment in Medicaid or a State Exchange. To assist in these activities, CMS released a proposed rule on November 3, 2010 that would provide enhanced Federal financial participation (FFP) to States to support the design, development and installation of enhanced Medicaid eligibility determination systems. OCIIO and CMS also issued guidance to help States design and implement the information technology (IT) needed to establish Exchanges. On October 29, 2010, OCIIO announced a competitive funding opportunity for States to design and implement the Information Technology (IT) infrastructure to operate Exchanges. Two-year grants will be awarded to up to five States or coalitions of States that have ambitious yet achievable proposals that can yield IT models and best practices that will benefit all States.

Modified Adjusted Gross Income

3. **Dr. Berwick, can you elaborate on the provision in PPACA that a state must treat kids losing Medicaid eligibility due to the Modified Adjusted Gross Income (MAGI) as targeted low-income kids (except inmates and certain state employees) and provide CHIP and how this interacts with the provision that prevents children from being made ineligible for Medicaid as a result of MAGI?**

Answer: CMS has not yet issued guidance on either MAGI or the maintenance of effort requirements so I cannot comment on the specifics. However, we are currently evaluating the need for future guidance on the maintenance of effort requirements, and will take this question into consideration. As CMS develops Affordable Care Act guidance for States, our primary concern is to ensure that the transition to coverage does not make any Medicaid-eligible children worse off. Congress was very clear that children should not lose coverage as a result of the legislation and we will be working with States to help them achieve that goal.

Express Lane

4. **Dr. Berwick, would you agree that the general purposes of transitioning to MAGI income counting rules are: to simplify the state variation that exists within Medicaid by moving a majority of the non-disabled Medicaid population to a uniform income counting rule (i.e., MAGI), and to ensure that there is coordination in income counting between Medicaid, CHIP, and the state exchanges to facilitate the PPACA screen and enroll requirements.**

Answer: Yes. The Administration shares Congress's vision of a simplified system that will permit people to move seamlessly between Medicaid, CHIP, and the Exchanges. The MAGI income counting rules will help achieve the "no wrong door" approach to eligibility.

5. **However, the CHIPRA Express lane provision permitted coordination between programs such as Medicaid, CHIP, TANF, and food stamps to facilitate enrollment. Can you comment on the issue that eligibility determinations based on Express Lane do not necessarily dove tail with MAGI income counting and the PPACA requirement to screen and enroll a child for Medicaid, CHIP, and the state exchanges?**

Answer: The Administration remains committed to the CHIPRA Express Lane option. The Affordable Care Act specifically provides an exception to MAGI income rules for States that elect the Express Lane option. Such States may rely on a finding made by an Express Lane Agency for purposes of determining Medicaid eligibility. We recognize that States that have elected the Express Lane option will need guidance about how to implement the new MAGI rules and we are working on providing such guidance. CMS would be happy to answer further questions once we have completed our guidance.

6. **Do you intend to maintain the policy of carving out a subset of the child population and use a different rule for determining Medicaid and CHIP eligibility?**

Answer: CMS is still developing its policy in this area; however, we would be happy to brief you on our guidance once it has been released. For now, our goal remains to avoid disrupting any existing coverage in Medicaid or CHIP, and to cover as many children as possible.

Paying for Physician Updates

If Congress does not act by November 30th, physicians who treat Medicare patients will face a payment cut of 23% as of December 1 and nearly 25% as of January 1, 2011.

7. **Please provide this Committee with a list of provisions in your jurisdiction or from HHS generally that would achieve the roughly $16B in savings necessary to prevent physicians from taking a payment cut between now and the end of 2011. Please provide this information to the committee before November 30.**

Answer: As you know, the Medicare and Medicaid Extenders Act of 2010 reverses the scheduled reduction in Medicare reimbursements and extends current Medicare payment rates to physicians through December 31, 2011.

Stable, predictable physician payments are critical to ensure Medicare is viewed as a dependable business partner. Fixing the SGR to provide stability in physician payments is a top priority, and I look forward to addressing this in the coming year.

Physician Payment Geographic Adjustments for 2010

Dr. Berwick, the health reform law includes a provision that requires the Secretary to analyze and evaluate geographic practice expense data and make appropriate adjustments to ensure accurate geographic adjustments by January 1, 2012. It also required additional reimbursement for rural physicians during the transition period in 2010 and 2011.

I understand that even though the Centers for Medicare and Medicaid Services (CMS) has an annual budget of over $700 billion the retroactive payments required by the new law for 2010 have not been made because, according to CMS, they have no money to pay for these adjustments.

8. **Please provide an explanation for the lack of payment and the date by which the 2010 retroactive payments will be made.**

Answer: CMS is currently developing the best course of action for addressing past claims that were processed under pre-Affordable Care Act rules. The volume of claims that must be adjusted is unprecedented and a careful process must be deployed to ensure that new claims coming into the Medicare program are processed timely and accurately, even as we address making the retroactive adjustments. CMS is working now to begin reprocessing these claims as expeditiously as possible. I look forward to working with you on this issue.

Medicare Advantage Cuts

The health care overhaul cut more than $200 billion out of the Medicare Advantage program. According to Medicare's chief actuary, this will result in a 50 percent cut in projected enrollment by 2017 – from 14.8 million to 7.4 million. This means there will be about 3 million less people in Medicare Advantage in 2017 than there are today. I'm worried that we are going back to the days when seniors in Iowa don't have the same options as seniors in Miami or New York City.
I'm also worried that seniors that are able to stay in Medicare Advantage are going to end up paying more for fewer benefits.

9. **Do you agree that my constituents in Iowa should have the same Medicare Advantage options as seniors in Miami or New York City?**

Answer: The Affordable Care Act preserves access to benefits across the country. Despite a payment freeze for 2011, Medicare Advantage (MA) enrollment will increase 5 percent, according to MA plans' bids. In addition, CMS' efforts and the Affordable Care Act are making MA plans stronger -- beneficiaries will have lower premiums and more comprehensive benefits in their MA plan in 2011.

Each and every beneficiary still has guaranteed access to Medicare benefits through Original Medicare. Furthermore, in their March 2010 report to Congress, MedPAC supported financial neutrality between FFS and MA and adjusting the benchmark was an appropriate solution to this imbalance.

In 2011, 98.4 percent of beneficiaries will have access to an MA plan with zero premiums. As far as benefits go, all MA plans will offer mandatory maximum out-of-pocket limits for all Part A and Part B services. All MA plans are required to meet or exceed published cost sharing standards similar to Original Medicare in service categories such as inpatient care, Part B drugs, durable medical equipment (DME), and mental health services. All MA plans must provide cost-sharing for skilled nursing, chemotherapy, and renal dialysis at Original Medicare levels, per the Affordable Care Act. Virtually all (99.7 percent) beneficiaries will have access to a MA plan that waives cost-sharing for preventive benefits in 2011.

Also, in your testimony you mention that "guaranteed" Medicare benefits will be protected. This use of the word "guaranteed" has been common among supporters of the health care law to cover up the fact that there will be deep cuts to extra benefits.

10. **Can you confirm that the Medicare Advantage cuts will result in some seniors paying higher cost-sharing, and losing benefits, such as dental and vision services after 2011?**

Answer: Ultimately, whether certain Medicare Advantage (MA) plans decide to alter their benefit package or leave a particular marketplace comes down to business decisions made by MA Organizations, which has been true since the beginning of the Part C program. Cost-sharing charged by plans and the supplemental benefits offered by plans change from year to year and

result from business decisions made by each MA Organization. As they do every year, beneficiaries need to reassess their options and pick a plan that best meets their needs, balancing their financial capacity with desired benefit packages.

I cannot speculate what will happen after 2011, but for now, this is not the case. In 2011, beneficiaries' access to a wide variety of MA plans remains virtually unchanged, and 99.7 percent of beneficiaries will have access to a MA plan. Further, benefits, on average, have remained stable between 2010 and 2011. CMS successfully eliminated many low-enrollment and duplicative plan options, providing clearer distinctions between plans for beneficiaries, while at the same time maintaining robust access. While the total number of MA plans has decreased by 16 percent in 2011, largely due to implementation of legislation that predated the Affordable Care Act, on average, there are 26 MA plans available in every county.

Double Counting Medicare Cuts

Dr. Berwick, since you raised the issue of extending the life of Medicare in your opening statement, I'd like to ask you about a quote from Medicare's Chief Actuary. In a December 23rd memo the Actuary's Office writes:

"To describe the full amount of HI trust fund savings as both improving the government's ability to pay for future Medicare benefits and financing new spending outside Medicare would essentially double-count a large share of those savings and thus overstate the improvement in the government's fiscal position."

11. **Do you agree with this statement and if so, how can the savings in the bill extend the life of the Medicare program while also paying for the new coverage expansion? If you say the money is extending the life of the Medicare program, doesn't that mean the new law isn't actually paid for?**

Answer: We are not double counting. The Affordable Care Act will both improve the overall financial position of the Federal government and extend the life of the Medicare Hospital Insurance (HI) trust fund. These are distinct accomplishments, which are accounted for through different mechanisms. CBO estimates that the Affordable Care Act will reduce the Federal deficit by more than $143 billion in the first decade. Part of the deficit reduction will come from reducing wasteful spending, and fraud and abuse in Medicare. The health reform legislation will also extend the life of the Medicare HI trust fund, since Medicare HI savings, as a matter of trust fund accounting, are credited toward that trust fund. Further, CMS' Actuaries project that the Affordable Care Act will extend the life of the HI Trust Fund by 12 years. These two accomplishments should not be conflated. Reducing the deficit improves the financial position of the Federal government overall, while extending the life of the HI trust fund helps ensure that Medicare continues to be a source of security for America's senior citizens.

Productivity Adjustments

The productivity adjustments in the new health law gauge payment updates for Part A providers to productivity gains of the overall economy. However, in an April 22 memorandum, Medicare's chief actuary, Rick Foster, said that he was ". . . not aware of any empirical evidence demonstrating the medical community's ability to achieve productivity improvements equal to those of the overall economy." For this reason, Mr. Foster estimated that "roughly 15 percent of Part A providers would become unprofitable . . . ," and subsequently, ". . . might end their participation in the program (possibly jeopardizing access to care for beneficiaries)."

12. **Dr. Berwick, you have recognized that these are only estimates of what the productivity adjustments might do to provider solvency and beneficiary access. Is it your opinion that despite historical evidence to the contrary, the medical community will be able to achieve productivity improvements equal to those of the overall economy? Please explain what CMS is doing to make sure that providers are capable of meeting these targets, and if they do not meet them, what CMS will do to prevent jeopardizing access to care for beneficiaries.**

Answer: There is no evidence that providers will not continue to serve beneficiaries. The Affordable Care Act was supported by the American Hospital Association and the American Medical Association, groups that would have been unlikely to back the law if they believed it would harm their members' financial viability. History shows providers will continue to serve Medicare patients. Congress has implemented larger savings targets for Medicare in the past, including in the 1997 Balanced Budget Act; in this and other cases, no access problems materialized. Such problems are even less likely to occur when Medicare savings and efficiencies are accompanied by coverage expansions, adding new sources of revenue for health care providers.

Further, in making these estimates, the Actuary did not consider a number of provisions in the law designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and certain providers in underserved areas and investments in health professional training programs to increase supply. These provisions will expand and strengthen the provider workforce and better secure access to care for all Medicare and Medicaid beneficiaries.

Sunshine Act

As you know, the health care law requires drug and device companies to begin reporting publicly the payments they make to physicians for educational programs, travel, meals, and consulting services. The regulations to implement this section of the law are due October of 2011 – yet at this point, it's unclear which agency at HHS will be charged with implementation. There are many technical details that need to be addressed with input from Congress, companies, and other stakeholders.

13. Can you tell us if CMS will be the lead agency on this important initiative and when we might see action on the regulations?

Answer: Yes, CMS will be the lead Agency. We expect to issues regulations during 2011.

Also, as you know, the statute requires physician-owned manufacturers and physician-owned group purchasing organizations to publicly report the financial interest of the physician-owners as well as payments made to those physicians. The HHS Office of Inspector General has stated that these entities should be closely scrutinized because of the potential conflicts of interest that can arise between physicians' responsibility to provide the best care and physicians' equity interests in these companies.

14. Do you agree with my view that the law provides room for inclusion of these physician-owned distributors?

Answer: The Affordable Care Act requires the Secretary to establish procedures for manufacturers and group purchasing organizations to submit certain physician ownership or investment information to the Secretary and to make the information available to the public.

The Affordable Care Act defines an applicable manufacturer that is subject to this provision and further describes the tasks that make an entity or an entity under common ownership an applicable manufacturer. Further, the Act instructs the Secretary to use the definitions included in the provision when establishing the procedures, but provides the Secretary with discretion to define other terms as appropriate.

We are aware of the importance of this provision and the concerns of the HHS Office of Inspector General regarding physician ownership and investment interests in manufacturers and group purchasing organizations. When drafting the regulations to implement this provision, we will carefully consider the application of this provision to physician-owned distribution entities.

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November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Bunning:

Questions for the Witness:

Medicare and Medicaid Solvency

Over twenty disability groups including the Paralyzed Veterans of America have written to you to express their concern that the inclusion of specialized, adjustable wheelchair seat cushions in the competitive bidding program will negatively impact the quality of, and access to, wheelchair seating for Medicare beneficiaries with disabilities. In particular, they are concerned that the existing coding structure used to categorize these items does not create distinct, homogenous groups of products that are essential to effectively bid them. Currently, there are over 3,000 products of varying materials, shapes, sizes, functions and cost assigned to one of four HCPCS codes. As a result, quality and access to the specific goods and services a beneficiary needs will diminish and overall costs to the beneficiary and the Medicare system will actually increase due to negative health care outcomes. A primary use of adjustable wheelchair seat cushions is to prevent and treat pressure ulcers/wounds (this is also one of the primary medical necessity conditions necessary for a beneficiary to qualify for Medicare coverage of such an item). The cost to heal a single wound ranges from $5,000 to over $40,000, while the Medicare allowable for adjustable seat cushions is less than $350.00.

1. **Can you provide a detail review of the inclusion of these products and the rationale behind their inclusion?**

Answer: For purposes of the DMEPOS competitive bidding program, CMS is required by statute to phase-in the highest cost and highest volume items and services and standard power mobility devices (PMDs) are among the highest cost and highest volume items and services.

Wheelchair seat cushions are necessary for some beneficiaries in order to effectively use PMDs. These PMD accessories and other PMD accessories were included in the standard PMD product category to allow the patient and his or her physician and health care team to work with one contract supplier in planning and coordinating the overall care, and to ensure that beneficiaries can obtain PMDs and all items needed for the proper use of the PMD equipment from one contract supplier.

Decisions about products included in the competitive bidding program were based upon Healthcare Common Procedure Coding System (HCPCS) classifications and not based on individual items. In other words, the individual items contained within the competitive bidding

product categories are identified using HCPCS codes, which are developed for items that are similar in function and purpose. In the case of wheelchair cushion products, these items must be tested and meet certain product requirements before they can be assigned to a particular code for Medicare billing and payment purposes.

It is important to note that there are additional protections under the competitive bidding program to ensure that beneficiaries with specific cushion needs maintain access to their prescribed wheelchair cushions. Under the physician authorization process, required by law and in regulations for the DMEPOS competitive bidding program, if a physician prescribes a specific product to avoid an adverse medical outcome for a beneficiary, such as a pressure ulcer, the contract supplier must furnish the prescribed brand, consult with the physician to find a suitable alternative brand, or assist the beneficiary in finding another contract supplier in the competitive bidding area to furnish the prescribed brand.

Additionally, CMS will have a number of measures in place to detect and address beneficiary access issues, should they arise. These measures include seeking beneficiary feedback in competitively bid areas through satisfaction surveys and conducting active claims analysis to identify utilization trends and monitor beneficiary access. CMS has also appointed an Acting Competitive Acquisition Ombudsman responsible for ensuring appropriate processes are in place to handle beneficiary complaints, should there be an issue with access to any products furnished through contract suppliers.

2. **Further, can you please explain the apparent conflict that exists between the final rule for competitive bidding which states that a competitive bidding product category will include items intended to address similar medical conditions; and, the inclusion of adjustable seat cushions, intended to address skin integrity issues, with power wheelchairs intended to address mobility issues? (Note that seating isn't even contained in the same Medicare Medical Policy as power wheelchairs and that seating is actually contra-indicated for use with some of the power wheelchairs being competitively bid. Furthermore, "skin protection is part of the Medicare descriptor in order to qualify for a "adjustable skin protection cushion.)**

Answer: As mentioned above, decisions about products included in the competitive bidding program were based upon Healthcare Common Procedure Coding System (HCPCS) classifications and not based on individual items. In other words, the individual items contained within the competitive bidding product categories are identified using HCPCS codes, which are developed for items that are similar in function and purpose. In the case of wheelchair cushion products, these items must be tested and meet certain product requirements before they can be assigned to a particular code for Medicare billing and payment purposes.

More specifically, each seat cushion product is reviewed by a Medicare coding analysis contractor to verify placement in a code. Each cushion is tested to ensure that it meets performance requirements for reducing pressure and all of the specific performance characteristics of each particular HCPCS code. Adjustable skin protection cushion products must meet all of the requirements of other skin protection cushion products and are further reviewed to ensure that they are adjustable.

The HCPCS is updated annually, or more frequently as needed, based on requests for changes submitted from various individuals and entities, including manufacturers and suppliers of DMEPOS items and services. HCPCS codes for wheelchair seating products and services have been significantly revised in recent years based on such requests and based on the Medicare program's needs. We will continue to use this process to ensure that codes reflect current technology and meet the needs of Medicare beneficiaries.

Because we understand that wheelchair seat cushions are necessary for some beneficiaries in order to effectively use power mobility devices (PMDs), these PMD accessories and other PMD accessories were included in the standard PMD product category in order to ensure that beneficiaries can obtain PMDs and all items needed for the proper use of the PMD equipment from one contract supplier. Bidding power wheelchairs and all related accessories under the program allows the patient and his or her physician and health care team to work with one contract supplier in planning and coordinating the overall care.

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Questions Submitted for the Record From Dr. Donald Berwick

Senator Cantwell:

Questions for the Witness:

Medicare Value Payment Modifier

I worked hard with my colleagues in the Senate to include a Medicare value payment modifier that will change the current Medicare physician fee schedule to shift from a payment system that rewards quantity to one that rewards quality and lower costs (section 3007 of the Patient Protection and Affordable Care Act). My intent was for this modifier to apply to physicians nationwide, not on a state-by-state basis (recognizing geographical differences in providing care which remain in the formula).

1. **What is CMS's current position on nationwide vs. state-by-state application of the modifier?**

Answer: Senator, I appreciate your interest and hard work on this very important issue. As you know, I believe in linking Medicare payments to improvements in quality and lower costs and that Medicare payment should appropriately reward provider efficiencies. This provision is an important aspect of our work in this area. CMS is still determining the best way to apply the modifier and intends to institute rulemaking and implement this provision within the statutory deadlines of the Affordable Care Act. Implementing the Affordable Care Act in a timely and transparent way is a high priority for the Administration and CMS.

Balancing Incentive Payment Program

I also worked with my colleague Senator Kohl, Chair of the Senate's Special Committee on Aging, on a provision, the Balancing Incentive Payment Program (BIPP) that will incentivize states to rebalance their Medicaid spending for long term care from institutional care to home and community-based services. Dr. Berwick, for program to realize its full potential, it is important to allow states the flexibility to target home and community-based services to "specific populations" and to offer different type, amount, duration, or scope of home and community-based services for such populations and to apply this principle to the BIPP using improved targeting authority that the 1915 (i) state plan amendment (Sec. 201) provides. This allows states to apply this funding in the most cost-effective and flexible manner possible.

2. **Dr. Berwick, is this something that CMS is willing to commit to allow states the optimum flexibility in implementing this provision?**

Answer: The Balancing Incentive Payment Program (BIPP) will help States provide more people with home and community-based services, which are often preferred by beneficiaries over nursing home or other institutional care. This is an important change in the delivery system, and I commend you for your leadership on it. I understand from my staff that we are working with you on the concern you raise in your question. As we move forward with the implementation of this provision, my staff and I are happy to continue to work with you, Senator Kohl, interested States and other stakeholders to ensure that the BIPP provides States with the maximum flexibility available under the law to provide more people with additional long-term care supports and options.

Prospective Payment System

It is critical that, as CMS implements the new Prospective Payment System (PPS), it implements it correctly as it applies to the Medicare End Stage Renal Disease (ESRD) program. Because dialysis centers were given the opportunity to opt out of the transition period, the Agency estimated the number of facilities that would elect to move into the bundle in 2011 rather than transition into the bundle. The amount of the four-year transition adjustment is driven by the number of dialysis facilities that opt out of the transition period and receive payment solely under the ESRD PPS. In the final rule, CMS estimated that 43 percent of facilities will opt out of the transition. This estimate results in an adjustment that cuts the payment amount by 3.1 percent. This would reduce payments to dialysis facilities by $6.75 per treatment in 2011, which will have a negative impact on patients. It is vital that the agency quickly substitute the actual number for its estimated number.

3. **Is CMS willing to take action to waive the rulemaking requirement and recalculate the transition adjustment based upon the actual number of facilities that opt out of the transition?**

Answer: CMS' calculation of the transition budget neutrality adjustment was based on the best available data to estimate payments during the transition period and our best projections of the number of facilities that would opt out of the transition period was based on the best available data. The transition budget neutrality adjustment will be updated each year of the transition (CY 2012 and CY 2013) to reflect actual data on providers electing to opt out. We are considering whether to prospectively correct for over- or understatement of the number of facilities that choose to opt-out of the transition when we update the adjustment for 2012 and will address this issue in future rulemaking. We are not in the position to change our final regulations and associated payment amounts for CY 2011; however, the future changes will ensure the most accurate payments moving forward.

Primary Care

The Affordable Care Act includes a provision, effective in 2013, requiring states to pay primary care physicians no less than 100 percent of Medicare payment rates in 2013 and 2014 for primary care services.

4. What is CMS's timeline for implementing guidance on this provision?

Answer: Section 1202 of the Health Care and Education Reconciliation Act of 2010 (HCERA) provides for 100 percent Federally-funded increases in Medicaid fee-for-service and managed care payments for primary care services in 2013 and 2014. We anticipate issuing guidance that will help States implement this provision in advance of its January 1, 2013 effective date.

Washington State providers have long been leaders in innovative care delivery. As a result, one of our most innovative providers—the Everett Clinic—is participating in the Physician Group Practice (PGP) Demonstration Project. All of the participants are committed to transforming Medicare's delivery system and believe that the Accountable Care Organization (ACO) model is important to transforming the current system. The Clinic has four concerns (which were also detailed in September 24, 2010 letter) that I would like to reiterate.

a. First, the design of PGP version 2 provides no incentives for small systems to participate. In addition, with no support from CMS for startup costs, implementation will actually cost money.

b. Second, the participants seek clarity on how "terms and conditions," such as pending physician fee schedule decreases and the Geographic Practice Component Indices (GPCI) adjustments will be reflected in the national fee-for-service (FFS) expenditure calculations. Such adjustments will have significant impacts on performance payment calculations. Clarification from CMS on these possible impacts and strategies for addressing these (such as a possible exemption for participants from National Medicare FFS expenditure targets) would be appreciated.

c. Third, there are problems with the retrospective nature of parts of the proposed model. Retrospective attribution of patients to a PGP prevents PGPs from targeting particular populations for cost-saving interventions.

d. Finally, issues of timing and the availability of data for both claims data and national FFS expenditure data remain. Usually, up to three years of good data are needed to make good projections.

5. These are all issues that the Everett Clinic, along with the Billings Clinic, and Park Nicollet expressed in their September 24, 2010 letter. Clarification of these issues will lead to continued positive collaboration between these PGP participants and

CMS. Will CMS continue conversations with the PGP participants to resolve these concerns in advance of the January 1, 2011 inception date?

Answer: We have appreciated the leadership that the Everett Clinic, Billings Clinic, and Park Nicollet have shown through their participation in the Physician Group Practice (PGP) demonstration and we are carefully considering the issues they have identified regarding the design of the PGP version 2 demonstration. We intend to continue working collaboratively with all the PGP sites to enhance quality, improve beneficiary outcomes, and increase efficiency of care.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Carper:

Questions for the Witness:

Waste and Fraud

From my work on this Committee, and my work on the Subcommittee on Federal Financial Management that I chair, I have learned about the many steps that The Centers for Medicare and Medicaid Services is taking to curb waste and fraud and to recover a lot of the overpayments made to providers. Some of these steps are in motion, others await implementation, and some cannot be implemented without Congressional action. I look forward to partnering with you and your team as the Administration and Congress seek new ways to reduce waste and fraud, while implementing our new health care reform legislation.

1. **Could you describe in more detail the additional authority the Affordable Care Act gives your agency to curb Medicare and Medicaid waste and fraud? Could you also describe some of the additional steps that your agency is taking to combat waste and fraud?**

Answer: The Affordable Care Act provides CMS with additional tools to help the Agency tailor interventions to address areas of the most significant risk. Enhanced screening requirements for providers and suppliers to enroll in Medicare, Medicaid, and CHIP, along with oversight controls such as a temporary enrollment moratorium and pre-payment review of claims in high risk areas, will allow the Agency to better focus its resources on addressing the areas of greatest concern and highest dollar impact.

To provide you with further examples, the Affordable Care Act requires States to report an expanded set of data elements to the Medicaid Management Information System (MMIS) that will strengthen CMS' program integrity work within State Medicaid programs. Section 6507 of the Affordable Care Act requires States to use the National Correct Coding Initiative to improve coding practices in Medicaid. CMS issued a State Medicaid Director (SMD) letter on September 1, 2010 to advise States on how to implement programs to meet these Section 6507 requirements. In addition, the Affordable Care Act requires data sharing between Federal entities to monitor and assess high risk program areas and better identify potential sources of fraud. CMS will expand its Integrated Data Repository (IDR) to include claims and payment data from other Federal agencies, and building on our efforts to better integrate Medicare and Medicaid data, intends to enter into data sharing and matching agreements with the Department of

Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential waste, fraud, and abuse throughout Federal health programs.

CMS currently has and is already using its authority to examine predictive analytics and modeling concepts through several pilots that will utilize new technologies supporting a combination of behavioral analysis, network analysis, and predictive analysis to identify fraud. While these technologies may hold great benefit in identifying and combating fraud, we plan to test them in a series of pilot programs to determine which of the myriad of approaches holds the most promise for Medicare before moving broadly to a wholesale application or system-wide changes. Therefore, CMS expects to conduct a number of pilots that will focus on identifying fraudulent providers on the front-end and recognizing complex patterns of fraud in improper claims and billing schemes.

Additionally, the Affordable Care Act requires both Medicare and Medicaid program integrity contractors to assemble and track performance statistics, including the number of overpayments identified, the number of fraud referrals, and the return on investment, and to provide such statistics to the Secretary and OIG as requested. In addition, the Affordable Care Act grants the Secretary new flexibility to utilize Health Care Fraud and Abuse Control funds to hire and train Federal employees for pursuing waste, fraud, and abuse in Medicare, rather than relying exclusively on contractors. All of these new authorities and analytical tools will help move CMS away from its historical "pay and chase" mode towards a closer alignment with strong fraud deterrents and increased enrollment screenings, new disclosure and transparency guidelines, and early identification of high-risk providers and suppliers.

This list of the new authorities to fight fraud in our programs is not exhaustive, but gives you an idea of the many ways in which CMS is able to ramp up its fraud, waste, and abuse efforts.

2. **From what I have learned from my staff, the Centers for Medicare and Medicaid Services has made the anti-waste and anti-fraud provisions of the Affordable Care Act a priority. Has your agency met all the implementation deadlines for the anti-waste and anti-fraud provisions contained in the Act?**

Answer: CMS has worked very hard to meet the Affordable Care Act deadlines, and to date, we have met substantially all statutory deadlines for implementing anti-waste, anti-fraud, and other provisions of the Affordable Care Act.

As Administrator, I will continue to insist that CMS work as aggressively as possible to meet the deadlines of the Affordable Care Act.

Recovery Audit Contractors

Many of my fellow committee members, including myself, pressed for the inclusion of the use of Recovery Audit Contractors in all of Medicare and Medicaid to recover overpayments in the Affordable Care Act. Through recovery auditing, internal auditors or outside contractors identify and recover improper payments, such as duplicate payments or payments for medical procedures that never happened. This innovative tool is widely

used in the private sector and now we have seen its successful use with Medicare. The relatively small pilot program covering just several states recovered $54 million in 2006, then $247 million in 2007, $392 million in 2008 and by 2009 a total of more than $1 billion dollars in Medicare overpayments was recouped and returned to the Trust Fund.

3. **When will the Recovery Audit Contractor provision of the Affordable Care Act be implemented? Do you expect continued success with this program?**

Answer: As you know, the Affordable Care Act expanded the use of Recovery Audit Contractors (RACs) from fee-for-service Medicare to Medicare Parts C and D and Medicaid. CMS expects that RACs will continue to be a successful component of our efforts to protect program integrity and prevent improper payments.

CMS is on schedule to meet the statutory deadline established by Congress for coordinating with and supporting State efforts in establishing State Medicaid RACs. CMS has notified States, through a State Medicaid Director letter issued October 1, 2010, that they must submit a State Plan Amendment to establish a RAC program or seek an exemption by December 31, 2010. Further, on November 5, 2010, CMS published a proposed regulation to help States reduce improper payments for Medicaid health care claims through the use of Medicaid RACs. The Affordable Care Act enables the Secretary, working through CMS, to allow extensions or exceptions to States, if necessary, and details regarding these processes are included in the proposed regulation. In addition, the proposed regulation outlines the requirements that States must meet and the Federal contribution CMS will provide to assist in funding the State RAC programs. CMS has provided significant technical assistance to States through all-State calls and webinars and has begun the coordination with States that have RAC contracts in place, as required by the statute. CMS will also work to ensure that States and their Medicaid RACs coordinate their recovery audits with other entities and to minimize the likelihood of overlapping audits.

CMS is striving to contract with RACs to identify fraud and overpayments in the Medicare Parts C and D programs in as expedient a manner as possible. Before the end of the year we intend to solicit comment on the use of RACs in the Part C program to allow stakeholder an opportunity to comment on the best possible structure for RAC programs. We are carefully considering the most effective use of RACs, given the payment structures for both programs and the other audit initiatives for these programs. While we want to take full advantage of the unique structure of the RAC program, we also want to ensure that we are not duplicating the efforts of other audit initiatives. This approach will maximize the return on investment that the Federal government will receive from contracting with these entities.

Delivery System Reform

One of my most important priorities as we were writing the health care reform law was to find ways to improve the quality and efficiency of our health care system. I am cautiously optimistic that the Center for Medicare and Medicaid Innovation that was launched yesterday will become one of the most effective tools that the health care reform law uses to improve and strengthen our health care system.

4. **Can you describe the implementation of the Center for Medicare and Medicaid Innovation and tell us how this new program and the other health care delivery system reforms in the Affordable Care Act will help to improve our nation's health?**

Answer: CMS is working to get the Center for Medicare and Medicaid Innovation (Innovation Center) up and running as quickly as possible. A Federal Register announcement of the Innovation Center, including its mission and organizational structure, was released on November 17, 2010. CMS is committed to working with stakeholder input on key operational aspects of the Center. Over the next few months, the Innovation Center will continue to engage with stakeholders across the health care sector including hospitals, doctors, consumers, payers, states, employers, advocates, relevant Federal agencies and others to obtain direct input on its operations and to build partnerships with those that are interested in its work. These consultations have been positive and productive in forming the relationships and partnerships with clinical and analytical experts that the Innovation Center will need in order to achieve its mission to improve the coordination, quality, and efficiency of health care services furnished to individuals receiving benefits under Medicare, Medicaid, or CHIP.

Already, the Innovation Center is starting preliminary work on projects including the Federally Qualified Health Center Advanced Primary Care Practice Demonstration, and the State Demonstrations to Fully Integrate Care for Dual-Eligible Individuals.

The Innovation Center will also test models that include establishing an "open innovation community" that serves as an information clearinghouse of best practices in health care innovation. Further, the Center will work with stakeholders to create learning communities that help other providers rapidly implement these new care models and adjust models as necessary to achieve optimal results. I am confident that the lessons learned through the Innovation Center for Innovation demonstrations will work to improve our care delivery system, and a better system will lead to better health for all Americans.

<u>New Medicare Benefits</u>

The Affordable Care Act increases the Medicare benefits available to seniors. For example, before the Affordable Care Act was passed, Medicare beneficiaries were only eligible for a physical during their first year in Medicare. Thanks to the new health care reform law, beginning in January 2011, Medicare beneficiaries will receive free annual checkups that include cognitive screening and free preventive care, including screenings for cancer and heart disease without cost-sharing. Seniors who hit the Medicare Part D "Donut Hole" will experience a 50 percent discount in their drug expenses. However, I rarely hear about these new Medicare benefits. Instead, many Delawareans are concerned that the Affordable Care Act made cuts to Medicare that will cause them to lose the coverage of services they rely on.

5. **What new benefits are available to Medicare beneficiaries as a result of the new health care reform law? What is CMS doing to set the record straight and**

communicate to seniors about what the real effect of the new health care reform law will be on Medicare?

Answer: The Affordable Care Act provides Medicare beneficiaries with enhanced benefits and lower out-of-pocket costs for many recommended preventive services. While Medicare already covers a comprehensive package of preventive benefits as well as a one-time "Welcome to Medicare" exam for new beneficiaries, before the enactment of the Affordable Care Act, Medicare did not cover annual check-ups for beneficiaries. Beginning in 2011, Medicare will cover an annual "wellness visit" at no cost to the beneficiary, so beneficiaries can work with their physicians to develop and update a personalized prevention plan. This new benefit will provide an ongoing focus on prevention that can be adapted as a beneficiary's health needs change over time.

In the past, many screening and preventive services were underutilized by Medicare beneficiaries in part because out-of-pocket costs have presented a financial barrier. Beginning in 2011, all preventive benefits covered by Medicare that are recommended with an A or B rating by the U.S. Preventive Services Task Force will be available to beneficiaries free of charge (without having to pay coinsurance or apply the Part B deductible). These important benefits include tests and procedures that may either prevent illnesses or detect them at an early stage when treatment is likely to work best, such as screenings for breast, cervical, and colorectal cancers, and screenings for cardiovascular disease, diabetes, and osteoporosis.

In addition, new provisions in the Affordable Care Act provide important new benefits to Medicare beneficiaries in the Medicare Part D prescription drug benefit. In 2010, seniors who purchase drugs within the coverage gap will receive a $250 rebate check. For 2011, CMS is initiating the phase-in of provisions to provide coverage for seniors in the coverage gap. The Secretary has entered into agreements with drug manufacturers to provide a 50 percent discount on brand name drugs and biologics purchased in the Part D coverage gap by Medicare beneficiaries enrolled in Part D who do not receive the low-income subsidy. The vast majority of brand-name Part D drugs are participating in the program for 2011.

Additionally, we are beginning to phase-in coverage of drugs in the coverage gap. The coverage for drugs in the gap will increase incrementally each year until 2020. In 2020, beneficiaries will pay only 25 percent of the costs of brand name and generic drugs until they reach the catastrophic limit (where they will then pay only the greater of a small copayment or 5 percent of the cost of drugs). Coverage in the donut hole on brand name drugs will be 75 percent when combined with the manufacturer discount, and Part D coverage on generic drugs will be 75 percent.

CMS and HHS have a responsibility to educate beneficiaries about their Medicare benefits and what coverage options are available to them. To that end, CMS will take a multi-pronged education and outreach approach, using advertising, news releases, public service announcements, local town hall meetings, and health fairs to reach beneficiaries. The new benefits and cost-sharing changes were explained in the 2011 Medicare & You Handbook, which was recently mailed to all beneficiaries.

Medicaid Drug Rebate Program

CMS has been dealing with the important and complex task of ACA implementation. There are several provisions in ACA that impact the Medicaid program and require agency rulemaking in order to be operationalized. One area that receives less attention is CMS's implementation of the Medicaid Drug Rebate program increases and expansions, which go into effect in 2010. For example, there are concerns about CMS's lack of clarity on some very technical rebate issues, including guidance related to line extensions. The lack of clarity could create access issues in states and this, in turn, could negatively affect vulnerable patient populations. For example, access could be jeopardized for patients in the mental health community or those suffering from chronic conditions. We owe it to patients for CMS to implement ACA in a manner that does not put at risk access to medicines and generate added confusion around health reform.

6. **Administrator Berwick, can you please respond as to how you are working with your staff to ensure a smooth and timely implementation of the ACA provisions impacting Medicaid rebates, specifically regarding the guidance around Medicaid rebates for line extensions, so that these patient access concerns are addressed?**

Answer: CMS has worked aggressively to implement changes to the Medicaid Drug Rebate Program as required by the Affordable Care Act.

Since the passage of the Affordable Care Act, CMS has sent two State Medicaid Director (SMD) letters providing guidance on the implementation of the drug rebate provisions in section 2501 of the Act. We are moving forward to implement these changes and are committed to providing timely and relevant information to stakeholders. We are also happy to consult directly with States to ensure that States continue to provide timely access to necessary medications. Because rebates are not processed until after prescription drugs have been dispensed to beneficiaries, we do not anticipate any negative impact on beneficiaries' access to important medications while clarifying regulations are developed.

Specifically, in our April 22nd SMD letter, we indicated that future guidance will be issued to provide information on the process that will be used to identify clotting factors, drugs with pediatric indications, and line extensions of existing drugs. CMS' April 22, 2010 SMD letter can be found at http://www.cms.gov/smdl/downloads/SMD10006.pdf and the September 28, 2010 SMD letter can be found at http://www.cms.gov/smdl/downloads/SMD10019.pdf.

High Performance Health Care

When I visited the Cleveland Clinic last year, I looked for best practices that our country's hospitals and health care providers could embrace. For example, I was impressed with how the Cleveland Clinic had made a significant investment in health information technology and electronic health records to increase the quality of their health care and to improve their patients' health.

7. **In your judgment, what are some of the best practices that high quality and efficient health care systems demonstrate? How does the health care reform law help our hospitals and health care providers emulate these high performing health care systems?**

Answer: Every high quality and efficient health care system is different and is uniquely designed to best meet the needs of the people it serves. The correct solutions for New York City will differ from those in rural Montana. However, high performing health care systems often have many traits in common. Efficient systems are often integrated systems, in which providers work together and communicate clearly in pursuit of the best possible outcome for each patient. High quality systems are frequently patient-centered, with an overarching focus on the patient that drives safe, error-free medicine based on an individual's wishes. High quality systems also tend to invest in health information technology such as electronic health records (EHRs), which can promote prompt and secure communications between providers, improve safety, and reduce unnecessary tests and procedures. CMS has worked closely with our colleagues at the HHS Office of the National Coordinator for Health Information Technology (ONC) to ensure that our payment programs properly incentivize hospital and physician adoption of EHRs that meet a high standard of clinical sophistication and interoperability while protecting patient privacy.

The Affordable Care Act provides a variety of tools to help replicate success throughout the country. For example, the Center for Medicare and Medicaid Innovation will test and study the most promising innovative payment and service delivery models. The Innovation Center will work with relevant Federal agencies and clinical and analytical experts, as well as local, national and regional providers, States and beneficiary organizations to identify and promote systems changes that can improve quality and outcomes for patients while containing costs. The Affordable Care Act will also reward high performing systems through value-based purchasing, while incentivizing others to improve their performance.

Prevention and Wellness

Our country faces an obesity epidemic that forces us to consider the possibility that our children may become the first American generation to have shorter lives than their predecessors. We have a responsibility to ensure that Americans have the tools and knowledge to change their own behavior and lifestyle. However, public health and education also have their limits.

8. **What do you see as the government's role in promoting prevention and wellness and what can we do to encourage Americans to take more responsibility for their own health and wellbeing?**

Answer: Our system is often faulted for its focus on health care for the sick, instead of promoting better health for all. CMS is implementing a variety of initiatives that will encourage prevention and move towards the goal of improving the health of the entire population. CMS can meaningfully contribute to improving prevention of a variety of health problems, including obesity, cardiovascular disease, and improving perinatal outcomes. In addition to expanding

health insurance coverage, the Affordable Care Act provides meaningful and affordable coverage of preventive health services.

The new "Annual Wellness Visit" benefit in Medicare will provide an ongoing focus on prevention that can be adapted as a beneficiary's health needs change over time. While Medicare covers a range of screening and preventive benefits, many of these services have been underutilized, in part because out-of-pocket costs have presented a financial barrier for beneficiaries. Beginning in 2011, all preventive benefits covered by Medicare that are recommended with an A or B rating by the U.S. Preventive Services Task Force will be available to beneficiaries free of charge (without having to pay coinsurance or apply the Part B deductible). Additionally, under the Affordable Care Act, States must provide pregnant women with Medicaid coverage of tobacco cessation services, including counseling and pharmacotherapy, and beginning in 2014 Medicaid will cover tobacco cessation drugs generally.

RUG-IV

9. **Although Congress has the ultimate responsibility for repealing the RUG-IV implementation delay contained in PPACA, if Congress does not act during the lame duck session, how will CMS implement the RUG-III hybrid in the interim?**

Answer: As you know, the Medicare and Medicaid Extenders Act of 2010 repeals the delay of the updated case-mix classification system for Medicare's skilled nursing facility (SNF) prospective payment system (known as RUG IV). This legislation will allow RUG IV to go into effect on October 1, 2010, consistent with the final SNF payment regulation for FY2011.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Cornyn:

Questions for the Witness:

Medicaid

Next year, the state of Texas must address an $18 billion budget gap. Since Medicaid comprises a quarter of the Texas state budget, finding reasonable ways for Texas – and every other state – to manage their programs is crucial. The maintenance of effort requirements in current law make it particularly difficult for states to effectively manage their programs, but I am interested in learning more about how CMS plan to interpret MOEs in areas where the statute is not specific.

1. **Specifically, could you tell me how CMS plans to interpret the maintenance of effort requirements with regard to Section 1915 waivers?**

Answer: CMS has not yet issued guidance on this maintenance of effort provision so I cannot comment on the specifics. However, we are currently evaluating the need for future guidance on the maintenance of effort requirements, and will take this question into consideration.

2. **In the future, the Medicaid expansions under the Patient Protection and Affordable Care Act place costly new burdens on the states. In Texas, the state will need to come up with $27 billion over the 2014 to 2023 period. How do you propose states pay for their share of the Medicaid expansions? Please be specific.**

Answer: The Affordable Care Act doesn't ask States to assume the cost of the Medicaid eligibility expansion on their own; the Act provides substantial financial support for States to help them accomplish the task. For the first three years of the expansion (2014-2016), States will receive 100 percent FMAP for expenditures related to the newly eligible adult population. By 2020, the Federal matching rate will decline to 90 percent, where it will remain. States that had expanded Medicaid eligibility levels prior to the Affordable Care Act also will receive significant Federal support beginning in 2014.

Numerous experts agree that States will actually realize a net savings from the provisions of the Affordable Care Act. The expansion of coverage will significantly reduce uncompensated care, which States currently cover in part. A reduction in uncompensated care will also decrease the cost-shifting that raises premiums for people with insurance, including State employees, by up to $1000 for a family plan. Many States also currently spend their own State dollars on programs to

cover the uninsured, which will not be necessary following the coverage expansion in the Affordable Care Act.

3. **Some states have Medicaid eligibility improper payment rates as high as 20%, but states are currently restricted from implementing reasonable measures to fix those eligibility improper payment rates. Would you be supportive of allowing states to use reasonable tools, such as requiring drivers licenses, to verify eligibility?**

Answer: The Payment Error Rate Measurement (PERM) program, which measures improper payments in the Medicaid program, estimates the eligibility improper payment rate based on review by the States of their respective eligibility policies and standards. States have flexibility under Federal law and regulations to adopt the tools they find reasonable to verify eligibility for their Medicaid programs. To the extent that high eligibility improper payment rates are identified, CMS requires States to submit a corrective action plan identifying root causes of errors and developing corrective actions specifically designed to reduce improper payments, including eligibility improper payments.

You asked specifically about the merits of permitting States to require drivers' licenses to verify eligibility in order to reduce eligibility improper payment rates. As you may know, the Deficit Reduction Act (DRA) included a citizenship documentation requirement, implementation of which initially required Medicaid applicants to submit original documents to confirm their eligibility. In the years following, some States reported that the main effect of the DRA requirement was to delay or deny benefits for eligible U.S. citizens who do not have easy access to these required documents. While States are still permitted to require documentation, including drivers' licenses, many States have taken advantage of the State option (enacted as part of the Children's Health Insurance Reauthorization Act of 2009) to comply with the DRA citizenship documentation requirement by matching Medicaid and CHIP application data against the Social Security Administration's database. We are very pleased with the results so far and continue to monitor eligibility closely to ensure that only eligible individuals receive Medicaid.

Medicare

I am concerned that CMS' Andy Griffith ad campaign material contains misinformation that may be confusing seniors about changes to the Medicare program. Recently, some of my Senate colleagues sent a letter to Secretary Sebelius to ask her whether HHS had consulted the Office of the Actuary at CMS (OACT) – an independent Medicare expert within CMS – about the mailings. Unfortunately, we did not get a direct answer.

4. **Could you tell me whether or not OACT has vetted the Andy Griffith ad campaign materials?**

Answer: The CMS Office of the Actuary (OACT) assists the Agency by providing timely, impartial, and authoritative estimates and analysis of health care financing and spending. OACT does not review educational materials for beneficiaries that are not specifically related to estimates of heath care financing and spending.

On October 19, 2010, the non-partisan Government Accountability Office (GAO) issued an opinion that found unequivocally that the Andy Griffith television advertisements did not violate the publicity or propaganda standard.

5. **Will you agree to have OACT vet all future mailings, TV ads, and other mass communications regarding the Medicare program in advance, and to abide by their recommendations?**

Answer: The CMS Office of the Actuary (OACT) assists the Agency by providing timely, impartial, and authoritative estimates and analysis of health care financing and spending. CMS consults with OACT whenever its actuarial expertise is relevant.

Deficit Commission

We all know that this country is in one of the worst fiscal crises ever. Our publically-held debt is more than $13 trillion and this year's budget deficit is around $1.3 trillion. President Obama created the bipartisan Deficit Commission to try to address the deficit – an idea that Senators Conrad and Gregg first developed and that I have supported. Last week, the Co-Chairs of the Commission released a draft proposal, and some of the recommendations affect CMS.

6. **As the Administration official charged with leading policy on Medicare and Medicaid, could you give us your thoughts on some of those draft recommendations? Specifically, I understand that paying lawyers less and reducing the cost of defensive medicine through tort reform saves $64 billion. Is that something you could be supportive of?**

Answer: While medical malpractice liability reform is not in my purview as CMS Administrator, I do agree that our medical liability system needs to be examined, to ensure that it meets four goals: 1) putting patient safety first and working to reduce preventable injuries; 2) fostering better communication between doctors and their patients; 3) ensuring that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits, and 4) reducing liability premiums.

As you know, prior to the enactment of health reform, the Administration took steps towards these goals by conducting a review of reforms that have been pursued, and instituting a program to provide grant funding for states and health systems to be able to develop innovative solutions to challenges with patient safety or medical liability.

7. **What are your thoughts on the Co-Chairs draft Deficit Commission recommendation to save $11 billion by better managing the care of dual eligibles through Medicaid managed care?**

Answer: I agree that better managing the care of dual eligibles presents an excellent opportunity to improve the quality of health care and use resources more efficiently. The Affordable Care Act establishes a Federal Coordinated Health Care Office whose role is to more effectively

integrate benefits under Medicare and Medicaid and better coordinate the care and needs of this medically needy population. Additionally, early next year the newly created Center for Medicare and Medicaid Innovation will award up to 15 State program design contracts to help States support Demonstration projects to better coordinate the care of dual eligibles. We are excited about the potential to better manage and improve care for the dually eligible population through the work of these two new offices. CMS plans to regularly meet with and update key stakeholders, including Congress, on our progress in this area.

However, at this time, it is premature for me to comment on any specific recommendations put forward by the Deficit Commission.

Independent Advisory Board

The Independent Advisory Board (IPAB) was created to address spending across the entire Medicare system, yet nearly half or more of the system was placed off limits for IPAB recommendations. Furthermore, OACT has stated that the depth of the Medicare cuts in the Patient Protection and Affordable Care Act may "jeopardize access to care."

8. **Can you explain how the IPAB will address growing Medicare costs when half the program is excluded and when current levels of Medicare cuts are unrealistic? What other areas do you believe should be cut under IPAB in the Medicare program?**

Answer: Experts agree that the Independent Payment Advisory Board (IPAB) will make care and coverage more affordable for seniors. It was one of the key parts of health reform that will set our system on a path to sustainability in the long run. We believe that the IPAB will address increasing Medicare costs by proposing changes that will extend the program's solvency, rein in health care expenses, and implement the health service delivery reforms that are so important to being able to provide efficient and quality health care. The CBO has estimated that IPAB will save $15.5 billion between 2010-2019. The Administration has expressed strong support for the creation of the IPAB.

Changes to Medicare are incorporated in estimates for both the budget and the HI Trust Fund. As a result of the changes and efficiencies in the Affordable Care Act, the Federal deficit has been reduced, and the Medicare Trust Funds are more sustainable.

CMS Actuary Report

In your testimony, you claim that the fiscal future of Medicare is stronger because of the Patient Protection and Affordable Care Act.

9. **Are you aware that your own CMS Actuary has stated, "In practice, the improved Part A financing cannot be simultaneously used to finance other Federal outlays (such as the coverage expansions under the PPACA) and to extend the trust fund, despite the appearance of this result from the respective accounting conventions"?**

Answer: I am aware that the Actuary made this assessment on December 23, 2009, but I would note that the CMS Actuary (OACT) made an estimate, as did CBO and others, and this statement was made before the enactment of the Affordable Care Act. It is important to remember that economic projections require making assumptions about the future which includes many uncertainties and is very difficult to predict. The degree of accuracy for these projections often varies. For instance, the Actuary underestimated the savings from the Balanced Budget Act and overestimated the cost of implementing the Medicare Part D prescription drug benefit.

We are not double counting. CMS has adhered to standard accounting practices in estimating the available savings in the Affordable Care Act. The outlooks and projections for the Hospital Insurance (HI) Trust Fund and the Federal budget are two separate calculations. Changes to Medicare are incorporated in estimates for both the budget and the HI Trust Fund. As a result of the program changes and efficiencies established by the Affordable Care Act, the Federal deficit has been reduced and the Medicare Trust Funds are more sustainable.

10. **Private health plans must meet risk-based capitalization requirements to show that they have enough money to pay the bills if something catastrophic happens. Based on your understanding of the Medicare program's finances, do you believe that the Medicare program could meet the same solvency requirements that private health plans must meet?**

Answer: Due to its unique size, scope, and nature as an entitlement program required by law to provide care to eligible beneficiaries, it would be difficult to draw a precise comparison between Medicare and the solvency requirements faced by private insurers. Nevertheless, Medicare remains a fiscally sound program. With the changes in the Affordable Care Act, Medicare's Trust Funds are solvent through 2029, which is a longer term window of solvency than any private insurer would have to meet. In addition, Medicare is subject to a comprehensive actuarial evaluation and report each year, which allows the Administration and Congress to continually assess the fiscal health of the Medicare program. Further, with nearly 50 million beneficiaries who depend on Medicare for their health care needs, Medicare draws upon a much larger risk pool than private insurers, which limits the likelihood that a small number of very sick patients could cause fiscal imbalances. Also, private insurers are not required to adhere to the same level of public transparency and open scrutiny as compared to a taxpayer-funded, public entity such as Medicare.

Improper Payment Rate

11. **CMS recently released its improper payment rates for 2010. The President has stated a goal of reducing the improper payment rate by 50% by 2012. What specific steps is CMS taking to achieve that?**

Answer: CMS is committed to meeting the President's goal to cut the Medicare error rate in half by 2012 and is on track to meet this goal. We are steadily working to reduce error rates in all Federal health care programs and ensure that appropriate payments are made.

CMS expects that it will be able to meet the President's goal through the implementation of the new authorities provided by Congress through the Affordable Care Act.

CMS is pursuing the following activities to reduce the Medicare FFS improper payment rate:

- Continuing to share data among MACs and developing strategies to decrease errors
- Increasing our use of pre-payment review of claims
- Issuing comparative billing reports for hospitals and other entities
- Focusing our medical review on error prone areas
- Conducting additional provider outreach and education on the proper billing for error prone areas
- Conducting more targeted reviews of problem providers
- Implementing face-to-face prescribing requirements for high dollar, high risk durable medical equipment items
- Finalizing a proposed regulation implementing new provider enrollment screening and revalidation risk categories
- Published an interim final rule requiring all physicians who order or refer for Medicare beneficiaries to be enrolled in Medicare

Medicare Fraud

12. **In effort to fight Medicare fraud, I have introduced legislation to move from a "pay and chase" approach to a "detect and prevent" approach. I understand that CMS has explored ways to do this as well. Could you provide an update on these efforts with specifics on what payment policy changes have been made to date?**

Answer: I appreciate your interest in this issue and certainly share your commitment in finding and developing new tools to help us move away from pay and chase and towards preventing fraud before it occurs. To that end, CMS currently has and is already using its authority to examine predictive analytics and modeling concepts through several pilots that will utilize new technologies supporting a combination of behavioral analysis, network analysis, and predictive analysis to identify fraud. While these technologies may hold great benefit in identifying and combating fraud, we plan to test them in a series of pilot programs to determine which of the myriad of approaches holds the most promise for Medicare before moving broadly to a wholesale application or system-wide changes. Therefore, CMS expects to conduct a number of pilots that will focus on identifying fraudulent providers on the front-end and recognizing complex patterns of fraud in improper claims and billing schemes.

CMS is very excited about the potential of these new data analysis and prediction tools to improve the Agency's ability to prevent fraudulent claims from ever entering our system. Before CMS expands predictive analytic tools to prepayment claims application, we are applying predictive analytics and modeling on a post-payment basis. This will allow us to do three things. First, it will help us ensure these technologies will not result in false positives – disrupting payments and business for legitimate providers. It is imperative the predictive models are developed and tested prior to implementation to avoid a high rate of false positives – we want to ensure that claims are paid for legitimate providers without disruption or hassle. Second, given there are many different types of predictive analytics and modeling technologies, it will

allow CMS to determine which ones are best suited to Medicare's unique needs. We first want to identify the predictive analytics that are cost-effective and will produce more successful fraud detection than other types of fraud detection measures. Third, incorporating this approach to our pre-payment processes will require significant systems changes. We want to ensure effective use of taxpayer funds before making a significant investment of CMS resources in complex system changes, and we want to ensure we are on the right track.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Crapo:

Questions for the Witness:

Medicaid

A May 2010 report from the Centers for Disease Control and Prevention found that individuals with Medicaid coverage were more likely to visit the emergency room in a 12-month period than those individuals with private insurance and the uninsured. Given the access issues in the Medicaid program, it is clear that emergency rooms have been the only access point for primary care for many Medicaid beneficiaries.

1. **Is there anything under the Patient Protection and Affordable Care Act (PPACA) that can help states to fix this problem? What will you, as CMS Administrator, do to provide states with additional resources or to help states bring on new providers to the Medicaid program?**

Answer: As Administrator of CMS, I am committed to ensuring access for Medicaid beneficiaries. Medicaid has a proven track record of delivering high quality care to vulnerable, low-income populations who do not have another source of care. While there are certainly isolated challenges, data suggests that access to care in Medicaid is comparable to access in the private market. Still, there is always room for improvement as we approach the Medicaid expansion in 2014. The Affordable Care Act includes a provision to help States boost their Medicaid reimbursement rates to Medicare levels for two years, which is a good first step.

In addition, the newly formed Medicaid and CHIP Payment and Access Commission (MACPAC) will also play an important role by providing research and analysis on provider payment rates and access in the Medicaid program. MACPAC will help analyze and evaluate changes to provider rate changes necessary to ensure that all Medicaid beneficiaries have access to care. We anticipate working closely with them as we do with MEDPAC, thinking seriously about how to sustain access to care in 2014 and beyond. My vision for Medicaid, and for Medicare, is to continue improvements that enable us to align payment and quality.

Medicare Advantage

On September 24, I sent a letter, along with Ranking Member Grassley and Senators Kyl and Hatch, to Rick Foster, Chief Actuary at the Centers for Medicare and Medicaid Services, regarding the impact of the Patient Protection and Affordable Care Act on the

Medicare Advantage program. This is an important program for my home state of Idaho with nearly 25% of Idaho's Medicare beneficiaries participating in the Medicare Advantage program. The letter indicates that provisions in the Patient Protection and Affordable Care Act "will cause a large increase in the out-of-pocket costs incurred by MA enrollees."

2. **How would you reconcile this analysis with the many promises made throughout the health care debate that PPACA will lower costs for seniors on Medicare?**

Answer: Cost-sharing charged by plans and the supplemental benefits offered by plans change from year to year and are based on business decisions made by each Medicare Advantage (MA) Organization. As they do every year, beneficiaries need to reassess their options and pick a plan that best meets their needs balancing their financial capacity with desired benefit packages. Each and every beneficiary still has guaranteed access to all Medicare benefits through Original Fee-For-Service Medicare.

In their March 2010 report to Congress, MedPAC supported financial neutrality between FFS and Medicare Advantage, and adjusting the benchmark was an appropriate solution to this imbalance. Prior to passage of the Affordable Care Act, MedPAC estimated that the cost of the MA program was equivalent to every Medicare beneficiary paying an additional Part B premium amount at a cost of about $1-3 per month, even the nearly 80 percent of beneficiaries who were enrolled in Original Medicare.

Nevertheless, CMS is very committed to strengthening the MA program for beneficiaries and improving the quality of all MA plans. As a result of our negotiation authority with MA plans, for the 2011 plan year we are returning an estimated $150 million in value to beneficiaries through better benefits or lower out-of-pocket costs.

The recently announced MA quality bonus program will provide bonuses for MA plans that improve quality – allowing plans to earn additional payments and providing improved quality for Medicare beneficiaries. In addition, under Affordable Care Act provisions, beginning in 2012, rebate dollars available to plans to provide additional benefits will be tied to quality ratings, which will further incentivize plans to improve the care they offer. These initiatives are in line with CMS' focus on improving quality within the healthcare system, fostering a "race to the top" environment where better quality plans will result in better choices for beneficiaries.

Britain's National Health Service

A recent article from *The Guardian* entitled, "NHS cuts to run deep as spending goes up", discusses the budgetary challenges faced by Britain's National Health Service. The article states that health trusts are desperate to save money and are resorting to the rationing of care, including doctors denying basic surgical procedures that could improve the lives of patients, closing of services for weeks at a time and longer waiting periods.

3. **You have often professed your admiration for the National Health Service – does this information change your views on the NHS or do you still support government-run health care?**

Answer: The Affordable Care Act is designed to protect and strengthen the system of private insurance in this country. It is a uniquely American solution to health care reform, designed to be implemented in full partnership with the States. The Secretary, a former governor, says that unlike most Federal laws that tell States to do things and don't make them partners or give resources, this is an exceptionally State-friendly law.

Throughout my professional career, I have fought to protect the ability of patients to make health care decisions in concert with their physicians. I strongly oppose rationing and am proud of the many provisions in the Affordable Care Act will reform our nation's health care system into one that provides better care, better health for populations, and reduced costs for everyone.

Ambulatory Surgery Centers

As you know, ambulatory surgery centers (ASCs) can save Medicare and taxpayers billions of dollars by performing some outpatient surgery procedures at a substantial discount from hospital outpatient department (HOPD) payment rates. However, Medicare seems to be encouraging these cases to be performed in the higher cost setting by adopting an artificially low payment update mechanism for ASCs – the CPI which does not reflect health care inflation and is not used for any other institutional provider in Medicare. Because of this, an increasing number of ASCs are being purchased or transformed into HOPD so that they can benefit from the higher Medicare payment rates. As you know, Senator Wyden and I asked that CMS use its current regulatory authority to update ASC payments by the market basket rather than CPI. I was disappointed that this year's ASC rule failed to do that.

4. **Do you plan to revisit this issue and use your administrative authority to update ASC payments by market basket next year?**

Answer: The hospital market basket is established by CMS after analyzing data transmitted in cost reports submitted to the Agency by Medicare-participating hospitals. As the Medicare Payment Advisory Commission and the Government Accountability Office have noted[1], ASC cost structures appear to be substantively different from those of hospitals and, therefore, an update factor established using the hospital market basket as calculated may not be an appropriate update factor for ASCs.

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[1] Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy." Page 108. Washington, DC: MedPAC. Last accessed online on December 9, 2010 at http://medpac.gov/documents/Mar10_EntireReport.pdf

Government Accountability Office. 2006. *Medicare: Payment for ambulatory surgical centers should be based on the hospital outpatient payment system.* GAO report: GAO–07–06. Washington, DC: GAO. Last accessed online on December 9,2010 at http://www.gao.gov/new.items/d0786.pdf

Section 1833(i)(2)(C) of the Social Security Act specifies that payment amounts established under the ASC payments system be increased by the percentage increase in the consumer price index for urban consumers (CPI-U), if the Secretary has not otherwise updated such amounts for that year. Congress did not change section 1833(i)(2)(C) to adopt a different update factor when it set the ASC update at 0 percent in 2008 and 2009, or in the Affordable Care Act when it required the annual update under the ASC payment system to be reduced by a productivity adjustment. In view of the existing statutory language, questions regarding the appropriateness of using the market basket for ASCs, and Congress' decision not to change this provision of the law when making other statutory changes to the ASC payment system, CMS has been using the CPI-U to update ASC rates. We will continue to discuss this matter with interested parties, including the ASC industry and Congress, and look forward to other opportunities, such as in the context of the CY 2012 outpatient and ASC rulemaking, to analyze and consider this matter further.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Ensign:

Question for the Witness:

Medicare Physician Fee Schedule

In the 2011 Medicare Physician Fee Schedule Final Rule, CMS included a new requirement that all paper test order forms for laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule must contain a physician signature, abandoning longstanding existing policy that a signature is not required on these forms.

1. **How does CMS expect laboratories, physicians, hospitals and nursing homes to adjust their business practices to the new policy and replace millions of test requisition forms in the field before January 1, 2010, without disrupting patient access to these services?**

Answer: While we do not think that beneficiary access to clinical laboratory services will be disrupted as a result of the physician (and qualified non-physician practitioner; NPP) signature policy, we are meeting with stakeholders to better understand their concerns, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories about the revised policy. CMS will take these concerns into account as we determine how best to proceed.

2. **Since physicians still must authenticate orders in the patient's chart, what is CMS's rationale for adopting this policy and what evidence exists that demonstrates that this policy will address CMS' concerns regarding fraud and abuse – as opposed to simply imposing a redundant paperwork burden that is likely to delay or even prevent care?**

Answer: We believe that our revised policy will not result in an increased burden on physicians and NPPs because it is our understanding that, in most instances when physicians and NPPs use requisition forms, they are annotating the patient's medical record with either a signature or an initial, as well as providing a signature on the requisition form provided to the lab. However, we are meeting with stakeholders to better understand their concerns about the revised policy, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories. CMS will take these concerns into account as we determine how best to proceed.

3. **Is CMS willing to delay implementation for one year to identify its rationale and engage with stakeholders to explore reasonable alternatives to address its concerns?**

Answer: As mentioned above, we are meeting with stakeholders to better understand their concerns, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories about the revised policy. CMS will take these concerns into account as we determine how best to proceed.

<u>Health Care Costs – Medical Liability</u>

I am concerned about the rising cost of health care. Altogether, medical liability adds billions to the cost of health care each year – which means higher health insurance premiums and higher medical costs for all Americans. The direct cost of medical liability coverage and the indirect cost of defensive medicine increases the amount the federal government must pay for Medicare, Medicaid, the State Children's Health Insurance Program, Veterans' Administration Health Care, health care for federal employees, and other government programs. The Congressional Budget Office has indicated that comprehensive medical liability reform legislation, similar to my Medical Care Access Protection Act (S. 45), would reduce the federal deficit by $54 billion over 10 years. And, the Deficit Commission's draft recommendations include a proposal to cap non-economic and punitive damages and make other changes in tort law – saving $64 billion in the period 2011-2020.

4. **Do you support proven medical liability reform measures that are modeled after the Texas and California laws in terms of caps on non-economic damages?**

Answer: While medical malpractice liability reform is not in my purview as CMS Administrator, I do agree that our medical liability system needs to be examined, to ensure that it meets four goals: 1) putting patient safety first and working to reduce preventable injuries; 2) fostering better communication between doctors and their patients; 3) ensuring that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits, and 4) reducing liability premiums.

As you know, prior to the enactment of health reform, the Administration took steps towards these goals by conducting a review of reforms that have been pursued, and instituting a program to provide grant funding for states and health systems to be able to develop innovative solutions to challenges with patient safety or medical liability.

5. **The health reform law contains significant cuts to the Medicare program – about $500 billion in cuts. These cuts will have a negative impact on seniors. Why would you support cutting Medicare benefits when there is an opportunity to save at least $54 billion by enacting comprehensive medical liability reform?**

Answer: First, it is important to note that the Affordable Care Act explicitly protects the guaranteed Medicare benefits on which so many individuals and seniors with disabilities rely.

These guaranteed benefits will not be cut, and changes in the medical malpractice system will have no impact on whether or not Medicare beneficiaries continue to receive their guaranteed benefits.

6. **I noticed that the Deficit Commission's draft recommendations include a proposal to cap non-economic and punitive damages – saving $64 billion over 10 years. I have been told by the Congressional Budget Office that my bill – the Medical Care Access Protection Act (S. 45) – which is modeled after the Texas stacked capped approach would save about $54 billion over 10 years. If comprehensive medical liability reform, similar to the Medical Care Access Protection Act, were enacted, it appears that such reform would pay for a significant portion of a physician payment fix. Shouldn't we consider enacting comprehensive medical liability reform as one of several pay fors to fully offset the cost of a physician payment fix?**

Answer: Fixing the SGR to provide stability in physician payments is a top priority, and I look forward to addressing this in the coming year. It is always challenging to find an offset that the majority of Congress can agree to; however the Administration is happy to work with you all on this issue. While malpractice reform is generally not within the purview of the CMS Administrator, I am supportive of examining and improving our medical liability system.

7. **In his speech to the American Medical Association in June 2009, President Obama indicated that too many doctors order unnecessary tests and treatments because they believe these acts will protect them from potential lawsuits. He said: "We need to explore a range of ideas about how to put patient safety first, let doctors focus on practicing medicine and encourage broader use of evidence-based guidelines." Furthermore, then candidate-Obama wrote a *New England Journal of Medicine* article, entitled "Modern Health Care for All Americans" and published on-line on September 25, 2008, where he stated that "I will also support legislation dictating that if you practice care in line with your medical societies' recommendations, you cannot be sued." Yet, the health reform law does basically nothing to reform medical malpractice laws – other than develop some state pilot projects. Why do you think meaningful health reform is absent in the health reform law and what are your views on providing medical liability reform to physicians who use evidence-based clinical practice guidelines?**

Answer: Malpractice reform is generally not within the purview of the CMS Administrator, but I am supportive of examining and improving our medical liability system. The State based demonstration projects undertaken by the Administration will help us learn much more about the types of changes in the medical liability system that will benefit providers and patients.

I think we can all agree on the need to reduce medical errors and find ways to encourage physicians and providers to use evidence-based guidelines to avoid preventable mistakes. The Demonstration projects funded by the Administration are designed to promote patient safety, foster better communication between doctors and patients, ensure fair compensation for medical injuries while reducing the incidence of frivolous lawsuits and reducing liability premiums.

These projects aim to generate very useful results that will guide further improvements in the medical liability system.

8. **Medicare payments to physicians are scheduled to be cut by about 40 percent in the coming decade. Physicians have faced payment cuts for each of the last 8 years, beginning in 2002. Do you think, as a way to preserve access to care for seniors, that Medicare beneficiaries should have the right to privately purchase health and medical services, at a price of their choosing, from physicians directly without forcing doctors out of Medicare and without beneficiaries being required to forgo their benefits?**

Answer: Medicare Part B, which covers physician and other services, is a voluntary program. Medicare beneficiaries are free not to enroll in Part B (or Part D, the prescription drug benefit) and they can purchase health and medical services privately, if they wish to do so.

9. **Currently, if a senior citizen wants to decline automatic enrollment in Medicare Part A when he or she turns age 65, he or she must also decline Social Security benefits. I do not think you should be punished for deciding not to participate in a government program; that's un-American. If Warren Buffet wants to opt-out of Medicare Part A for whatever reason and wants to "donate" his Part A benefit to the federal government, he should be able to do so without being forced to give-up his Social Security benefits. What are your views on this matter?**

Answer: Medicare Part A is an entitlement for Americans who have reached age 65, for certain people with disabilities, for those with end-stage renal disease, and other limited populations as specified by Congress. These Americans are entitled to Medicare by virtue of their payroll contributions while they worked. However, no one is obligated to *use* their Medicare Part A benefits. Beneficiaries who are entitled to Part A are not obligated to pay any monthly premium. Beneficiaries are not obligated to carry a Medicare card if they do not wish to use Medicare. They are also not obligated to give hospitals and providers their Medicare card if they do not want Medicare billed.

Beneficiaries who choose not to use Medicare are still entitled to and can receive their Social Security benefits. Entitlement to Medicare Part A is tied to entitlement to Social Security benefits in Section 226 of the Social Security Act. It would require legislation to change the automatic enrollment in Medicare Part A upon entitlement to monthly Social Security benefits.

10. **During Wednesday's hearing, I briefly mentioned that I sent a letter to Secretary Sebelius on August 3, 2010, concerning the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Health Care Act. I am concerned that the interim final rule includes a provision that may negatively impact employers who may have products and services that could fall under the requirements related to value-based insurance design as part of their offering of preventive services. It's been more than three months since I sent my letter and I have not received a written response or telephone call from the Secretary. Surprisingly, my staff received a call**

from and HHS staffer on this issue the day before your hearing, but my questions remain unanswered. This response is completely unacceptable to me – particularly given that the Interim Final Rule applies to group health plans and health insurers for policy years beginning on or after September 23, 2010, unless the plan meets the grandfather provision. Furthermore, the comment period for the interim final rule ended on September 17, 2010. I know this matter falls outside of your jurisdiction as CMS Administrator – but I have been waiting for a written response from the Secretary for quite some time now and am disappointed that my staff received a call on this issue on the eve of your hearing. Can you please help me obtain: (1) a timeline from the Secretary in terms of when a Final Rule for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services will be issued; (2) information on whether any changes can and will be made on the value-based insurance design provision prior to the issuance of a Final Rule; and (3) assurances that I receive a timely written response from the Secretary on this issue?

Answer: As you noted, this issue is not in my purview as CMS Administrator. However, the Interim Final Rule for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services was issued by HHS, the Department of Treasury, and the Department of Labor (DOL) on July 19, 2010. It is my understanding that the Department received your letter reflecting your concerns regarding value-based insurance design and the Secretary sent you a response.

As you noted, the comment period on this rule has now closed, and HHS, Treasury, and DOL are working together to release guidance on value-based insurance design in the coming weeks.

11. **I'd like to seek further clarification on one of the healthy behavior-related questions I raised at Wednesday's hearing and continue our conversation on this topic. During the health reform debate, Senator Carper and I worked hard to develop a bipartisan amendment to encourage Americans to engage in healthy behaviors. Our amendment codified and improved the existing HIPAA wellness regulations which allow group health plans to provide rewards, such as premium rebates, to Americans for meeting a health factor-related standard. We increased the available reward under this program from 20% to 30% of the cost of employee-only coverage under the plan. We also gave the Secretaries of Health, Labor and Treasury to increase this reward up to 50%. I recognize that I asked this question, but I would like to seek clarification on it – How can we apply this policy to the Medicare and Medicaid programs to encourage Medicare and Medicaid beneficiaries to engage in healthy behaviors?**

Answer: I appreciate your interest in finding ways to incentivize people to engage in healthy behaviors. We agree that our health care system must do a better job of promoting health for everyone, instead of only focusing on care for the sick.

While premium rebates for healthy behavior are currently not authorized under Medicare and Medicaid, I believe the Affordable Care Act will do a great deal to incentivize healthier behaviors in these programs. For example, Medicare beneficiaries will now have access to

annual wellness visits and recommended preventive screenings with no cost-sharing. Annual visits and screenings will provide an important opportunity for physicians and patients to discuss healthy behaviors and individualized prevention strategies. Additionally, States are required to provide tobacco cessation services to pregnant women in Medicaid and in some States, Medicaid beneficiaries will be eligible for incentives based on the completion of programs that lead to adoption of healthy behaviors.

12. At Wednesday's hearing, I indicated that we need to create more transparency in the health care system so that Americans can make more informed decisions. If people are given responsibility for their decisions, and there is transparency to the financial consequences to those decisions, I believe that Americans will choose to maximize both their health and their financial benefit. As mentioned, companies, like Safeway, have discovered that a colonoscopy can cost anywhere between $900 and $8,600. Businesses, like Safeway, in the private sector already utilize their own data to compare and examine the cost and effectiveness of the care their workers and beneficiaries are receiving. It seems to me that we should expand that research effort. As CMS Administrator, will you allow qualified organizations to access Medicare data to determine more effective health care solutions while placing a premium on the privacy and security of Medicare beneficiaries?

Answer: As a part of the Department of Health and Human Services' Open Government Plan, we are working to promote transparency and improve public understanding of the Medicare and Medicaid programs by making de-identified data more broadly available through several approaches. We are producing dashboards designed to make aggregated data from Medicare claims more accessible to consumers and researchers. The Medicare Inpatient Hospital Dashboard is available on CMS' web site now and we expect to release additional dashboards in the next few months. We have also contributed publicly available, de-identified Medicare-related data sets to the federal data web site (www.data.gov). This web site allows researchers to easily download the de-identified files. With feedback from researchers, data entrepreneurs, and consumers, we are continuing to develop new de-identified public data sets with useful data elements. By simplifying and making data more accessible through tools like dashboards, we hope to accelerate efforts to improve the nation's health care delivery and payment systems.

13. As discussed at Wednesday's hearing, we know that prices can be driven down if consumers know what the prices are. Seeking further clarification on this topic, do you foresee price transparency being an area in which you and others within HHS can develop a way for all consumers to know what the price and quality of the service is that they are purchasing?

Answer: I agree that transparency can play an important role in finding the most effective health care solution. CMS posts information on the health and drug plans available to beneficiaries through the Medicare Plan Finder online tool (www.Medicare.gov). We have also begun the process of streamlining private plan offerings so people with Medicare can make more meaningful choices based on the price and quality of the plan. The new consumer health care and insurance finder web site (www.HealthCare.gov) created under the Affordable Care Act is now providing important new pricing and benefits information for private insurance plans offered to

individuals and families, giving consumers the power to compare cost estimates and the benefit offered by different plans. These new data, much of which have never been completely available to the public before, represent a major step forward for insurance market transparency and will help lead to consumers having a better understanding of their choices, a market that is more competitive, and a market that becomes more responsive to what consumers need.

With respect to price transparency, CMS posts information on the health and drug plans available to beneficiaries through the Medicare Plan Finder online tool at www.Medicare.gov. We have also begun the process of streamlining private plan offerings so people with Medicare can make more meaningful choices – based on price and quality offered. In addition, we are implementing provisions from the Affordable Care Act around value based purchasing that would adjust provider payments based on the quality and value of the service provided.

14. Do you see a role for price transparency in either Medicare or in health reform as it is implemented - and if you do how would you implement price transparency so consumers would know the price of a medical service?

Answer: The Administration is strongly committed to price transparency, but wants to be mindful that this information is shared in a meaningful way that will enable consumers to make smart choices.

CMS posts information on the health and drug plans available to beneficiaries through the Medicare Plan Finder online tool (www.Medicare.gov). We have also begun the process of streamlining private plan offerings so people with Medicare can make more meaningful choices based on the price and quality of the plan. The new consumer health care and insurance finder web site (www.HealthCare.gov) created under the Affordable Care Act is now providing important new pricing and benefits information for private insurance plans offered to individuals and families, giving consumers the power to compare cost estimates and the benefit offered by different plans. These new data, much of which have never been completely available to the public before, represent a major step forward for insurance market transparency and will help lead to consumers having a better understanding of their choices, a market that is more competitive, and a market that becomes more responsive to what consumers need.

Additionally, CMS has a number of initiatives underway that will bring transparency to Medicare beneficiaries and intends to expand these efforts in the years to come. CMS has begun to implement new authorities in the Affordable Care Act to develop efficiency measurements related to hospital performance and to implement a hospital value-based transparency (VBP) program. We want to be sure that we develop measures that can provide an equitable comparison between resources used across different hospitals and provide beneficiaries with more transparent overviews of hospital performance. Further, CMS already has Hospital Compare and Nursing Home Compare websites, where patients can examine the quality of a particular hospital or nursing home on a number of measures, as well as the Five-Star Quality Rating website where people with Medicare can examine the star rating of various private plan options. The Affordable Care Act also requires the creation of a Physician Compare website.

15. I have been working to get rid of the Medicare therapy caps because these arbitrary caps are not good health care policy. Congress has extended either the prior moratoria or the current exceptions process many times over the years. The current exceptions process expires on December 31, 2010. I am concerned that extension of the therapy caps exceptions process could get caught up in the debate over extending the SGR fix, extending the CR, extending the tax cuts, etc. I have no doubt that it is our intention to extend the therapy caps exceptions process as we have done so many times in the past.

a. In the event that Congress is unable to act by December 31, 2010, will you extend the exceptions process administratively?

Answer: CMS does not have the authority to extend the therapy cap exceptions process administratively; extending the process requires legislative action. The Medicare and Medicaid Extenders Act of 2010, recently passed by Congress, extends the therapy cap exceptions process through December 31, 2011. CMS will work expeditiously to implement the extension.

b. I would also ask that you think about what should be the future policy. Should it be an extension of the exceptions process or is there another way that we can structure this payment system to help in that effort?

Answer: CMS is aware that Congress has stepped in to continue the exceptions process on several occasions in the past. While we are continuing to examine ways to more appropriately pay for therapy services, we stand ready to expeditiously implement the extension recently approved by Congress.

16. As you know, CMS recently issued its final physician fee schedule rule, which included the multiple procedure payment reduction (MPPR) for all outpatient therapy services. I am aware that CMS's rationale behind the drastic cuts was the assumption that duplicate clinical labor and supplies are included in the practice expense relative value units (PE RVUs) when multiple services (two or more) are furnished to a patient in a single session.

a. If the goal of health care reform is to ensure a payment system based on quality and transparency, how does the recent decision to apply a multiple procedure payment reduction to therapy services further that objective of payment for quality and transparency?

Answer: I strongly share the goal of ensuring quality and transparency in our payment systems. Throughout the rulemaking process for the CY 2011 physician fee schedule (PFS) rule, we invited public comment on the proposal to apply the multiple procedure payment reduction (MPPR) policy to reduce duplicative payment for clinical labor and supplies of therapy services. Further, to promote transparency and in support of the proposal, we included the results of our analysis of claims data from CY 2009 in the proposed rule. This analysis found that for five high-volume pairs of therapy services billed in a single session (which account for more than half of therapy claims paid under the PFS), the duplication in practice expense is between 28 and

56 percent of the total practice expense for the lower-paying service. Subsequently, we responded to public comments by finalizing a more conservative MPPR policy of 25 percent, instead of the proposed 50 percent. P.L. 111-286 then amended the MPPR policy to reduce payments by 20 percent under the Physician Fee Schedule. We do not believe that appropriately valuing payment for services will reduce the quality of therapy services or limit patients' access to medically reasonable and necessary therapy services.

b. Would you agree that quality is linked to appropriate payment for necessary services? And in order to provide quality services, would you agree that providers need a stable and adequate payment environment? With this in mind, what is the rationale for a minus 7% cut in therapy services in the recent fee schedule rule and how does this foster quality care?

Answer: We strive to provide predictable and adequate payments to providers as well as ensure quality of patient care. In a 2009 study, the Government Accountability Office concluded that an MPPR policy could be appropriate for multiple physical therapy services provided by the same provider to the same beneficiary on the same day. Under the MPPR policy, by reducing duplicative payment for clinical labor and supplies of certain therapy services when furnished together to a patient in a single session, Medicare payment for these services is more precise. We have no evidence that would suggest that the MPPR policy will reduce the quality of therapy services. However, we will closely monitor access to care and patterns of delivery for therapy services, including any changes in the delivery of same day therapy services that may be inappropriate.

c. Would you work with my office and the committee to develop a more accurate and predictable payment policy for therapy services?

Answer: I look forward to working with you and other members of the Committee to strengthen the Medicare program, including Medicare's outpatient therapy benefit.

17. The health reform bill expands Medicaid to include a new segment of the population – low-income childless adults. It also establishes 133 percent of the Federal Poverty Level as the new mandatory minimum Medicaid income eligibility level for this population. I recognize that the Reconciliation bill covers 100 percent of Medicaid costs in Nevada and other states for individuals newly enrolled as a result of the expansion of eligibility to 133 percent of the Federal Poverty Level. This increased assistance is available to states when the law goes into effect in 2014. But the federal government's responsibility will drop down to 90 percent for 2020 and beyond, shifting more and more expense to my home state. It is also my understanding that states are estimating a significant increase in the number of individuals who qualify for the Medicaid program under current Medicaid standards due to the individual mandate requirement included in the Patient Protection and Affordable Care Act. Individuals who are Medicaid-eligible under current standards are covered at the regular FMAP and do not qualify for the assistance that is available for individuals who are eligible for the Medicaid program due to eligibility expansions. How is

CMS planning to work with states to ease the fiscal burden imposed by these Medicaid expansion provisions?

Answer: I know States are struggling; I recently attended the annual Medicaid Directors' conference and heard from States about the challenges the face as their Medicaid budgets grow. That's why the Affordable Care Act doesn't ask States to assume the cost of the Medicaid eligibility expansion on their own. The Affordable Care Act provides substantial financial support for states to help them accomplish the task. For the first three years of the expansion (2014-2016), states will receive 100 percent FMAP for expenditures related to the newly eligible adult population. By 2020, the federal matching rate for the newly eligible group will decline to 90 percent, where it will remain. States that had expanded Medicaid eligibility levels prior to the Affordable Care Act also will receive significant federal support beginning in 2014.

We recognize that many States will have to upgrade their eligibility systems to accommodate the Medicaid expansion and to achieve the Affordable Care Act's requirements for seamless enrollment procedures between Medicaid and the new State Exchanges. Working with the new Office of Consumer Information and Insurance Oversight, CMS issued guidance to help States design and implement the information technology (IT) needed to establish Exchanges. To assist in these activities, CMS released a proposed rule that would provide enhanced Federal matching funds to States to design, develop, and install enhanced Medicaid eligibility determination systems. As proposed, the 90 percent matching rate will be available for eligibility systems until December 31, 2015, and the 75 percent match will be available for maintenance and operations of such systems. This support, along with the generous matching rates that I described above, will help ease the burden on States as they implement the Medicaid expansion provisions of the Affordable Care Act.

18. How are the limitations under the health reform law restricting states from managing their Medicaid budgets during this fiscal crisis?

Answer: I recognize the challenge that the current fiscal environment has posed for State budgets including the increased enrollment in Medicaid, which is designed to serve more people during downturns, as people lose jobs and their job-based coverage. The federal government has already given States significant help in maintaining their Medicaid programs through the enhanced FMAP initially provided in the American Recovery and Reinvestment Act (Recovery Act), and extended more recently through June 2011. CBO estimates that the Recovery Act provided $87 billion to States for Medicaid fiscal relief through the end of 2010, and will provide an additional $16 billion between January and June 2011. Maintenance of effort provisions in both the Recovery Act and the Affordable Care Act are intended to prevent people from losing coverage as we begin the implementation of health reform. We know that States are facing difficult economic times and have to make tough choices. But we need to take this step-by-step. States are anticipating a slower rate of enrollment growth over the next year, which will decrease pressure on their budgets. And in 2013, additional money will be available for increased primary care provider payments, followed by significant federal financing for new enrollment in 2014.

19. Last month British Health Secretary Andrew Lansley announced that the National Institute for Health and Clinical Excellence (NICE) – Great Britain's health care

rationing agency – would play a less central role in the health care decisions of the UK's National Health Service. For years, NICE has been denying access to certain treatments purely for cost reasons. Do you see NICE as a model for CMS in regard to comparative effectiveness? How will CMS' role in regard to comparative effectiveness differ from the rationing by NICE?

Answer: I am confident that our country's approach and use of comparative effectiveness research will be uniquely American. Senator, I can assure you that CMS will adhere to current law, which prohibits Medicare from denying coverage solely based on the results of comparative effectiveness research. Further, I'm aware that the non-governmental nonprofit Patient Centered Outcomes Research Institute (PCORI), established to set priorities and a research agenda for comparative effectiveness research, may not mandate coverage, reimbursement, or other policies for any public or private payer.

Comparative effectiveness is not rationing, but entails a comparison of treatment options so patients and their providers can make the best treatment decisions. I strongly oppose arbitrary limits on the care Americans receive. The Affordable Care Act gives States and consumers new tools with which to ensure that treatment decisions are based on the best available clinical evidence.

Comparative effectiveness research will fill gaps in our current knowledge base and empower patients and clinicians to make fully-informed and better treatment decisions that meet an individual's unique health needs. Its sole goal is giving patients more information and more choices.

20. **President Obama in a presidential proclamation during Breast Cancer Awareness Month said, "we reaffirm our commitment to supporting breast cancer research, and to educating all Americans about its risk factors, detection, and treatment."[1] But, while our leaders say they are working to fight breast cancer – which kills 40,000 American women a year – the Food and Drug Administration will be making a decision in mid-December whether to withdraw its 2008 approval of Avastin for use in breast cancer treatment. An FDA panel concluded this summer that Avastin was not showing enough promise in the treatment of breast cancer. In the manufacturer's phase III trial, nearly 50 percent of patients receiving the medicine saw their tumors shrink. If the full FDA revokes approval of Avastin, many women whose lives have been lengthened will see their lifeline cut off. The drug is prescribed for 17,500 patients annually. Do you think it is the role of the FDA to pull a life extending drug from the market or should this decision be made by doctors and patients? It is an expensive treatment but if the FDA pulls it, is it likely that private insurers, Medicare, and Medicaid, will stop paying for the drug?**

Answer: The Food and Drug Administration (FDA) and CMS have separate and unique roles and authorities under statute. Avastin was approved under FDA's accelerated approval

[1] Presidential Proclamation, http://www.whitehouse.gov/the-press-office/2010/10/01/presidential-proclamation-national-breast-cancer-awareness-month

regulations (21 CFR 314, subpart H), which permit FDA to approve a drug on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval under this regulation may be subject to a requirement that the applicant further study the drug to verify and describe its clinical benefit. In contrast, CMS' evidence reviews focus on whether a particular item or service is "reasonable and necessary" for the Medicare population. With some narrow exceptions specifically authorized by statute, CMS' coverage decisions do not consider cost. Medicare coverage decisions are based upon whether a product is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, as mandated by statute.

I cannot speak to FDA deliberations over particular products or possible future FDA actions. While CMS does periodically consider new information about the Medicare-covered drugs or treatments and evaluate whether changes in coverage decisions are warranted, it would be premature to indicate possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions. I would note, however, that, generally, Medicaid coverage of a drug is contingent upon that drug having FDA approval.

21. If a doctor prescribes a therapy that in her view will achieve the best outcome for a patient, but it is subject to a "least costly alternative" policy and is not the CMS-preferred therapy, would the patient be required to pay out of pocket for that therapy? Would this be the case even though that is the therapy that in the doctor's expert medical opinion is best for that patient?

Answer: I recognize the critical importance of the physician-patient relationship, especially in deciding an appropriate drug therapy treatment. The Medicare statute covers items and services for the Medicare population that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Medicare Part B (Medical Insurance) covers drugs that are given by infusion or injection and are given as part of a doctor's service. Medicare also offers comprehensive prescription drug coverage under Part D (prescription drug coverage).

22. Your Office of the Actuary has projected that the new law's cuts to Medicare Advantage plans will reduce enrollment in 2017 by half compared to previous projections and significantly increase beneficiary out-of-pocket costs. However, we have all heard the President say that the health reform law won't result in anyone losing the coverage they already have. How can you reconcile your department's support for the law and the President's statements? What are you planning on telling Medicare Advantage enrollees when their plans start to disappear?

Answer: Despite a payment freeze for 2011, MA enrollment will increase 5 percent, according to MA plans' bids. In addition, CMS' efforts and the Affordable Care Act are making MA plans stronger – beneficiaries will have lower premiums and more comprehensive benefits in their MA plan in 2011.

For example:

- The weighted average for all MA premiums will be 1 percent lower in 2011 than premiums this year – compared to a 15 percent premium increase between 2009 and 2010.
- 98.4 percent of beneficiaries will have access to an MA plan with no premium in 2011.
- Virtually all (99.7 percent) beneficiaries will have access to a MA plan that waives cost-sharing for preventive benefits in 2011.
- All MA plans will offer mandatory maximum out-of-pocket limits for all Part A and Part B services.
- All MA plans are required to meet or exceed published cost sharing standards similar to Original Medicare in service categories such as inpatient care, Part B drugs, durable medical equipment (DME), and mental health services. All MA plans must provide cost-sharing for skilled nursing, chemotherapy, and renal dialysis at Original Medicare levels, per the Affordable Care Act.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Enzi:

Questions for the Witness:

Medicaid

1. **In light of the current statutory Maintenance of Effort ("MOE") requirements, are states permitted to make any reductions in current benefits or increases in cost sharing?**

Answer: Maintenance of Effort (MOE) provisions are intended to prevent people from losing coverage as we begin the implementation of health reform. The Recovery Act and Affordable Care Act MOE requirements are designed to maintain current eligibility standards, methodologies and procedures. While States do have flexibility to make other changes to their programs, CMS has not yet issued guidance on this maintenance of effort provision so I cannot comment on the specifics. However, we are currently evaluating the need for future guidance on the maintenance of effort requirements. We know that States are facing difficult economic times and have to make tough choices. But we need to take this step-by-step. States are anticipating a slower rate of enrollment growth over the next year, which will decrease pressure on their budgets. And in 2013, additional money will be available for increased primary care provider payments, followed by significant federal financing for new enrollment in 2014.

2. **In Fiscal year 2010, how much did states spend on their Medicaid programs?**

Answer: While expenditure reporting for FY 2010 is still underway, the CMS Office of the Actuary projects that States will have spent approximately $133.5 billion on Medicaid in FY 2010.

3. **Do you believe states should be forced to fire police and firemen, cut teacher salaries, and raise state college tuition costs because the Federal government prohibits them from making any real changes to their Medicaid programs?**

Answer: I recognize the challenge that the current fiscal environment has posed for State budgets including the increased enrollment in Medicaid, which is designed to serve more people during downturns, as people lose jobs and their job-based coverage. The federal government has already given States significant help in maintaining their Medicaid programs through the enhanced FMAP initially provided in the American Recovery and Reinvestment Act (Recovery Act), and extended more recently through June 2011. CBO estimates that the Recovery Act

provided $87 billion to States for Medicaid fiscal relief through the end of 2010, and will provide an additional $16 billion between January and June 2011. This financial support has helped States avoid cutting Medicaid and has indeed allowed States to reorient dollars to support other State and local needs.

Nevertheless, I know States are struggling and are concerned about the challenges facing their States as their Medicaid budgets grow. That's why the Affordable Care Act doesn't ask States to assume the cost of the Medicaid eligibility expansion on their own. The Affordable Care Act provides significant fiscal support for states too, providing 100 percent FMAP for newly covered individuals. And CMS has recently put out a proposed rule that would provide states 90 percent Federal matching funds for information technology (IT) investments related to the Affordable Care Act. In the meantime, we are looking at all opportunities to work with States on issues ranging from IT development to care coordination to help them operate their programs efficiently and with the best interests of beneficiaries in mind.

4. **Do you know the percentage of all physicians who currently accept Medicaid patients? Do you have percentages broken out by the following medical specialties: 1) cardiology, 2) oncology, and, 3) neurology?**

Answer: States set the payment rates that often contribute to a provider's decision whether or not to participate in Medicaid. The Federal government reviews Medicaid State plans to ensure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population. Percentages of participating physicians may be available on an individual State basis, but the Federal government does not track this information.

In addition, the newly formed Medicaid and CHIP Payment and Access Commission (MACPAC) will also play an important role in this discussion by providing research and analysis on provider payment rates and access in the Medicaid program. MACPAC will help analyze and evaluate provider rates to determine if changes are necessary to ensure that all Medicaid beneficiaries have access to care. CMS anticipates working closely with them as we do with MedPAC, thinking seriously about how to sustain access to care in 2014 and beyond. My vision for Medicaid, and for Medicare, is to continue improvements that enable us to better align payment and quality.

5. **Do you believe that an individual has health care if they cannot see a doctor?**

Answer: Access to providers is a critical component of health care. As Administrator of CMS, I am committed to ensuring access for Medicaid beneficiaries. Medicaid has a proven track record of delivering high quality care to vulnerable, low-income populations who do not have another source of care. While there are certainly isolated challenges, data suggests that access to care in Medicaid is comparable to access in the private market. Congress was wise to establish the Medicaid and CHIP Payment and Access Commission to help assess and improve Medicaid, and we at CMS look forward to working with MACPAC.

6. **Can you explain the rationale for why 14 million Americans are going to forced into a seriously deficient Medicaid program and be denied the right to chose the health plan that best meets their needs?**

Answer: As CMS Administrator, it is a priority to ensure that the Medicaid program is as strong as possible and meets the health care needs of the millions of beneficiaries who depend on the program for critical services. Medicaid is designed to cover people who would otherwise have difficulty finding affordable, comprehensive health insurance coverage in the private market: people who are low-income, elderly, or have disabilities or complicated chronic conditions. Both as originally designed, and under the Affordable Care Act, Medicaid offers States the opportunity to, within the framework laid out in federal law, design coverage that meets the needs of their State and this particularly vulnerable group of individuals. States are then eligible for Federal matching funds to support their expenditures. The Medicaid program offers important cost-sharing protections too, to ensure that cost is not a barrier to health care for the lowest income individuals.

Health Care Costs

The new health care law encourages the adoption of new models, like Accountable Care Organizations, to organize primary care, specialists and hospitals into new networks. Dr. Bob Berenson published a study in the February 2010 issue of Health Affairs, which found that "evidence from two decades of hospital mergers and acquisitions nationally demonstrates that consolidating hospital markets drives up prices." He reported that greater integration of providers enhanced their bargaining power, which resulted in higher rates and premiums.

7. **Do you disagree with Dr. Berenson's findings?**

Answer: In the current fee-for-service, uncoordinated marketplace for care, increased provider market power may result in higher prices and premiums as Dr. Berenson seems to suggest. Accountable Care Organizations (ACOs) and other innovative delivery system models will be explicitly designed to provide financial incentives for health care entities to provide high quality, patient-centered and coordinated care at lower costs to beneficiaries. Better coordination among providers will improve patient care and is also expected to produce savings in our health care system.

8. **Is it possible that Accountable Care Organizations could actually increase health care costs?**

Answer: Under the payment model laid out in Section 1899(d) of the Social Security Act, as added by the Affordable Care Act, Accountable Care Organizations (ACOs) are eligible to receive shared savings when the ACO's actual expenditures for its assigned Medicare beneficiaries fall below the ACO's specified benchmark amount and the ACO meets quality performance standards. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare beneficiaries assigned to the ACO.

These cost savings are expected to come through the coordinated care that an ACO will be able to provide to its patients. In order to receive shared savings, an ACO must not only demonstrate savings compared to its benchmark, but must also meet quality and outcomes targets that will be set by CMS. We expect cost savings from the ACO's efforts to coordinate care and we look forward to the innovative approaches ACOs will use to improve coordination of care for Medicare beneficiaries.

Medicare Actuary

9. **Medicare's Chief Actuary, Richard Foster has said that as a result of the provider payment cuts in the new law, 15% of all hospitals, nursing homes and other similar providers could be operating at a loss by 2019. Do you agree or disagree with your actuary's analysis?**

Answer: I am aware that the Actuary made these assessments at various points in the past, however it is important to remember that uncertainty surrounds any projections. Even the Actuary states that projections are not set in stone, and are subject to greater uncertainty than normal. In looking at history, OACT underestimated the savings from the Balanced Budget Act and overestimated the cost of implementing the Medicare Part D prescription drug benefit. We are committed to ensuring access to high quality care for all our beneficiaries.

10. **Mr. Foster further noted that these payment cuts may cause providers to "end their participation in the program," and possibly jeopardize access to care for beneficiaries. Do you believe that hospitals, nursing homes and other providers will continue to operate while losing money?**

Answer: There is no evidence that providers will not continue to serve beneficiaries. The Affordable Care Act was supported by the American Hospital Association and the American Medical Association, groups that would have been unlikely to back the law if they believed it would harm their members' financial viability. History shows providers will continue to serve Medicare patients. Congress has implemented larger savings targets for Medicare in the past, including in the 1997 Balanced Budget Act; in this and other cases, no access problems materialized. Such problems are even less likely to occur when Medicare savings and efficiencies are accompanied by coverage expansions, adding new sources of revenues for health care providers.

Further, in making these estimates, the Actuary overlooked a number of provisions in the law 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. These provisions will expand and strengthen the provider workforce and better secure access to care for all Medicare and Medicaid beneficiaries.

11. **What specific actions will you take to prevent Medicare patients from seeing reductions in their access to care as a result of these payment cuts?**

Answer: As noted earlier, there is no evidence that beneficiaries will face access to care reductions as a result of the Affordable Care Act. On the contrary, many provisions in the Act are designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and certain providers in underserved areas, and investments in health professional training programs will. These provisions will expand and strengthen the provider workforce and better secure access to care for all beneficiaries.

Medicare Coverage

A Medicare contractor has issued a draft Local Coverage Decision that states that for the first time CMS will cap the number of diabetic test strips given to seniors on Medicare. Current Medicare practice allows physicians to authorize the use of higher numbers of diabetic test strips. The American Association of Clinical Endocrinologists has described this policy as a well-intentioned, but clinically naive formula and asked CMS to leave the management of diabetes related glucose excursions in the hands of doctors and patients.

12. Do you disagree with the statement issued by the Clinical Endocrinologists?

Answer: The physician-patient relationship is an important part of high quality care, especially in the treatment of individuals with diabetes. CMS has no intention of replacing the judgment of a doctor.

Based upon comments received on the proposed revision to the *Glucose Monitors LCD,* on December 14, 2010, the DME Medicare Administrative Contractors (DME MACs) issued notices that the proposed revision to the Glucose Monitoring policy has been withdrawn. Under the current LCD policy, which remains in effect, Medicare beneficiaries are able to get more diabetes test strips/lancets when their physician certifies the need for additional test strips/lancets.

13. Do you believe that C-M-S staff better understand the needs of diabetic patients than their doctors?

Answer: Physicians know how to best treat their patients with diabetes. If a physician certifies the need for additional test strips/lancets, the Medicare beneficiary will be able to get more test strips under the current LCD policy.

14. As a clinician yourself, do you believe that CMS should be overriding the decisions of physicians?

Answer: The physician-patient relationship is an important part of high quality care. As mentioned previously, I think physicians know how to best treat the unique health care needs of their patients. CMS has no intention of replacing the judgment of individual physicians.

Under the current LCD policy, which remains in effect, Medicare beneficiaries are able to get more diabetes test strips/lancets when their physician certifies the need for additional test strips/lancets.

15. If you had a patient who routinely had low blood sugar levels, should you have the ability to have that patient test every time before they drive their car, or should Medicare be able to override your medical judgment?

Answer: As a physician, I recognize and honor the critical importance of the physician-patient relationship. I think physicians know how to best treat their patients' unique health care situations. Under the current LCD coverage policy, which continues to be in effect, if the patient's physician certifies the need for additional test strips/lancets, Medicare beneficiaries can get more test strips/lancets.

Medicare Advantage

16. How many beneficiaries do you estimate will be enrolled in the Medicare Advantage program in 2019?

Answer: In the 2010 Annual Report to the Board of Trustees, the 2019 enrollment in the Medicare Advantage program was projected to be about 7.6 million.

17. How many plans do you estimate will be participating in the Medicare Advantage program in 2019?

Answer: The CMS Office of the Actuary does not project the number of participating plans, only beneficiary enrollment and cost information.

18. Please describe all of the benefits that are currently provided to beneficiaries enrolled in Medicare Advantage plans.

Answer: Medicare Advantage enrollees are guaranteed the same Part A & B benefits available to beneficiaries enrolled in Original Medicare, including hospital stay coverage and coverage for physician services. Supplemental benefits provided through rebates vary greatly from plan to plan and by geographic area, but include and are not limited to: premium and cost sharing reductions, dental and vision benefits, or health club memberships such as Silver Sneakers. It should be noted, however, that the nearly 80 percent of beneficiaries in Original Medicare do not receive these "extra benefits."

Electronic Medical Records

In 2009, Congress authorized spending $20-30 billion to pay bonus payments to physicians and hospitals that are meaningful users of health information technology.

19. Please provide a detailed summary of how much of this money has already been spent and how it was used.

Answer: As authorized by the Health Information Technology for Economic and Clinical health (HITECH) Act, CMS has been working diligently to enact the Medicare and Medicaid programs

to provide incentive payments to eligible providers. We expect to begin making Medicare incentive payments in May 2011.

The HITECH Act provides program implementation funding of $140 million per year for fiscal years (FYs) 2009 through 2015 and $65 million for FY 2016. In implementing the incentive programs, CMS and States have begun to incur administrative costs.

To date, CMS has obligated approximately $67.7 million in expenditures related to the administration of the Medicare incentive program and approximately $30.1 million related to the administration of the Medicaid incentive program. Implementation activities include building a national data repository to support disbursement of incentives to eligible providers and developing interfaces between systems at CMS and at Medicaid State Agencies.
The HITECH Act also establishes 90 percent Federal financial participation (FFP) payment for State expenses related to administration of the Medicaid incentive payments. States were eligible for payment of the 90 percent match beginning in FY 2009, and, to date, have incurred an estimated $62.2 million in expenditures.

In addition, the HHS Office of the National Coordinator for Health Information Technology (ONC) has also begun implementation and oversight of HITECH activities within their purview, launching eight new grants programs for States, communities, and providers; setting up new advisory committees and workgroups; and building Federal capacity to oversee these efforts. To date, these efforts have resulted in the obligation of approximately $1.8 billion of the $2 billion appropriated to ONC in HITECH for HIT activities.

20. Do you believe that after all of this money has been spent, the majority of Americans will have interoperable electronic health records?

Answer: The HITECH Act represents an historic investment in health information technology (HIT), lays the groundwork necessary to pursue the President's goals related to improved health care quality and efficiency, and will help transform the way health care is practiced and delivered. Our goal is to assure that there are interoperable electronic health records (EHRs) for the majority of Americans and that the health care providers are using this technology to improve the quality of care.

CMS and ONC have worked collaboratively to establish a strong program that will provide incentives for adopting and using EHRs that have the necessary capabilities and standards for collecting and sharing health information. ONC has led several efforts to improve the support structures necessary for the nationwide adoption of interoperable EHRs. Central among these efforts are CMS' "meaningful use" rulemaking and ONC's standards and certification criteria rulemaking. The "meaningful use" rule set the requirements that eligible health care providers will need to satisfy in order to qualify for incentive payments. The standards and certification criteria rule specifies the technical capabilities, and standards, that certified EHR technology will need to meet, and establishes an initial set of standards for interoperability.

By laying this important structural groundwork, CMS and ONC have established a framework that all providers can rely on in adopting interoperable EHRs, which we expect will lead to a

significant expansion in their use. We look forward to working with providers and other stakeholders during future rulemaking that will further solidify this expansion.

21. How does the Administration plan to prevent this funding for new electronic health records from replicating the same inefficiencies and flaws in our current paper based system?

Answer: The implementation of electronic health records (EHRs) on a national level will be an influential factor for improving both the effectiveness and efficiency in the delivery of care. The incremental, staged approach we have adopted for establishing meaningful use requirements will ensure that providers will not receive incentive payments unless they have demonstrated meaningful use of certified EHR technology. In addition, the meaningful use standard is designed to incentivize improvements in the quality and efficiency of health care.

As we build on this foundation, we anticipate actively assessing and reviewing the progress health care providers have made to ensure quality and efficiency standards are being met and to share and disseminate best practices.

In the 2011 Medicare Physician Fee Schedule Final Rule, CMS included a new requirement that all paper test order forms for laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule must contain a physician signature, abandoning longstanding existing policy that a signature is not required on these forms.

Both the new health care law and the so called stimulus law emphasized the need to move toward an electronic-based medical record system, yet this new rule imposes new paperwork burdens.

22. At a time when health care institutions should be focused on this transition to EHRs, what is the rationale for imposing an additional layer of paperwork burdens?

Answer: Through the Medicare and Medicaid electronic health record (EHR) incentive programs, we are encouraging health care providers to adopt and meaningfully use certified EHRs and certainly do not want to undo the progress made with these programs. We do not believe our revised policy imposes an additional burden on physicians and non-physician practitioners (NPPs). It is our understanding that, in most instances when physicians and NPPs use requisition forms, they are annotating the patient's medical record with either a signature or an initial, as well as providing a signature on the requisition form provided to the lab. However, we are meeting with stakeholders to better understand their concerns about the revised policy, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories. We will take these concerns into account as we determine how best to proceed.

23. What is CMS's rationale for requiring a hard-copy signature on paper requisitions that potentially will prevent or delay Medicare patients from getting much-needed laboratory testing if the physician fails to sign the form or uses initials rather than a legible signature?

Answer: While we do not think that beneficiary access to clinical laboratory services will be disrupted as a result of the physician (and qualified non-physician practitioner or NPP) signature policy, we are meeting with stakeholders to better understand their concerns, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories about the revised policy. We will take these concerns into account as we determine how best to proceed.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Hatch:

Medicaid Expansion

As you may already know, there is bipartisan concern on the impact of the massive Medicaid expansion in the new health care law and its impact on our state budgets, which collectively face almost $200 billion in deficits. Starting in 2014, the new law will require states to extend Medicaid eligibility to ALL non-elderly individuals with family incomes below 133 percent of federal poverty level. This massive entitlement expansion will account for more than half of the newly covered individuals. I am being told by my state officials that a full implementation of this new provision will result in a 50 percent increase in the size of their Medicaid program at an astronomical cost of $834 million. I hope CMS is seriously considering and examining the impact of the Medicaid expansion on cash-strapped state budgets. I would like to know two things from you:

1. **What will be the impact of this massive expansion on existing Medicaid populations that are already afflicted with significant access issues due to provider underpayments?**

Answer: As Administrator of CMS, I am committed to ensuring access for Medicaid beneficiaries. Medicaid has a proven track record of delivering high quality care to vulnerable, low-income populations who do not have another source of care. While there are certainly isolated challenges, data suggests that access to care in Medicaid is comparable to access in the private market. Still, there is always room for improvement as we approach the Medicaid expansion in 2014. The Affordable Care Act includes a provision to help States boost their Medicaid reimbursement rates for certain services to Medicare levels for two years, which is a good first step.

In addition, the newly formed Medicaid and CHIP Payment and Access Commission (MACPAC) will also play an important role by providing research and analysis on provider payment rates and access in the Medicaid program. MACPAC will help analyze and evaluate changes to provider rate changes necessary to ensure that all Medicaid beneficiaries have access to care. We anticipate working closely with them as we do with MedPAC, thinking seriously about how to sustain access to care in 2014 and beyond. My vision for Medicaid, and for Medicare, is to continue improvements that enable us to align payment and quality.

2. **What is the true long-term cost of this unfunded mandate on our states?**

Answer: The Affordable Care Act asks that all sectors of the nation come together to contribute to the shared goal of reducing the number of uninsured Americans and improving health care, but the federal government will cover a vast majority of the costs of the Medicaid expansion. For the first three years of the Medicaid expansion (2014-2016), States will receive 100 percent FMAP for expenditures related to the newly-eligible adult population. By 2020, the Federal matching rate will decline to 90 percent, where it will remain. States that had expanded Medicaid eligibility levels prior to the Affordable Care Act also will receive significant Federal support beginning in 2014.

Numerous experts agree that States will actually realize a net savings from the provisions of the Affordable Care Act. The expansion of coverage will significantly reduce uncompensated care, which States currently cover in part. A reduction in uncompensated care will also decrease the cost shifting that raises premiums for people with insurance, including State employees, by up to $1,000 annually for a family plan. Many States also currently spend their own State resources on programs to cover the uninsured, which will not be necessary following the coverage expansions in the Affordable Care Act.

Finally, States stand to receive more than $10 billion over 10 years in new funding for prevention and workforce training. Investment in primary care clinics and community health centers will create jobs for health care providers and ancillary staff, all of whom generate local economic activity.

FDA-approved drugs

As part of the goals outlined in your "Triple Aim" to improve health care, your plan entails providing better care for patients around the dimensions of safety, effectiveness, patient-centeredness, timeliness, efficiency and equity.

3. **Since the medical products approved by the FDA have been proven to be safe and efficacious, is it your belief that Medicare should cover all FDA-approved products? If not, can you please describe the instances where Medicare should not cover an FDA-approved product?**

Answer: The Food and Drug Administration (FDA) and CMS have separate and unique roles and authorities under statute. FDA clears, licenses or approves medical products based on standards such as reasonable assurance of a device's safety and effectiveness or substantial evidence to show that a drug is safe and effective for use under the conditions prescribed in the proposed labeling. In contrast, CMS' evidence reviews focus on whether a particular item or service is "reasonable and necessary" for the Medicare population. With some exceptions specifically authorized by statute (for example, coverage of additional preventive benefits), CMS' coverage decisions do not consider cost. Medicare coverage decisions are ordinarily based upon whether a product is reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, as mandated by statute.

There are instances where FDA clearance or approval and Medicare coverage or payment may differ. FDA approved products are often used for off-label uses that have not been reviewed by FDA. The Medicare program in many cases makes payment for many of these off-label uses of prescription drugs, particularly in cancer care. There are also instances where Medicare does not make payment for a labeled use of a technology.

4. **The doctor-patient relationship is essential to the practice of medicine in the U.S. A doctor's ability to choose what therapy is most appropriate for their patient is very important. As such, we have developed a strong system that provides coverage of products used "off-label" if that treatment is deemed appropriate by a physician and is supported by some proof of concept. Many times an "off-label" product will be competing against products that have gone through the rigorous FDA approval process for that intended use. What are your thoughts on the coverage of "off-label" uses?**

Answer: As a physician, I agree that the doctor-patient relationship is central to the delivery of high-quality health care. That relationship primarily shapes the patient's perspective in decision-making regarding the treatment of disease. Medicare covers services and items that are reasonable and necessary for diagnosis and treatment of a medical condition in the Medicare population and meet the standards of good medical practice. As such, Medicare does not deny coverage of drugs and biological products used off-label based solely on the absence of FDA-approved labeling for a particular use. However, we may take into consideration non-indication findings, such as recommendations from recognized compendia.

5. **With the advent of biotechnology and new discoveries around the human genome, I believe we are changing the direction of our health systems to focus on personalized medicine. The FDA and NIH have begun looking at new ways to focus medicine away from average responses and a one-size-fits-all model to a more targeted approach that utilizes biomarkers, diagnostics and other information specific to individuals. Do you believe the current CMS coverage process is able to appropriately adapt to innovative diagnostics and targeted therapies? And if not, what step has or will CMS take to handle these types of products?**

Answer: The possibilities that personalized medicine bring are truly incredible: personalized medicine may enable us to predict individual risk or susceptibility to future disease, preempt the progression of disease, or target medicines and dosages more precisely and safely to each patient. At CMS, the Council on Technology and Innovation (CTI) oversees the Agency's cross-cutting work on coordinating coverage, coding, and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities. Our goal is to promote the adoption of more targeted approaches to care that can increase quality and avoid unnecessary health care costs.

Most recently, CMS and the FDA jointly announced a proposal for parallel review of certain medical products. The process under consideration would allow for concurrent evaluations of pre-market, FDA-regulated medical products when the product sponsor and both Agencies agree

to such parallel review. Through concurrent review of relevant evidence, the process could reduce the time between FDA marketing approval and CMS national coverage determinations, and accelerate Medicare beneficiaries' access to innovative technologies.

Medicare Shared Savings Program

As you may know, Senate Finance Committee report language relating to the Medicare Shared Savings Program enacted in the ACA specifically states that eligible practitioners for Accountable Care Organizations include "physicians, regardless of specialty." House Ways and Means Committee report language states, "the Secretary could permit the formation of ACOs that are principally composed of primary care physicians whose specialties are oncology, cardiology, nephrology, or other specialties that serve beneficiaries being treated for chronic conditions."

6. **Does CMS intend to release a proposed rule on the Medicare Shared Savings Program before the end of the year? Will this proposed rule also allow for ACOs that are principally composed of specialists?**

Answer: CMS is working diligently to develop the Shared Savings Program. In addition to the work within the Agency, we are actively soliciting stakeholder feedback in the design of the program. On November 17, 2010, a request for information appeared in the *Federal Register* regarding certain aspects of the program and we are now reviewing the comments that were submitted in response. In addition, we have held several formal listening sessions to gain feedback from stakeholders. To ensure the success of the Shared Savings Program, CMS intends to maintain an open dialogue with providers and other stakeholders and engage in a process of continuous communication. We are working expeditiously to incorporate the input we have received thus far and expect to issue a proposed rule in the coming months.

The goal of the Shared Savings Program is to improve care coordination for all Medicare beneficiaries. We understand the important role specialists play in ensuring successful care coordination for Medicare beneficiaries. Accordingly, as we develop the program, we are considering the role all providers have in promoting the coordination of care.

Community Mental Health Centers

As you know, CMS issued the final rule for hospital outpatient services earlier this month. This rule makes several significant changes to the way community mental health centers (CMHCs) are reimbursed for providing mental health services to Medicare beneficiaries. Among them is a 41.7 percent cut in payments for 2011 and a requirement enacted in the health reform law stating that CMHCs must provide at least 40 percent of their services to non-Medicare beneficiaries.

7. **Did CMS analyze the impact the 41.7 percent reimbursement cut to CMHCs and the new 40 percent requirement will have on beneficiaries seeking care? If so, what did you find?**

Answer: I believe it is very important that Medicare beneficiaries have access to the care they need in the communities in which they live. With respect to the payment changes recently adopted for Community Mental Health Centers (CMHCs), I would note that CMS ultimately finalized a transition for the CMHC rates, which instead resulted in a 21.1 percent reduction from current payments to CMHCs. These payment rate changes were based on data analyses which showed that the new payment rates are more appropriately aligned with the costs of providing care. With respect to the Affordable Care Act requirement that CMHCs provide at least 40 percent of their services to non-Medicare beneficiaries, we have not yet had an opportunity to conduct a thorough analysis of this provision. However, I am confident that Medicare beneficiaries in need of mental health services will be able to obtain the care they need, through partial hospitalization programs in either a hospital outpatient department or CMHC, or through other community programs.

8. **In the final rule, CMS suggests that beneficiaries displaced from CMHCs seek care at hospital-based CMHCs as an alternative care setting. However, a study of CMHCs commissioned by CMS last year found that if CMHCs are suddenly unable to serve Medicare beneficiaries, these beneficiaries will have significant difficulties finding appropriate mental health services in a timely manner. The report said that alternative treatment sites such as state psychiatric facilities often have waiting lists and that these delays in access to care are continuing to grow longer. What does CMS recommend on addressing these access problems?**

Answer: I am committed to ensuring that all Medicare beneficiaries have access to the right care at the right time. Based on past experience and data, I do not believe that a reduction in payment will result in CMHC closures and would note that past rate reductions have not resulted in significant net CMHC closures. On the contrary, many new CMHCs have opened. However, in the event that a CMHC closes, other mental health options remain for beneficiaries including hospital outpatient partial hospitalization programs, individual outpatient mental health services, and other outpatient programs.

I also feel it is worth noting the reasoning behind the payment cuts for CMHCs. While CMS has worked diligently to make the mental health services offered in CMHCs equal to those offered in hospitals, for the past several years the data has indicated a lower cost structure and less intensive mental health services being provided in CMHCs than in hospitals. Therefore, we determined that it is not appropriate to continue paying CMHCs at the same rate as hospitals. The new payment rate will be phased in over two years, which will help CMHCs adjust to the lower payments.

I am not familiar with the study you reference, but I do not believe that any policy that CMS has adopted will jeopardize Medicare beneficiaries' access to mental health treatment.

9. **What is the status of implementation of the requirement for immediate reporting of crimes that take place in nursing homes and how CMS is informing nursing homes of this requirement?**

Answer: Elder justice and the prevention and detection of elder abuse is of the utmost importance to the Administration and the Department of Health and Human Services. The Department is currently working with CMS and other agencies within the Department on the implementation of the requirement for immediate reporting of crimes that take place in nursing homes.

10. What steps is CMS taking to provide accurate information to Medicare beneficiaries and to ensure that the people hired by CMS are trained to properly inform beneficiaries of their health care options?

Answer: CMS and HHS have a responsibility to educate beneficiaries about how Medicare works and what is available to them under the law. To that end, CMS has a multipronged education and outreach approach, including advertising, news releases, public service announcements, local town hall meetings, and health fairs to reach beneficiaries. Care is taken to ensure that the information disseminated through official outlets such as beneficiary mailers, the *Medicare & You Handbook,* 1-800-MEDICARE, www.medicare.gov, and local State Health Insurance Assistance Programs are accurate and comprehensive in order to assist beneficiaries in acquiring the information they need about their coverage.

For example, all newly hired 1-800- MEDICARE Customer Service Representatives (CSRs) receive 3 weeks of formal classroom training. In addition, new CSRs take practice calls and participate in simulation exercises. Certification by passing a written examination and test calls is required prior to taking live calls. Once on the floor, new CSRs are given one-on-one assistance and mentoring by an experienced CSR and have the ability to utilize expert support staff for real time assistance. We continuously conduct refresher training and row meetings to reinforce specific topics, scripts, and initiatives. These activities ensure CSRs have an up-to-date understanding of the Medicare program and can accurately respond to questions.
Each seasoned 1-800 MEDICARE CSR receives 4 quality assurance reviews per month. Additional quality call monitoring is conducted for new CSRs or for those with lower performance. CSRs listen to their recorded calls with their supervisors and corrective actions are taken where applicable. All of these measures help ensure that beneficiaries receive quick and consistent answers to their Medicare questions.

Please inform me on the current state of play on what efforts are being planned and are already in place on sharing of de-identified Medicare claims data to better inform our consumers.

Answer: As a part of the Department of Health and Human Services' Open Government Plan, we are working to promote transparency and improve public understanding of the Medicare and Medicaid programs by making de-identified data more broadly available through several approaches. We are producing dashboards designed to make aggregated data from Medicare claims more accessible to consumers and researchers. The Medicare Inpatient Hospital Dashboard is available on CMS' web site now. We have also contributed publicly available, de-identified Medicare-related data sets to the federal data web site (www.data.gov). This website allows researchers to easily download the de-identified files. With feedback from researchers,

data entrepreneurs, and consumers, we are continuing to develop new de-identified public data sets with useful data elements.

11. Fly-by-night operators winning bid contracts was a problem when CMS first attempted to launch Round 1. CMS has made assurances that this time around steps would be taken to ensure that bona fide providers are in fact those accepted to the program. Is this still a problem? If so, what steps are being taken to resolve it?

Answer: CMS has implemented a number of activities designed to strengthen the integrity of the enrollment process for all Medicare durable medical equipment (DME) suppliers; new enrollment requirements include: ensuring that all DME suppliers are accredited, requiring all DME suppliers to obtain and maintain a $50,000 surety bond for program participation, and allowing CMS to deny or revoke a supplier's enrollment if CMS determines that they are not in compliance with DMEPOS quality standards.

In addition, as part of the Round 1 Rebid for competitive bidding in the 9 competitive bidding areas, CMS instituted a number of operational improvements that have resulted in better compliance, more bidders, and improved bids. Some examples of these key operational improvements include an upgraded bidder education program completed prior to the opening of the bid window, a new and improved online bidding system, and an enhanced bid evaluation process, which included a comprehensive upfront licensing verification process, a bona fide bid evaluation process, and increased scrutiny of expansion plans for suppliers new to an area or product category. We are confident that when the competitive bidding program begins on January 1, 2011 Medicare beneficiaries will have access to quality DMEPOS items and services from contract suppliers they can trust.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Kyl:

Questions for the Witness:

On September 23, 2010, the Durable Medical Equipment Medicare Administrative Contractors issued a draft Local Coverage Decision (LCD)[1] for the coverage of glucose monitors.

The current CMS coverage policy covers 100 strips/lancets every three months for patients not on insulin and 300 strips/lancets every three months for patients on insulin. For both insulin and non-insulin dependent diabetics, the current policy covers larger quantities of strips in cases where a physician provides clinical documentation of the need.

The new proposed policy would still cover 100 strips/lancets every three months for patients not on insulin, but would eliminate the option for a physician to order more frequent testing. The proposed LCD simply states that "quantities of testing supplies in excess of these amounts will be denied as not reasonable and necessary."[2]

As for insulin dependent patients, the revisions would create new differentiations based on how often the patients inject:

- **For those injecting once per day: 200 strips/lancets every three months. This is 100 strips less than covered under the current rule, and there is no option for coverage of additional testing at the physician's discretion.**

- **For those injecting more than once per day: 400 strips/lancets every three months. This is 100 strips more than covered under the current rule. Within this category of insulin dependent diabetics injecting more than once per day, there is an option for coverage of 600 strips/lancets per three months, but only upon justification that includes submission of extensive documentation by the physician as well as a detailed testing results log by the beneficiary.**

Stripping physician discretion out of diabetes monitoring and treatment flies in the face of established treatment guidelines, which is why many physician and patient groups have spoken out against this proposed LCD. For example, the American Association of Clinical

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[1] LCD for Glucose Monitors, LCD ID Number DL11530.
[2] *Id.*, p. 5

Endocrinologists (AACE) opposes the proposed LCD, calling it a "CMS regulatory intrusion into a decision-making process that should occur between doctors and patients." The AACE further notes that, if this LCD is implemented, "[D]octors and patients will be forced to return to a pre-1980 state of ignorance regarding instantaneous blood glucose status."[3]

Similarly, the National Caucus and Center on Black Aged (NCBA) states that the "Draft LCD ignores existing clinical guidelines surrounding blood glucose control" and "interferes with the physician-patient partnership, which is essential to the treatment of diabetes."[4]

CMS empowers its Medicare Administrative Contractors to set and implement coverage policies. As a result, you are ultimately responsible for LCDs promulgated during your tenure as CMS Administrator. You were personally made aware of this proposed LCD in a letter addressed to you from CCS Medical dated November 8, 2010. (See attached.)

I find this proposed LCD extremely concerning in light of your well-known record of statements favoring rationing[5] and your preference for "standardization to the best-known method above clinician autonomy as a rule for care."[6] This is exactly the kind of heavy-handed government intrusion into medical decision making that has resulted in 58% of Americans supporting repeal of President Obama's health care plan.[7]

Please provide responses to the following questions:

1. **Is there a medical reason for putting an absolute cap on the amount of glucose testing a patient can have access to?**

Answer: Generally, local coverage determinations (LCDs) specify under what clinical circumstances a service is considered to be "reasonable and necessary" for the Medicare population. They are administrative and educational tools to assist providers in submitting correct claims for payment. Medicare claims processing contractors develop LCD policies by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. LCDs are developed via a transparent process in which a draft (or proposed) policy is posted and open for public comment;

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[3] American Association of Clinical Endocrinologists letter to Dr. Paul Hughes. Medical Director, DME MAC, Jurisdiction A, NHIC, Dr. Adrian Oleck, Medical Director, DME MAC, Jurisdiction B, National Government Services, Dr. Robert Hoover, Jr., Medical Director, DME MAC, Jurisdiction C, CIGNA Government Services, Dr. Richard Whitten, Medical Director, DME MAC, Jurisdiction D, Noridian Administrative Services (November 8, 2010).

[4] The National Caucus and Center on Black Aged letter to Dr. Robert Hoover, Medical Director, DME MAC, Jurisdiction C, CIGNA Government Services (November 8, 2010).

[5] *See, e.g.*, Rethinking Comparative Effectiveness Research: An Interview with Dr. Donald Berwick," *Biotechnology Healthcare* (June 2009).

[6] "Escape Fire," Speech to 11th annual National Forum on Quality Improvement in Health Care (Dec. 1999), in *Escape Fire: Designs for the Future of Health Care* by Dr. Donald Berwick (Jossey-Bass 2004), p. 205-206.

[7] "Health Care Law: 58% Favor Repeal of Health Care Law, 37% Oppose Repeal," Rasmussen Reports (November 15, 2010). Accessible at http://www.rasmussenreports.com/public_content/politics/current_events/healthcare/health_care_law

the draft policy may be revised or withdrawn in response to comments, as appropriate; and a final LCD is then posted and made effective following a notice period.

Based upon comments received on the proposed revision to the *Glucose Monitors LCD,* on December 14, 2010, the DME Medicare Administrative Contractors (DME MACs) issued notices that the proposed revision to the Glucose Monitoring policy has been withdrawn. Under the current LCD policy, which remains in effect, Medicare beneficiaries are able to get more diabetes test strips/lancets when their physician certifies the need for additional test strips/lancets.

2. **Please provide data on how many beneficiaries will be affected by the proposed LCD. At a minimum, please provide data showing how many non-insulin dependent diabetics in Medicare submitted claims for more than 100 strips/lancets per three months in 2009. Additionally, how many insulin dependent diabetics in Medicare submitted claims for more than 300 strips/lancets per three months in 2009? How many for more than 600?**

Answer: The data on the number of Medicare beneficiaries that would have been impacted by the draft LCD is not readily available. However, the draft LCD was withdrawn by the DME MACs on December 14, 2010 and the current LCD policy continues to remain in effect. Under the current policy, if the patient's physician certifies the need for additional test strips/lancets, the patient will be able to receive more than the standard coverage level.

3. **Please provide data supporting the reduction in coverage of glucose monitoring for insulin dependent diabetics injecting once per day, from 300 strips per three months under the current coverage policy to 200 strips per three months under the proposed policy.**

Answer: As mentioned previously, the draft LCD has been withdrawn and the current policy remains in effect. Under the current LCD, Medicare beneficiaries will be able to receive more diabetes test strips/lancets if their physician certifies the need for additional test strips/lancets.

4. **Regardless of whether the final policy covers 200 or 300 strips/lancets per three months for insulin dependent diabetics injecting once per day, will you commit to maintaining coverage for additional testing at a physician's discretion for this patient group, without imposing unduly burdensome documentation requirements?**

Answer: CMS is committed to supporting the physicians in their efforts to provide medical care tailored to an individual Medicare beneficiary's needs. Under the current Glucose Monitoring LCD policy, which will remain in effect, if a physician certifies the need for additional test strips/lancets, a Medicare beneficiary can obtain additional test strips/lancets to more closely monitor their glucose levels.

5. **Will you commit to maintaining coverage for additional testing beyond 100 strips/lancets per three months for non-insulin dependent diabetics at a physician's discretion, without imposing unduly burdensome documentation requirements?**

Answer: The physician-patient relationship is an important part of high quality care, especially in the treatment of individuals with diabetes. If a physician certifies the need for additional test strips/lancets, Medicare beneficiaries will be able to get more test strips/lancets under the current LCD policy.

However, the HHS Office of Inspector General (OIG) identified glucose test strips as an area of abuse in an August 2010 report, citing poor documentation of medical necessity. These items are the second highest contributor to the Medicare claims payment error rate for durable medical equipment. As such, CMS' documentation policy for test strips/lancets attempts to balance the need for sufficient documentation to support a claim with the burden associated with such a requirement.

6. **Requiring elderly, sickly patients to keep a detailed testing results log is unworkable. Will you commit to maintaining coverage for more than 600 strips/lancets per three months, if the treating physician provides reasonable documentation of the need, without also requiring a testing results log?**

Answer: CMS' glucose monitors coverage policy seeks to strike a balance between the need for additional documentation and the burden associated with such a requirement. If a physician certifies the need for additional test strips/lancets, Medicare beneficiaries will be able to get more test strips/lancets under the current LCD policy. Documentation requirements, however, are critical to controlling waste, fraud and abuse as cited in an August 2010 OIG report that identified glucose test strips as an area of abuse as a result of repeated poor documentation of medical necessity.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Menendez:

Questions for the Witness:

Child-only Coverage

As a pediatrician, you know better than any of us that children are not little adults and have unique health care needs that must gain special attention in the health care system. Furthermore, during the consideration of the Affordable Care Act, this Committee passed an amendment that I authored to establish a child-only option in the insurance exchange plans. Committee members discussed the point that there are a number of children in this nation, including citizen children in immigrant families, the children of our nation's Veterans, or children of family members with employee-only coverage, that may very well need to have the option of purchasing child-only coverage. Moreover, earlier this month, the Census Bureau reported that 1 in 12 kids in this country now lives with their grandparents, who may have Medicare coverage and thus would need to purchase a child-only plan for their grandchild.

1. **As you work with your colleagues at HHS to implement this provision, how does the Administration assure that the coverage offered will meet the unique needs of children (including the need for adequacy of a comprehensive pediatric provider network, pediatric-specific quality measures, etc.) within these child-only plans but also by all products offered to children in the insurance exchanges?**

Answer: The Administration is committed to ensuring that children and families receive the full benefits provided to them in the Affordable Care Act, including adequacy of provider networks and adequate quality measures. We understand the need for child-only policies and are committed to ensuring children get the high-quality care they need until 2014 and thereafter. The Affordable Care Act requires that plans in the Exchanges must offer services for children, including vision and dental care. As we move forward in planning for the Exchanges, we are committed to ensuring comprehensive pediatric benefits.

CHIP

According to the Robert Wood Johnson Foundation, due to health reform in Massachusetts and the adoption of MassHealth, the uninsured rate dropped in Massachusetts to just 1.7% for children – the lowest rate for children in the nation. That rate stands in sharp contrast to rates of 14% or more in other states. According to a parallel report by the Urban

Institute in Health Affairs, the reasons cited for that very low rate of uninsured is because of the expansion of CHIP in Massachusetts and improved coverage of the lowest income children that previously had been eligible but unenrolled in Medicaid – these low numbers were achieved through "a combination of the states' community-based outreach efforts, the simplification of the MassHealth enrollment process, and coverage expansions that were implemented for parents."

2. **Dr. Berwick, is that your experience? What are the parallels that CHIP Reauthorization and the Affordable Care Act will provide to the remaining 9 million uninsured children in this country?**

Answer: Massachusetts' experience shows us that it is possible to enroll almost every child in a health insurance program. The keys to Massachusetts' success were outreach to children who were eligible for, but not enrolled in, Medicaid and CHIP, a simplified enrollment and renewal process, community-based assistance and – perhaps most importantly – a clear commitment to coverage. I should note that Massachusetts is not the only State that has been making great strides. I recently visited a Louisiana eligibility office and learned how they have reduced the portion of children losing coverage at renewals for procedural reasons to less than 1 percent. As a direct result of these efforts, Louisiana's uninsured rate for children is 5 percent.

Both CHIPRA and the Affordable Care Act include a number of provisions aimed at increasing participation in Medicaid and CHIP. CHIPRA created outreach and enrollment grants, bonus payments to States that significantly increase enrollment and adopt at least five of eight outreach improvements and eligibility simplifications. States were also given "Express Lane" eligibility options, allowing them to use data from other assistance programs like the school lunch program and food stamps to determine whether children are eligible for Medicaid and CHIP. The Affordable Care Act included enrollment simplification provisions that will enable individuals to apply for and renew Medicaid eligibility online and permit hospitals to make preliminary determinations of Medicaid eligibility. By simplifying income eligibility rules and creating a "no wrong door" approach to enrollment, the Affordable Care Act will also help ensure that there is proper coordination between Medicaid, CHIP and the new Health Insurance Exchanges, so that children are placed in the appropriate program without having to apply separately to each.

Wage Index Floor

As you know, in 2005, CMS created the imputed wage index floor for states, like New Jersey, that are considered by the federal government to be all-urban states for Medicare payment purposes. This floor corrected years of unequal treatment for New Jersey's hospitals by providing them with benefits similar to those granted to healthcare institutions in 49 other states through the rural hospital wage index floor. This floor is set to expire next year and I believe that this floor needs to be made permanent. The majority of other states have a permanent floor in place, except NJ. Allowing the floor to expire would once again subject New Jersey's hospitals—and possibly others—to a significant competitive disadvantage and dramatically impact their ability to continue providing affordable, accessible and quality healthcare to the residents of our state.

3. **Would you will be willing to look into this issue and follow up with my office?**

Answer: We would be happy to work with your office on this issue. I strongly believe that Medicare payments for all providers should be fair and equitable and should ensure Medicare beneficiaries' access to high quality care, regardless of where they live or happen to seek care. One important aspect of the Affordable Care Act is that it requires an evaluation of geographic-based payments to multiple provider types. Additionally, HHS has recently commissioned a study by the Institute of Medicine (IOM) to examine regional variation in Medicare spending and quality, and provide recommendations to address unnecessary variation, improve the quality of care, and improve payment accuracy.

IOM's first report on Medicare's geographic adjustment factors is due in May 2011, and I would be happy to keep you informed on the status of IOM's research into this issue.

Improving payment accuracy is a priority for CMS, and we will continue to explore options to address unjustified geographic variation in reimbursement rates and improve the wage index system.

Healthcare-associated infections

Dr. Berwick, your experience as one of the nation's leading authorities on healthcare quality and improvement issues as well as your dedication to patient safety, particularly in the area of healthcare-associated infections, is a great asset to CMS. As you know, HAIs are a serious threat to public health that cost our health care system millions, yet are largely preventable with the appropriate steps. CMS and HHS have acknowledged the economic and human toll of HAI's and have presented a series of reasonable measures through the 2009 HHS Action Plan to Prevent HAIs. Congress concurred with these recommendations as part of the new health care reform law and, with my amendment, included them as priority measures for the initial phase of Hospital Value Based Purchasing program that begins in fiscal year 2013.

4. **How does CMS plan to ensure that all of the required measures from the Action Plan, including MRSA and C-diff, are integrated into the hospital VBP program for implementation in fiscal year 2013?**

Answer: The Affordable Care Act requires that we include healthcare-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections, in the first year of the Value-Based Purchasing (VBP) program (FY 2013). The Act also stipulates that a measure may not be selected for use under the program for a performance period unless it is a measure under the Medicare Inpatient Quality Reporting system and has been on the Hospital Compare website for at least one year prior to the performance period.

This latter requirement limits the number of measures from the HHS Action Plan that will be eligible for inclusion under the VBP program in FY 2013. The Surgical Care Improvement Project (SCIP) measures are a targeted metric of the HHS Action Plan and are currently part of

the Inpatient Quality Reporting system, which would allow us to include these measures in the VBP program in the first year. Two additional measures from the HHS Action Plan are being added to the Inpatient Quality Reporting program – the Central Line-Associated Bloodstream Infection measure (reporting beginning in 2011) and the Surgical Site Infection measure (reporting beginning in 2012). These measures can be incorporated into VBP after they have been reported on Hospital Compare for one year. We are working internally and with the Centers for Disease Control and Prevention (CDC) on the details of other HHS Action Plan measures that may be incorporated into the Inpatient Quality Reporting program and the VBP program in the future.

Medicare Advantage

I am concerned that the formula used to set Medicare Advantage payment rates for Puerto Rico may not work well for a variety of reasons. The Chairman and I submitted a colloquy on this issue during healthcare reform negotiations and, recently, I sent you and Secretary Sebelius a letter, with Resident Commissioner Pierluisi, asking that you conduct your analysis on this issue quickly and, if appropriate, use your authority to employ an alternative calculation method to determine a more appropriate method in Puerto Rico.

5. **Would you be willing to continue to work with me and others on this issue?**

Answer: Both the Department of Health and Human Services and CMS remain committed to fully investigating this situation. We understand your concern involving Medicare Advantage payment rates in Puerto Rico and will follow up with you on the results of our analysis. I look forward to continuing to work with you on this important issue.

Delivery System Reform

Under the new healthcare reform law, Congress created several new exciting models designed to tie physician payments to quality patient care – specifically ACOs, bundled payments, expanded quality measure development and value-based purchasing.

6. **What plans does CMS have, when appropriate, to incorporate emergency care into these new payment models and also include representatives of emergency medicine in the development of these measures?**

Answer: CMS is committed to doing its part in ensuring that the care furnished to beneficiaries in hospital emergency departments (ED) is high quality, efficient, and effective. To accomplish this goal, we have incorporated a number of quality measures pertaining to emergency care in our hospital quality reporting programs. For example, our hospital quality data programs include quality measures directed at the amount of time it takes to begin potentially life-saving interventions that are often initiated in the ED, such as administering aspirin and fibrinolytic therapy for patients experiencing heart attack symptoms.

The law requires that CMS undertake a consensus-based process in the development of measures for our hospital quality reporting programs. The quality measures that we adopt for these programs meet this consensus requirement, which includes public comment and a dialogue with stakeholders. I am committed to continuing this strategy of engaging all interested stakeholders, including the emergency medicine community, as we consider additional quality measures going forward.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Roberts:

Questions for the Witness:

Local Coverage Determination

CMS has recently proposed a local coverage determination (LCD) to restrict the number of times seniors with non-insulin dependent diabetes can test their blood sugar by limiting them to one test strip per day, regardless of what their doctor recommends. Doctors understand that diabetes care is an exceedingly complex and personalized enterprise.

1. **Why is CMS replacing the judgment of a doctor on how many times their patient should test their blood sugar with a "CMS-knows-best" approach?**

Answer: CMS has no intention of replacing the judgment of a doctor.

Provenge

CMS has also initiated a national coverage determination investigation into the Medicare coverage of the life-extending prostate cancer therapy Provenge. Provenge is a therapeutic vaccine approved by the Food and Drug Administration to treat late-stage prostate cancer through an innovative process that removes immune system cells from patients, exposes them to cancer cells and an immune system stimulator, and then injects them back into the patient. Provenge has been shown to increase life expectancy by an average of four months- but sometimes longer with one patient living an additional seven years. In addition, Provenge is special because of its lack of side effects as compared to traditional chemotherapy. So not only can patients live longer, but their quality of life will be better. Medicare coverage for FDA-approved drugs is usually automatic.

2. **Why did CMS initiate a coverage investigation so soon after Provenge was approved? Why is CMS seeking to substitute its judgment for not only patients and doctors, but for the FDA- the gold standard for drug approval worldwide? Are you questioning the FDA's decision?**

Answer: Since the FDA approved PROVENGE, it has been covered on a case-by-case basis by some, but not all, local Medicare contractors. To promote greater consistency in coverage for Medicare beneficiaries, CMS recently opened a National Coverage Analysis, which will lead to a National Coverage Determination (NCD) on coverage for this treatment. The FDA and CMS

have separate and unique roles and authorities under statute. FDA clears, licenses or approves medical products based on standards such as reasonable assurance of a device's safety and effectiveness or substantial evidence to show that a drug is safe and effective for use under the conditions prescribed in the proposed labeling. In contrast, CMS' evidence reviews focus on whether a particular item or service is "reasonable and necessary" for the Medicare population. With some exceptions specifically authorized by statute (for example, coverage of additional preventive benefits), CMS' coverage decisions do not consider cost. Medicare coverage decisions are based upon whether a product is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, as mandated by statute.

A recent meeting of our Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) advisory panel concluded that there is sufficient evidence for CMS to make a coverage decision on on-label uses of PROVENGE, but not enough to make a decision on off-label use. While the panel did not make an actual coverage recommendation, it heard testimony from a broad spectrum of providers, advocates, and experts, and has shared its conclusions with CMS. CMS is currently in the process of considering all available clinical evidence, including the evidence gathered at the MEDCAC meeting, and will issue a proposed decision with an opportunity for public comment before any final determination is made.

FDA-approved Products

In your recent speech before America's Health Insurance Plans (AHIP) in September, you focused on the goals outlined in your "Triple Aim" to improve health care. Central to your plan is to provide better care for patients around the dimensions of safety, effectiveness, patient-centeredness, timeliness, efficiency and equity. You also mention the need to reduce per capita costs by eliminating waste -- which I believe in--with a specific caveat saying that this should not be done by withholding from us or our neighbors any care that helps them. I know that the FDA for instance approves treatments that are safe and efficacious for the U.S. population.

3. **Can you comment or are you of the belief that an FDA approved product should always be covered by Medicare? If not can you please elaborate on the factors that you would use in limiting or denying seniors access to approved treatments?**

Answer: The FDA and CMS have separate and unique roles and authorities under statute. FDA clears, licenses, or approves devices, biologics, or drugs based on standards such as reasonable assurance of a device's safety and effectiveness or substantial evidence to show that a drug is safe and effective for use under the conditions prescribed in the proposed labeling. In contrast, the Medicare program is a purchaser of items and services for a very specific, generally elderly, subpopulation and makes payment based on a determination that the item or service falls within the statutorily defined scope of Medicare benefits and is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. With some exceptions specifically authorized by statute (for example, coverage of additional preventive benefits), CMS' coverage decisions do not consider cost.

4. **Do you agree that the value of a treatment is a matter that should be decided by the doctor and patient?**

Answer: Absolutely. In my opinion, patients and their physicians should be empowered with information that helps them better evaluate whether a treatment, drug, or surgical procedure is appropriate for their individual health care situation.

Personal Responsibility Waivers

I have been shocked by the number of PPACA waivers that have been coming out of the Department of Health and Human Services. According to the New York Times, one hundred and eleven waivers have been granted to employers to allow them to avoid the new health insurance mandates.

5. **Isn't this an admission that PPACA's policies are causing insurance costs to go up? When will the American people get a waiver from Obamacare?**

Answer: This Administration is working to bring greater transparency to the insurance market, and improve the quality of health insurance, while helping to ensure that people can keep the coverage they have. In 2014, high quality coverage will be offered at an affordable price in the new insurance Exchanges and annual dollar limits on coverage of essential health benefits will be prohibited in most plans. As the annual dollar limit prohibition is phased in over the next three years, the Department has set up a process where plans can apply for a one-year waiver if they can show that there would otherwise be a significant decrease in access to benefits, or a significant increase in premiums. This waiver applies only to the annual limit requirement and only lasts for one year.

Comparative Effectiveness Research

I am concerned about the potential for comparative effectiveness research (CER) to be misused by policy-makers in "one-size-fits-all" decisions that deny patients access to treatments that best meet their needs. I was encouraged by Secretary Sebelius' statement to this committee last year that the purpose of such research "is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions."

6. **Would you agree with that statement?**

Answer: Yes. Comparative effectiveness research entails a clinical comparison of treatment options so patients and their providers can make the best treatment decisions. I believe such research is one of many elements needed to build a high-quality, value-oriented health system. It will fill gaps in our current knowledge base and empower patients and clinicians to make fully-informed and better treatment decisions that meet individual health needs. The great potential of comparative effectiveness research is not in restricting patients from needed care. Instead, it will greatly increase the likelihood that care the patient receives will in fact be the care the patient needs for his or her condition.

7. **The Medicare Payment Advisory Commission (MEDPAC) has discussed the possibility of using CER to set broad policy about whether a particular test or treatment is similar to other alternatives, and to only pay for the "least costly alternative." This type of one-size-fits-all use of CER in Medicare is exactly what has concerned me from the start. I agree we need to deal with rising Medicare spending, but not at the expense of patients who don't fit the statistical average. Do you believe that an FDA approved product should always be covered by Medicare? If not, can you please elaborate on the factors that you would use in limiting or denying seniors' access to approved treatments?**

Answer: Senator, I can assure you that CMS will adhere to current law, which prohibits Medicare from denying coverage solely based on the results of comparative effectiveness research. Further, I'm aware that the Patient Centered Outcomes Research Institute (PCORI) may not mandate coverage, reimbursement, or other policies for any public or private payer.

The great potential of this research is not in restricting patients from needed care. Instead, it will greatly increase the likelihood that care the patient receives will in fact be the care the patient needs for his or her condition.

The Food and Drug Administration (FDA) and CMS have separate and unique roles and authorities under statute. FDA clears, licenses, or approves devices, biologics, or drugs based on standards such as reasonable assurance of a device's safety and effectiveness or substantial evidence to show that a drug is safe and effective for use under the conditions prescribed in the proposed labeling. In contrast, CMS' evidence reviews focus on whether a particular item or service is "reasonable and necessary" for the Medicare population. With some exceptions specifically authorized by statute (for example, coverage of additional preventive benefits), CMS' coverage decisions do not consider cost. Medicare coverage decisions are based upon whether a product is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, as mandated by statute.

<u>Ambulance Fee Schedule</u>

On November 2, CMS released the final rule on the changes to the ambulance Medicare fee schedule for 2011. In the final rule, CMS proposes a policy whereby ambulance suppliers will be required to bill in fractional numbers. This changes a long-standing policy that instructed suppliers to bill mileage in whole numbers- a change that will take $45 to $80 million annually out of the ambulance fee schedule.

Congress established the ambulance fee schedule in the Balanced Budget Act, and designed it to be budget neutral. In addition, the Senate Finance Committee has increased reimbursement for ambulance services, including rural services, to ensure that our seniors continue to have access to these vital life saving first responder and health care services. Thus, this new policy by CMS undermines the intent of Congress and this Committee. Of particular concern, rural providers receive a mileage rate bump to help offset their low transport volume and will therefore be disproportionately disadvantaged by the policy change.

8. Will you keep the fee schedule budget neutral and make the necessary adjustments to payment rates to offset the losses to providers resulting from the policy change?

Answer: I am committed to assuring that Medicare beneficiaries, including those in rural areas, have access to high-quality, efficient ambulance services. I am also committed to ensuring that providers are reimbursed fairly and accurately. The fractional mileage reporting policy is a concrete step toward reimbursing ambulance providers more accurately. Under this revised billing policy, ambulance providers will be reimbursed for their transport distance to the closest tenth of a mile, rounding up, as compared to rounding up to the closest whole mile.

This new policy has no effect on the ambulance fee schedule rates. Rather, it only changes our billing procedures to make billing and payment more accurate and appropriate by reducing the amount of payment for a distance the beneficiary was never transported. CMS will closely monitor the effects of the policy so we can consider any appropriate adjustments in future rulemaking.

Critical Access Hospitals

In my state fully two-thirds of hospitals are Critical Access Hospitals. Our 83 CAH's serve disproportionately higher numbers of Medicare and Medicaid patients, have more difficulty attracting and retaining physicians and other providers, and do not have comparable access to capital. For these reasons, it is exceedingly difficult for these hospitals to comply with CMS policies such as the requirement that physicians have direct supervision over hospital-provided therapeutic services.

9. Will you work with me to ensure that the rural health care safety net is protected and that the unique issues facing rural providers are appropriately considered?

Answer: Yes, I am happy to work with you to ensure that the health care needs of rural America are appropriately met. This Administration has made extensive use of Rural Health Extension Offices to help address the unique challenges that providers in rural areas face.

You specifically mention physician supervision requirements for hospital-provided outpatient therapeutic services. I would like to note that in the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period that was released last month, CMS extends the notice of non-enforcement for CAHs and also small rural hospitals to the direct supervision requirement for therapeutic services provided to hospital outpatients.

As we work to implement health reform, we are aware of the exceptional challenges people in rural communities face in accessing high-quality care and we will continue to engage with stakeholders at every opportunity. Many rural providers, including Critical Access Hospitals, face unique staffing challenges, and we will take this into consideration during future implementation and rule making. As a child growing up in rural Connecticut, I often saw my father, who was a country physician, work day and night to provide care to patients in our small town and surrounding rural community. This experience gives me first-hand knowledge of the

unique circumstances that rural providers face. I am committed to continuing to work with you to address the concerns of rural providers.

Medicare Physician Fee Schedule

In the 2011 Medicare Physician Fee Schedule Final Rule, CMS included a new requirement that all paper test order forms for laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule must contain a physician signature, abandoning longstanding existing policy that a signature is not required on these forms. I am concerned that this new policy, due to be implemented January 1, 2011, will disrupt patient access to clinical lab services.

10. **Will CMS consider delaying implementation of this new policy for one year to identify the concerns underlying the new policy and work with stakeholders to find alternative ways of addressing those concerns that will not compromise seniors' access to services?**

Answer: While we do not think that beneficiary access to clinical laboratory services will be negatively impacted as a result of the physician (and qualified non-physician practitioner; NPP), signature policy, we are meeting with stakeholders to better understand their concerns, including the need for additional time to educate all affected physicians, NPPs, and clinical diagnostic laboratories about the revised policy. CMS will take these concerns into account as we determine how best to proceed.

Competitive Bidding

11. **With respect to the Medicare DMEPOS Competitive Bidding Program that will be implemented January 1, 2011, what steps has CMS taken to ensure that contract suppliers will be able to furnish the diabetes testing supplies currently used by beneficiaries in the Round 1 competitive bidding areas?**

Answer: CMS has contracted with suppliers to meet the demand for mail order of a wide variety of brands of diabetic testing supplies in the Round 1 Rebid areas. Beneficiaries will have access to all the top selling brands of diabetic testing supplies in the nine competitively bid areas. If CMS determines that additional suppliers are needed under the Round 1 Rebid to ensure access to particular brands of diabetic testing supplies that are necessary for beneficiary-owned glucose monitors, additional mail-order diabetic supply contracts can be added.

Suppliers under the DMEPOS competitive bidding program must comply with the physician authorization process and all other terms of their contracts, including the nondiscrimination requirement. Under the physician authorization process, if a physician or treating practitioner prescribes a particular brand of item and documents in the beneficiary's medical record the reason why the particular brand is needed in order to avoid an adverse medical outcome, the contract supplier must furnish the prescribed brand, consult with the physician to find an appropriate alternative brand, or work with another contract supplier to furnish the prescribed brand. The nondiscrimination term of the contract requires that the brands of items made

available by the contract supplier under a competitive bidding program must be the same brands of items that the supplier makes available to other customers. Failure to comply with the physician authorization process, the non-discrimination requirement, or any other terms of the competitive bidding contract constitutes a breach of contract and can result in termination of a supplier's contract.

For the national mail order program and all future competitions for diabetic test strips, additional protections will be in place to further ensure access to a wide range of products, both before and after contracts are awarded. The statute requires that before a contract is awarded under a future competition for diabetic test strips, the bidding supplier must demonstrate that its bid covers at least 50 percent of available types of test strip products. In addition, suppliers awarded contracts for furnishing diabetic test strips in the future will be required to meet a new "anti-switching" contract term recently established in our regulations that prohibits suppliers from influencing or incentivizing beneficiaries to switch from the brand of test strips they are currently using to another brand of test strips.

12. With respect to the Medicare DMEPOS Competitive Bidding Program that will be implemented January 1, 2010, if the Anti-Switching Rule (42 C.F.R. § 414.422(e)(3)) is important to prohibit suppliers from persuading beneficiaries to switch testing systems, why is it not important to have this rule in the nine areas where the competitive bidding program will first be implemented?

Answer: While suppliers have an inherent incentive to furnish a wide variety of items to attract business and we expect that most beneficiaries will have no problem getting the popular brands of diabetic strips advertised on television and widely distributed by pharmacies, we included a proposal in the CY 2011 physician fee schedule rule based on advice from the PAOC for additional protections in the context of a National Mail Order program. We did not propose to apply the policy in the Round One rebid, as we cannot make it apply retroactively to the Round One rebid since the bidding and the awarding of contracts has already been completed. However, given the incentives in the program and the limited size of the Round One rebid, we expect that most beneficiaries will have no problem getting the brand of test strips they want.

Additionally, our existing regulations include protections to ensure a beneficiary's ability to receive the brand of test strips the beneficiary and their physician have selected. The anti-switching proposal would be an extra, added protection for the beneficiary. When a physician or treating practitioner prescribes a particular brand of a competitively bid item – including diabetic testing supplies – the contract supplier must furnish the prescribed brand, consult with the physician to find an appropriate alternative brand, or work with another contract supplier to furnish the prescribed brand. The contract supplier is also required to furnish the same product lines to Medicare patients that it furnishes to non-Medicare patients. Also, existing protections against aggressive telemarketing continue to apply in addition to the features of the program that result in choice and quality for beneficiaries.

We will closely monitor all contract suppliers to ensure that they are in full compliance with the terms of their contracts and are furnishing quality products and services under the program.

13. With respect to the Medicare DMEPOS Competitive Bidding Program that will be implemented January 1, 2010, please provide information on the number of bidders, including their size and location, for the Kansas City bidding area as well as the number of winning bidders, including their size and location.

Answer: There were 213 bidders for the Kansas City competitive bidding area (CBA) who participated in the Round 1 Rebid for the DMEPOS Competitive Bidding Program. 36.6 percent of these bidders were small suppliers, that is, they had $3.5 million or less in gross annual receipts from Medicare and non-Medicare revenue. These bidders had 296 locations. Not including the mail order diabetic supply product category, 70.0 percent of the bidders furnished items in the CBA prior to competitive bidding.

Ninety-one contracts were awarded to 48 bidders in the Kansas City CBA; 37.5 percent of the contract suppliers are small. The contract suppliers have 78 locations within the CBA. Not including the mail order diabetic supply product category, 79.1 percent of the contract suppliers furnished items in the CBA prior to competitive bidding.

A complete list of the contract suppliers (those with winding bids) for the Kansas City CBA can be found at this link:
http://www.cms.gov/DMEPOSCompetitiveBid/01A2_Contract_Supplier_Lists.asp#TopOfPage

Obesity

It has been widely reported that obesity among U.S. adults is rising alarmingly. Experts predict that, if the trends continue, 41 percent of the U.S. adult population will be obese within five years, and over 51 percent by the year 2030. This epidemic not only has human costs, but also poses large economic costs to the health care system. Obesity is estimated to account for 9.1 percent of U.S. annual health care spending- nearly $150 billion this year.

A recent New York Times article reported that several next-generation pharmacologic treatments for obesity are currently in the works. These new products may hold promise; however, a broad statutory exclusion would prevent them from being available under Medicaid or Medicare Part D.

14. Are you willing to look into the coverage exclusions for weight loss medicines and advise this Committee regarding the proper incentives for development of, and access to, safe and effective anti-obesity treatments?

Answer: As you know, drugs used for weight loss are not covered under the basic Part D benefit and are among the prescription drugs that States can exclude from Medicaid coverage. However, as you indicated, the obesity rate in the United States is rising alarmingly, and I share your concerns about this serious public health problem. I would be happy to work with the Congress to determine whether there is evidence that coverage of weight loss drugs under Medicare or Medicaid would be effective in combating obesity.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Snowe:

Questions for the Witness:

CMS Actuary Report

In considering a monumental issue such as health reform, we rely heavily on the Congressional Budget Office, the Joint Committee on Taxation and the CMS Actuary for independent, accurate and timely analysis. Throughout the process, I voiced strong concern that artificial and arbitrary deadlines were driving the process while critical questions on key issues remained unanswered. In April, approximately one month after the two health reform bills were signed into law, the Chief Actuary of CMS, Mr. Richard Foster, released an analysis which contained some startling revelations. Mr. Foster characterized some of the Medicare cuts in the health reform bill as "unrealistic." Foster suggests that "*15 percent of Part A providers would become unprofitable within the 10-year projection period*." Foster also said that Medicare cuts "*cannot be simultaneously used to finance other federal outlays (such as the coverage expansions) and to extend the [life of the Medicare] trust fund*, despite the appearance of this result from the respective accounting conventions."

1. **Many providers in Maine are concerned about the aggressive savings targets contained in the health reform law. For example, 43 percent of Maine home health agencies – who for the most part will not benefit from reductions in the number of uninsured – are already operating in the red before cuts in that industry even begin. To what extent do you agree or disagree with Mr. Foster's analysis?**

Answer: I am aware that the CMS Actuary made these assessments at various points. It is important to remember that economic projections require making assumptions about the future which includes many uncertainties and is very difficult to predict. The degree of accuracy for these projections often varies. For instance, the Actuary underestimated the savings from the Balanced Budget Act and overestimated the cost of implementing the Medicare Part D prescription drug benefit.

One of the many responsibilities that we have at CMS is to ensure that beneficiaries maintain access to the medical care that they need, including home health services. However, Medicare Payment Advisory Commission (MedPAC) analyses have repeatedly shown that home health industry profit margins are high, which seem to indicate that Medicare payments are in excess of

industry costs. Most recently (in its March 2010 report), MedPAC found that in general, home health agencies (both non-profit and for-profit companies) have a substantial profit margin that will be able to sustain these reductions. Nevertheless, we will continue to monitor access to home health services. If you have concerns about particular home health agencies in your state, I would be happy to work with you and those agencies to better understand their concerns.

2. **One of the glaring omissions from the health reform bill was the failure to include the true cost of a solution to problems caused by the Medicare sustainable growth rate formula, which threatens to cut physician payments by 21 percent on November 30th. The Administration has indicated support for a 13-month extension. Given that so many offsets have already been used for health reform, does the Administration have a preferred means to pay for the SGR patch?**

Answer: As you know, the Medicare and Medicaid Extenders Act of 2010 reverses the scheduled reduction in Medicare reimbursements and extends current Medicare payment rates to physicians through December 31, 2011.

Stable, predictable physician payments are critical to ensure Medicare is viewed as a dependable business partner. Fixing the SGR to provide stability in physician payments is a top priority, and I look forward to addressing this in the coming year.

Maine Medicare Reimbursement

One of the themes that I hear time and time again from Maine hospitals is that they are essentially *penalized* under the current Medicare reimbursement structure for being *efficient* providers of health care. According to the Maine Hospital Association, Maine's Medicare hospital payment to cost ratio is 79.1 percent while the national Medicare hospital payment to cost ratio average is 90.6 percent. Yet although Maine hospitals are providing *lower cost* care compared to the national average, they are providing *higher quality* care at the same time.

The fact is Maine has been *continually recognized* for their outstanding efforts on cost and quality. Maine's hospitals are 3rd best in the country as cited in the Agency on Healthcare Research & Quality's 2008 National Healthcare Quality & Disparities Reports. *And last summer, your organization recognized Portland as being one of 10 model communities* able to provide high quality, low cost care. The Dartmouth Atlas Project looked at the 306 hospital referral regions across the country and in these ten communities, their quality scores are well above average. Yet they spend *16 percent less* per Medicare patient than the national average and have a slower real annual growth rate – *3 percent versus 3.5 percent* – nationwide.

3. **Maine hospitals argue that the hospital wage index is the driving force behind this inequity. It puts them at a disadvantage to places like Boston and contributes to the shortage of physicians in my state. The current jumble of reclassifications and adjustments to the wage index has created a complicated and inequitable system.**

To what extent is wage index reform a priority at CMS and how can the wage index be improved?

Answer: I share the President's and the Secretary's commitment to developing and implementing policies that advance health care quality and value, reduce unnecessary utilization, and accurately pay providers. HHS has recently commissioned a study by the Institute of Medicine to examine regional variation in Medicare spending and quality, and provide recommendations to address unnecessary variation, improve the quality of care, and improve payment accuracy. In my experience, many of America's rural areas have been on the cutting edge leading change and improvement in health care. These are the places that come up with new and better ways to address the unique circumstances of their communities. I want to cultivate this creativity in rural areas through new authorities such as the Center for Medicare and Medicaid Innovation and I look forward to working with you on those activities. This is a priority for CMS, and we will continue to explore options to address unjustified geographic variation in reimbursement rates and improve the wage index system.

4. **The health reform law requires the Secretary to develop efficiency measures in value based purchasing by FY2014. How can you use existing data at the Department to promote high performing hospitals with low costs?**

Answer: As part of our efforts to improve care for our beneficiaries and reduce costs, I share your interest in working quickly to develop efficiency measures for the Medicare program. CMS is in the process of developing efficiency measures applicable to hospitals and will be seeking comment on this issue early next year. We will take into account comments from all interested stakeholders, including any comments from the Maine Hospital Association, on our proposed measures.

Maine and Medicaid

Today, many states are struggling to sustain Medicaid programs that they can no longer afford. According to the Rockefeller Institute, *state tax collections could take five years or more from when the recession began in December 2007 to recover to prerecession levels.* The situation is particularly acute in states that have generous levels of Medicaid eligibility. Even though a state may have been able to support extensive programs in the past, doesn't mean the federal government should assume that they can maintain these investments through the economic downturn. It's also critical to keep in mind that states with high eligibility often have low provider rates as a consequence of that choice . . . and some states cannot afford to cut provider rates any further. Yet as a result of health reform, in the *short term*, states with high levels of Medicaid eligibility must carry a much heavier burden in the maintenance of effort requirement than states with minimal Medicaid eligibility . . . and in the *long term*, states with high levels of eligibility for parent coverage will shoulder a larger share of the cost of that coverage than states that chose to spend their budget dollars elsewhere.

5. **Do you believe that federally mandated coverage levels should be reimbursed equitably? If so, how can this be achieved?**

Answer: Medicaid is a State-Federal partnership and over the program's history, different States have made different coverage choices. In addition to providing generous Federal funding for newly-eligible enrollees, in the Affordable Care Act Congress attempted to level the playing field over time by providing enhanced funding for States that had already expanded coverage. States that currently offer health coverage statewide to parents and non-pregnant, childless adults with income that is at least 100 percent of the federal poverty level will receive an increased FMAP to reduce the State share of costs attributable to previously eligible childless adults under 133 percent of the FPL. These "expansion States" will receive an increase in FMAP equal to a specified percentage of the gap between their regular Medicaid matching rates and the enhanced matching rate provided to other States. Under the terms of the law, the "transition percentage" increases annually and will reach 100 percent in 2019. In 2019 and thereafter, expansion states will be responsible for the same State share of the costs of covering non-pregnant, childless adults as non-expansion States.

6. **Are you concerned that given the dire fiscal situation in the states, combined with using Medicaid as a major platform for extending health coverage to the uninsured, that states will be unable to afford investments and improvements in long term care for those eligible for both Medicare and Medicaid?**

Answer: The Administration is concerned with the rising cost of long-term care and we support efforts to rebalance the long-term care system to both improve care and increase overall efficiency. Far from being a burden, we expect that the Affordable Care Act will pave the way to control long-term care costs over time with new tools to help States improve the delivery of long-term care services and potentially reduce costs. Expansion of the Money Follows the Person (MFP) demonstration and new and enhanced State Plan options will enable States to move away from expensive, institution-based care and build their home and community-based services infrastructure and capacity. This will enable States to develop a stronger support infrastructure and have a more balanced, less costly, long-term care system.

Improving care for dual eligibles – those eligible for both Medicare and Medicaid – is also high priority for CMS. The fragmented, uncoordinated care most of these beneficiaries receive today is not advancing their health and is contributing to inefficiency in the health system. Duals demonstrations will be part of the Center for Medicare and Medicaid Innovation (the Innovation Center) portfolio of delivery system and payment demonstrations. The Innovation Center recently announced an upcoming opportunity for States to apply for contracts to support development of demonstration models aimed at improving quality, care coordination, cost-effectiveness, and overall experience of care for dually eligible beneficiaries. The Innovation Center expects to award design contracts to as many as 15 state programs for up to $1 million each to begin this work.

7. **Last year, at a Finance Committee health reform roundtable, the National Governors Association suggested that states should be credited for generating savings to Medicare when making Medicaid investments for this population. Do you agree with this assessment? How could this be accomplished?**

Answer: The Administration is very excited about the promising opportunities that the Affordable Care Act created for CMS to test care delivery and payment reforms in the Medicare and Medicaid programs. With the creation of the new Center for Medicare and Medicaid Innovation (Innovation Center) and the Federal Coordinated Health Care Office (FCHCO), CMS now has enhanced tools to implement demonstrations that focus on individuals eligible for both Medicare and Medicaid (otherwise known as dual eligibles). These demonstrations will assess the possibility of savings for both States and the Federal government, as well as enhanced quality of care for the dual eligible population. We look forward to working with a range of interested stakeholders as the Innovation Center and FCHCO launch a range of new initiatives.

Drug Importation

Not long after the Administration struck an $80 billion deal with the pharmaceutical industry in exchange for their support of health reform, a *New York Times* article entitled "Drug Makers Raise Prices in the Face of Health Care Reform" found that last year's average brand drug price increase of over 9 percent represents the highest annual rate of inflation for drug prices since 1992! This single price increase alone will yield at least twice what the industry pledged for reform. So in other words, we have the industry setting a new pricing baseline that is entirely off kilter with the rest of the economy . . . widely unaffordable for the American people . . . and clearly unsustainable for the future.

At the same time, press accounts suggest that the deal included a private promise by the Administration that it wouldn't support importation. This is highly disappointing as the savings from drug importation are undeniable. Consumers would save $80 billion . . . not to mention that CBO estimates the federal government would save $19.4 billion.

8. **To what extent is the Administration willing to support drug importation, as well as any other method of extracting greater savings on prescription drugs as a means to pay for Medicare priorities, including SGR reform?**

Answer: Stable, predictable physician payments are critical to ensure Medicare is viewed as a dependable business partner, and the Administration is pleased that Congress has approved a 13-month "fix" for Medicare physician payments. Fixing the SGR to provide stability in physician payments is a top priority, and I look forward to seeing this addressed legislatively. The Administration's FY 2011 budget request contains proposals that generate savings which Congress could choose to use to offset some of the cost of fixing the sustainable growth rate (SGR) formula.

This Administration is strongly committed to ensuring safe access to innovative drug therapies for all Americans. The Administration supports a program to allow Americans to buy safe and effective drugs from other countries, and included $5 million in the Fiscal Year 2010 and 2011 budget requests to allow the Food and Drug Administration (FDA) to begin working with stakeholders to develop policy options related to drug importation and to address some of the implementation challenges like improving supply chain security.

Comparative Effectiveness

There can be little doubt that we should leverage our national investment in medical knowledge so that providers and patients alike may know which alternatives work best. Despite spending more than $30 billion per year on NIH research alone, sorting out how to apply our knowledge of prevention, diagnosis, and treatment is often difficult. That is why obtaining objective evidence is key to reforming our spending. Yet we cannot lose sight of the patient in these discussions. In practice we might see that some alternatives might be more expensive, but because they work far better, they represent good value. So research should first establish the relative benefit of the product or service in improving health . . . as well as whether particular subsets of patients – such as women or seniors, groups that historically have been under-represented in research studies – might benefit more.

9. **How will CMS use comparative effectiveness research so that patients remain a primary focus rather than cost? What areas do you consider the highest priority?**

Answer: The Affordable Care Act established a non-governmental nonprofit Patient-Centered Outcomes Research Institute (PCORI) to set priorities and a research agenda for comparative clinical effectiveness research. The purpose of PCORI is to support research to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other stakeholders about which interventions are most effective for which patients under specific circumstances.

CMS will adhere to current law, which prohibits Medicare from denying coverage solely based on the results of comparative effectiveness research. Further, I'm aware that the PCORI may not mandate coverage, reimbursement, or other policies for any public or private payer. The great potential of this research is not in restricting patients from needed care. Instead, it will greatly increase the likelihood that care the patient receives will in fact be the care the patient needs for his or her condition.

Medicare Advantage

In your testimony, in regard to Medicare Advantage, you state that seniors and people living with disabilities will have clearer plan choices offering better benefits. You also tout that in 2011, premiums are lower and enrollment is projected to be higher than ever before. Last month, Harvard Pilgrim dropped its private fee-for-service plan affecting 22,000 senior citizens in Massachusetts, New Hampshire, and Maine, largely due to reductions from previous legislation but also in anticipation of the cuts to Medicare Advantage made by health reform. In presenting information to seniors, it appears that the Administration often takes an overly sunny view on the effects of health reform, when the reality is quite different.

The seniors who are losing access to their plan now have to make new choices. Today, 75 percent of current MA beneficiaries are on a plan that is 3 stars or less or unrated. As of April 2010, 42 percent of Maine residents using Medicare Advantage are enrolled in two or three starred plans, and 28 percent of Maine beneficiaries are enrolled in plans that are not

currently rated. While Medicare.gov has a website where consumers can compare Medicare Advantage plans, the data is often presented in a complicated manner and we have no definitive idea as to how many beneficiaries understand and utilize this information.

10. How we can better communicate health care quality measurements and data to consumers so that they can make better-informed decisions?

Answer: CMS has always been committed to improving the communication of quality measurements and data to beneficiaries to promote better-informed decisions about their health care. CMS publishes and delivers our Medicare & You Handbook annually to every household with a Medicare-eligible resident in an effort to educate our beneficiaries about Medicare. This handbook is tailored for every State and contains special information about available Medicare Advantage (MA) plans including member satisfaction results and cost-sharing information for each plan.

CMS makes a constant effort to update our online tools to enhance the presentation and ease of use for Medicare beneficiaries. For example, for the 2011 plan year:

- In past years, CMS has had two online tools: one for Part D, which was the Medicare Plan Finder, and another for MA, known as the Medicare Options Compare. For this year we have one online tool for both Part D and MA called the Medicare Plan Finder;
- The new Plan Finder online tool was updated to present a single overall summary plan rating for MA-PDs which includes both Part C & D services; and
- A "low performer" icon was added to Plan Finder which displays next to plans that have consistently performed poorly during the past three years.

CMS also continually updates the measures that feed into our 5-star ratings system in an effort to improve and refine both the presentation and effectiveness of the quality measures.

Medical Residency Training Program

Rules promulgated by your agency provide that a hospital can receive an adjustment to its FTE resident cap if it establishes a new medical residency training program. The regulations define "new medical residency training program" as one that "receives initial accreditation by the appropriate accrediting body." It has come to my attention that hospitals located in several states established new programs in accordance with the regulation and received a cap adjustment, including a program in my own state, have subsequently been denied Medicare funding for their graduate medical education programs by your agency. In addition to denying new funding, CMS is requiring these facilities to pay back Medicare funds that they had previously received. The agency has taken this position despite the fact that the institutions followed the clear and unambiguous standard in your agency's regulation and, in at least one case, the specific written guidance of a CMS official. This abrupt change in policy, done in the absence of an agency rulemaking, is highly troubling, especially since it has adversely affected the training of physicians in my State.

11. Is it your policy to require your agency to comply with its own clear and legally established standards? If so, do you intend to revisit the agency's reversal in policy that penalized medical institutions that relied on agency guidance to their own detriment?

Answer: The Medicare program provides a substantial contribution to the training of physicians across the country by compensating hospitals for the direct and indirect costs incurred in training medical residents. I am committed to supporting Medicare's role in training physicians in order to ensure continued beneficiary access to high quality care. While I believe it is important for our nation to develop our provider workforce, I also believe that CMS must abide by the statutory requirements set forth for the Medicare program.

For purposes of determining graduate medical education payments, the Medicare statute establishes a cap on the number of residents for which a teaching hospital may receive payment. Hospitals that have not previously trained residents, and wish to become teaching hospitals, may do so by establishing new medical residency programs. New teaching hospitals have a three-year growth period in which to establish new programs, after which a resident cap is permanently set. In light of the statutorily mandated cap, it is important to be deliberate in the determinations regarding the establishment of resident caps to ensure that resident slots at new teaching hospitals are only given to programs that are truly new, and not for programs that existed at one hospital and were transferred to a non-teaching hospital.

In the FY 2010 Hospital Inpatient Prospective Payment System Final Rule, we noted that some hospitals and Medicare contractors may have misunderstood the regulations regarding what constitutes a new program and inappropriately viewed programs that had transferred to a non-teaching hospital to be new programs. In that rule, CMS clarified our policy regarding determinations of whether a particular residency program is a new program. To make the determination of whether a program is new or merely a transfer of a previously existing program to another hospital, the Medicare contractor and CMS review the relevant characteristics of the residency program. A program that transfers to a non-teaching hospital, but has the same residency program director, the same teaching staff, and the same residents as a program that existed at another teaching hospital is not a new program for Medicare cap purposes. If a hospital does not agree with the determination of their program, the usual administrative appeals process is available.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Stabenow:

Questions for the Witness:

Graduate Nursing Education

The Affordable Care Act included a provision I authored to test how Medicare could support Graduate Nursing Education. If successful, this modest fund would help to create hundreds more advanced practice registered nurses who would help to provide healthcare in current health professional shortage areas and would help provide care to many of the 32 million Americans who will have health insurance coverage thanks to the Affordable Care Act.

1. **Can you update me on what is being done to implement this provision successfully? This would help us train more professionals to provide primary care, particularly in medically underserved and rural communities.**

Answer: Senator, thank you for your leadership on this subject. We know there is a need for increased clinical training programs for advance practice nurses in community settings. The Graduate Nurse Education Demonstration included in the Affordable Care Act provides payment for up to five eligible hospitals for the hospitals' reasonable costs for the provision of qualified clinical training to advance practice nurses. We believe that this demonstration will help to show how to develop programs to improve the relevance of clinical training for Medicare beneficiaries.

CMS is currently in the planning and development phase of the demonstration. We have already reached out to many stakeholder organizations that represent advanced practice nurses for input and we will continue to seek advice on how to effectively design the demonstration. We anticipate soliciting applications in 2011 and will continue to communicate with you and others about how best to implement this demonstration.

Medicaid Managed Care Plans

Medicaid managed care plans must meet specific consumer protection standards articulated in HIPAA, including mental health and substance use disorder parity. But the interim final rule on the Wellstone-Domenici requirement does not yet specifically apply to Medicaid managed care.

2. **Can you please update the Committee on progress on any specific written guidance being developed for state Medicaid agencies making clear their obligations to ensure managed care plans they contract with are meeting the standards in the statute and regulations for parity level coverage of mental illness and substance use disorders?**

Answer: The Administration and CMS are strongly committed to implementing the Medicaid managed care requirements set forth in the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. On November 4, 2009, CMS issued initial guidance to States in a State Health Official letter. Since the publication of this letter, CMS has consulted its partners within the Department and is considering what additional guidance to States may be needed.

3. **Additionally, as part of the interim final rule, CMS asked for comments from interested parties on how to most effectively ensure equity between medical-surgical benefits and behavioral benefits. Can you please update the Committee on where CMS is in considering comments that were submitted and moving forward to publish a final regulation?**

Answer: Responsibility for the mental health parity regulation has been transferred to the HHS Office of Consumer Information and Insurance Oversight (OCIIO). HHS will continue to consider the comments received from various stakeholders on how to most effectively ensure equity between medical-surgical benefits and behavioral benefits and does not currently have a definite deadline for publishing the final rule. In addition, the Department is considering issuing future guidance to assist in implementing the new requirements for the increased cost exemption under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act.

Diabetes

More than 24 million Americans have diabetes, and nearly 60 million have prediabetes, but a large percentage of these individuals do not know they are at risk. In Michigan alone, there are over 2 million people with prediabetes. We need to screen for diabetes and prediabetes, particularly among our seniors. Recent numbers show that 72% of the Medicare population either has diabetes (30%) or prediabetes (42%), and have a screening benefit available to them, but only about 10 percent of beneficiaries are using it.

4. **How can we make sure that this screening benefit, which is paid for, can find and get these seniors the care they deserve?**

Answer: The Affordable Care Act provides Medicare beneficiaries with enhanced benefits and lower out-of-pocket costs for many recommended preventive services. While Medicare already covers a comprehensive package of preventive benefits as well as a one-time "Welcome to Medicare" exam for new beneficiaries, before the enactment of the Affordable Care Act, Medicare did not cover annual check-ups for beneficiaries. Beginning in 2011, Medicare will cover an annual "wellness visit" at no cost to the beneficiary, so beneficiaries can work with their physicians to develop and update a personalized prevention plan. This new benefit will

provide an ongoing focus on prevention that can be adapted as a beneficiary's health needs change over time and will provide an opportunity for physicians to discuss needed tests, like diabetes screening, with their patients.

In the past, many screening and preventive services were underutilized by Medicare beneficiaries in part because out-of-pocket costs presented a financial barrier. Beginning in 2011, all preventive benefits covered by Medicare that are recommended with an A or B rating by the U.S. Preventive Services Task Force will be available to beneficiaries free of charge (without having to pay coinsurance or apply the Part B deductible). These important benefits include tests and procedures that may either prevent illnesses or detect them at an early stage when treatment is likely to work best, such as screenings for diabetes, cardiovascular disease, and osteoporosis, as well as breast, cervical, and colorectal cancers.

CMS and HHS have a responsibility to educate beneficiaries about their Medicare benefits and what coverage options are available to them. To help educate beneficiaries about these new benefits, CMS will take a multi-pronged education and outreach approach, using advertising, news releases, public service announcements, local town hall meetings, and health fairs to reach beneficiaries. The new benefits and cost-sharing changes were explained in the 2011 Medicare & You Handbook, which also highlights Medicare's existing preventive benefits, including diabetes screening and other services for those living with diabetes.

Medicare Geographic Adjustments

Almost all of the Finance Committee members represent states where Medicare's geographic adjustments have led to physician payment rates that are lower than we thought they ought to be. We addressed that in the Affordable Care Act with provisions that increased the work and practice expense indexes in states where Medicare payments tend to be below the national average. In Michigan, for example, these provisions are expected to increase payments to physicians by 1.8%. We made these increases retroactive to January 1 and assumed that CMS would automatically adjust claims filed before the law was passed and implemented. But I have heard that physicians have only received payment at the new rates for claims on or after June 1 but not for claims filed during the previous six months.

5. What steps is CMS taking to address the delay?

Answer: CMS is currently developing the best course of action for addressing past claims that were processed under pre-Affordable Care Act rules. The volume of claims that must be adjusted is unprecedented and a careful process must be deployed to ensure that new claims coming into the Medicare program are processed timely and accurately, even as we address making the retroactive adjustments. CMS is working now to begin reprocessing these claims as expeditiously as possible. I look forward to working with you on this issue.

Patient Access

Currently, CMS includes prompt pay discounts extended to wholesalers as price concessions in the ASP calculation and this artificially reduces the reimbursement amount physicians receive for Part B drugs. This reduction in reimbursement is threatening our nation's highly efficient drug distribution system.

Also, it is particularly harmful for community oncology practices, where 84 percent of cancer patients are treated. And this could have an impact on patients if community oncology practices close in Michigan and across the country.

I am a co-sponsor of bipartisan legislation that would address this situation by excluding customary "prompt pay" discounts from the ASP calculation. Congress already excluded these terms from the Medicaid Average Manufacturer Price ("AMP") methodology.

6. **Would it be possible for you and your staff to review this legislation and then work with the bill's cosponsors and stakeholders to see if we can improve this reimbursement system to protect patient access to community oncology practices?**

Answer: CMS is committed to paying appropriately for all goods and services in the Medicare program. We would be happy to examine this proposed legislation and discuss it further with you and your Congressional colleagues.

Coordinating Care

I was very pleased about the announcement that Michigan would be part of the new "multi-payer" demonstration project, which you mentioned in your testimony. This new initiative shows real creativity and thoughtfulness. We really need such leadership going forward in 2014 when health reform is fully implemented. Coordinating between multiple public and private payers will be challenging but something we can do.

7. **In gearing up for 2014, what are the top three things you hope to accomplish at CMS to prepare the agency?**

Answer: CMS can and should be a major force and a trustworthy partner for the continual improvement of health and health care in this country. With over 100 million beneficiaries depending on us each day, CMS has an important role to play in improving our nation's health care delivery system while attending diligently to the crucial, day-to-day work of our operations and preserving and enhancing the integrity of our payments, our programs, and the Trust Funds.

My work as CMS Administrator is shaped by three major, overarching goals that will reduce costs while improving quality: first, providing better care for individuals – care that is more effective, more patient-centered, timelier, and more equitable; second, assuring better health for populations by addressing underlying causes of poor health, like physical inactivity, behavioral risk factors, and poor nutrition; and third, reducing costs by improving care, eliminating waste

and needless hassles, reducing preventable complications in care, and coordinating care for patients who are journeying through the system.

CMS must make meaningful, measurable progress on all three of these goals to prepare for 2014. That means improving the quality of health care by avoiding preventable errors, infections, and readmissions to the hospital. We must also do a much better job of preventing disease and illness. The Affordable Care Act takes important steps in this direction, by ensuring that Medicare beneficiaries receive needed preventive screenings and tests, as well as an Annual Wellness Benefit with no copayments.

Finally, we must move away from a fragmented system to an integrated person-centered delivery system. Through the Center on Medicare and Medicaid Innovation, CMS will be testing a variety of new models to better deliver care. The Affordable Care Act also establishes a Federal Coordinated Health Care office to better coordinate the care for those enrolled in both Medicare and Medicaid. These tools will give CMS an important opportunity to contribute to the development of a more modern health care system that provides the high quality, integrated care that all patients want and expect. However, CMS cannot do this work alone and neither can government as a whole. Collaboration will be essential to meeting all of these goals, and I am eager to work with you, members of the Committee, and public and private stakeholders in pursuit of these aims.

United States Senate Committee on Finance
Public Hearing
"Strengthening Medicare and Medicaid: Taking Steps to Modernize America's Health Care System"
November 17, 2010

Questions Submitted for the Record From Dr. Donald Berwick

Senator Wyden:

Questions for the Witness:

Medicare Hospice Benefit

The Affordable Care Act (ACA) included a provision directing the Secretary of HHS to collect, beginning early next year, additional data and information regarding the Medicare hospice benefit. Last month, over two dozen Senators delivered a bipartisan letter to you on this topic. As you know, the Medicare Hospice Benefit has provided high quality end of life care and support to patients and their families for almost 30 years. As hospices' reimbursement is based on a per diem benefit, CMS has limited data as to the range of services, treatment and supplies that are currently being provided, however. I understand that CMS began collecting some limited provider information from hospices in 2008.

1. **What steps is your agency taking to ensure that it has a comprehensive picture of the hospice care model?**

Answer: CMS is actively exploring ways to refine and enhance its hospice data collection through the Medicare hospice claim and the Medicare cost report. During the past 18 months, CMS officials have met with various hospice representatives to discuss the industry's suggestions for changes to data collected on Medicare claims and Medicare cost reports. As a result of these meetings with the hospice industry representatives, CMS began to collect information on clinician visits in 15-minute increments on the hospice claim beginning in January 2010.

We are constantly working to balance the need for additional data collection, while also considering the potential burden that collection may cause hospice providers. It is CMS' priority to collect the data needed to understand hospice resource usage for purposes of reforming hospice payments as required by section 3132 of the Affordable Care Act.

Shared Savings Program

As you know, the Affordable Care Act's Shared Savings Program authorizes doctors and providers to come together to form Accountable Care Organizations (ACOs). The premise is straight-forward: organizations that improve health outcomes and reduce costs can share in the savings. Of course, ACOs will only be successful if the doctors and providers who come together are accountable for addressing a large majority of a given population's personal health care needs.

Medicare beneficiaries with end stage renal disease (ESRD) suffer from multiple co-morbidities. ESRD patients are a population that accounts for less than one percent of the overall Medicare population but approximately six percent of total Medicare costs in 2008 according to the United States Renal Data System 2010 report. With regular and constant contact with their patients, nephrologists and dialysis providers are principally responsible for coordinating care for advanced kidney disease patients. This makes them uniquely suited to deliver on the promise of ACOs. In fact, in recently completed successful demonstration programs with CMS, several dialysis providers created innovative integrated care models for this population within the Medicare Advantage program which reduced mortality, reduced hospitalizations and lowered the overall cost of care.

2. **Will dialysis providers and nephrologists be considered as primary care professionals under the Shared Savings Program and therefore be considered by CMS for inclusion as part of ACOs?**

Answer: The goal of the Shared Savings Program is to improve care coordination for all patients, including Medicare beneficiaries with end-stage renal disease (ESRD). Dialysis providers and nephrologists play a critically important role in ensuring successful care coordination for Medicare beneficiaries with ESRD. As we develop the Shared Savings Program, we are considering the role of providers across the health care delivery system in promoting the coordination of care. In addition, the development of the program, including the roles of various providers involved in the coordination of care, will be informed by the comments we receive from stakeholders and others through the notice and comment rulemaking process.

<u>Competitive Bidding</u>

Under competitive bidding, specialized wheelchair seating, like cushions designed to address skin integrity problems, were included with products that address mobility. Disabled beneficiaries are concerned that this could mean that winning bidders will seek to promote seating cushions that cost them the least, rather than the cushion that would be most appropriate to address the unique individual's medical needs.

3. **Why were these products included with products that are dissimilar? Has anyone at CMS looked at the amount of dollars saved – if any – by including these cushions in competitive bidding against the cost of wound care?**

Answer: Wheelchair seat cushions are necessary for some beneficiaries in order to effectively use power mobility devices (PMDs). These PMD accessories and other PMD accessories were included in the standard PMD product category within the competitive bidding program to allow the patient and his or her physician and health care team to work with one contract supplier in planning and coordinating overall care, and to ensure that beneficiaries can obtain PMDs and all items needed for the proper use of the PMD equipment from one contract supplier.

Decisions about products included in the competitive bidding program were based upon Healthcare Common Procedure Coding System (HCPCS) classifications and not based on individual items. In other words, the individual items contained within the competitive bidding product categories are identified using HCPCS codes, which are developed for items that are

similar in function and purpose. In the case of wheelchair cushion products, these items must be tested and meet certain product requirements before they can be assigned to a particular code for Medicare billing and payment purposes.

The HCPCS is updated annually, or more frequently as needed, based on requests for changes submitted from various individuals and entities, including manufacturers and suppliers of DMEPOS items and services. HCPCS codes for wheelchair seating products and services have been significantly revised in recent years based on such requests and the Medicare program's needs. We will continue to use this process to ensure that codes reflect current technology and meet the needs of Medicare beneficiaries.

It is important to note that there are additional protections under the competitive bidding program to ensure that beneficiaries with specific cushion needs maintain access to their prescribed wheelchair cushions. Under the physician authorization process, required by law and in regulations for the DMEPOS competitive bidding program, if a physician prescribes a specific product to avoid an adverse medical outcome for a beneficiary, such as a pressure ulcer, the contract supplier must furnish the prescribed brand, consult with the physician to find a suitable alternative brand, or assist the beneficiary in finding another contract supplier in the competitive bidding area to furnish the prescribed brand.

Additionally, CMS will have a number of measures in place to detect and address beneficiary access issues, should they arise. These measures include seeking beneficiary feedback in competitively bid areas through satisfaction surveys and conducting active claims analysis to identify utilization trends and monitor beneficiary access. CMS has also appointed an Acting Competitive Acquisition Ombudsman responsible for ensuring appropriate processes are in place to handle beneficiary complaints, should there be an issue with access to any products furnished through contract suppliers.

Independence at Home

The Independence at Home (IAH) program focuses on improving care and reducing expenditures for the highest cost Medicare beneficiaries – those individuals with multiple chronic diseases who account for up to 85 percent of Medicare spending and typically have poor outcomes under the current highly fragmented fee-for-service traditional Medicare reimbursement system. Through utilization of physician and nurse practitioner directed home-based, multi-disciplinary primary care teams, the IAH program is designed to provide comprehensive, coordinated, continuous, and accessible care to high-need populations at home while coordinating their health care across all treatment settings. Using this approach, the IAH program aims to reduce preventable hospitalizations, lower the need for hospital readmissions, reduce emergency room visits, and improve health outcomes commensurate with the beneficiaries' stage of chronic illness while achieving increased beneficiary and family caregiver satisfaction.

Section 3024 of the Patient Protection and Affordable Care Act (PPACA), stipulates that the IAH demonstration "shall begin no later than January 1, 2012". At the same time, Congress provided that, for each of the Fiscal Years 2010 through 2015, CMS will receive from the Part A and Part B Trust Funds $5 million for the purposes of administering and

carrying out the IAH program; therefore, CMS will receive significant funding for the IAH program this fiscal year, which could be used to begin the implementation process.

4. **Is CMS willing to implement the program before the deadline? What is CMS doing, if anything, to speed up implementation of IAH?**

Answer: CMS is working diligently to meet the Independence at Home (IAH) demonstration implementation date of January 1, 2012 and are currently in the process of designing the demonstration. Specifically, we are studying the applicability of models for shared savings, gathering lessons learned from other similar experiences, and engaging health care providers that are likely to participate in the demonstration. So far, we have met with the Department of Veterans Affairs (VA) to learn about the VA's experience with a similar VA program; the American Association of Home Care Physicians (which represents physicians who are among those most likely to participate in the IAH demonstration) to seek their input; and individual practices that have characteristics of an 'independence at home medical practice' as described in the Affordable Care Act. These meeting have brought greater understanding of these models and patient populations.

Pursuant to the language in Section 3024 of the Patient Protection and Affordable Care Act (PPACA), the Independence at Home (IAH) demonstration program is to terminate in 2015, regardless of whether the program achieves its objectives of saving money and improving patient outcomes. However, in Section 3021 of PPACA, the Secretary has the authority under the CMS Innovation Center to expand, including on a nationwide basis, delivery reforms if the Secretary determines that such expansion is expected to reduce spending without reducing the quality of care or improve the quality of care and reduce spending and the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending.

5. **Are you willing to take the authority granted to the innovation center to expand the Independence at Home program-wide, if it meets these goals?**

Answer: Models that we are considering for incorporation and expansion under the Center for Medicare and Medicaid Innovation will be carefully evaluated for their viability and potential for promoting coordinated, seamless, and person-centered care that will improve care, improve health and lower costs. In addition, selected models will be expected to produce results on short-term deliverables in weeks and months – not years. We are interested in models that have the potential for widespread use and those that can be scaled to have a meaningful impact on the population. We look forward to working with stakeholders involved with the IAH demonstration program to determine whether this promising model can meet these criteria.

United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

Opening Statement of U.S. Senator Chuck Grassley
Ranking Member of the Committee on Finance
Hearing with CMS Administrator Donald Berwick
Wednesday, November 17, 2010

Thank you, Dr. Berwick, for being here today. I take the importance of this Committee and our Constitutional role as the United States Senate very seriously. You were nominated by President Obama to serve as CMS Administrator on April 19th. You and I met personally in June to discuss your nomination and despite repeated requests from me and my colleagues we were never able to get a nomination hearing. Instead, you were appointed under a recess appointment on July 7th.

I believe that was incredibly unfortunate for you and for the position that you now hold. I think you should have had the opportunity to stand before this Committee and explain yourself, defend yourself, and make the case, in person, that you are the right person to be CMS Administrator. You were nominated 213 days ago and appointed 134 days ago and, yet, this is our first chance to get you before this Committee to testify and answer some questions. The phrase "better late than never" comes to mind.

Today, the Centers for Medicare and Medicaid Services has over 4,400 employees – not including thousands of outside contractors – and an annual budget of over $700 billion. That's a bigger budget than the Pentagon. Through the Medicare, Medicaid and CHIP programs, the Centers for Medicare and Medicaid Services provides health care coverage to about 1 in every 3 Americans – almost 100 million people. That's a lot of people – but that number is set to grow even more. The partisan health care overhaul will add about 16 million to the Medicaid program with a total price tag for the federal government of about $434 billion. This expansion will begin under your watch.

In addition to this massive coverage expansion, you have been given unprecedented authority to implement new payment and delivery models. Your decisions in this area will influence a significant amount of economic activity and determine how the new health law affects the health care coverage that millions of Americans rely on. We need to discuss your thoughts on the pending $500 billion in Medicare cuts and the massive Medicaid expansion that you are charged with implementing.

The Office of the Actuary and providers across the country have expressed serious concerns that the deep Medicare cuts will hurt access to care and may hinder quality improvements. And both Republican and Democratic governors are worried the Medicaid expansion will bankrupt state budgets. While some supporters of the health care law may label these claims as partisan scare tactics or misinformation, we take these claims very seriously.

With all that is changing in the health care system and the sheer number of people that rely on your agency for care, you have one of the most important jobs in the government today. That is why it is so disappointing that you were recess appointed without even a hearing. It contradicts promises made by candidate-Obama about having the most open and transparent administration in history.

I take oversight and government transparency very seriously. I hope you share my enthusiasm. I hope you will show an even greater commitment to transparency and collaboration than any of your predecessors. But based on the number of letters that have are still outstanding, I'm concerned about the depth of that commitment. The American people deserve nothing less. Thank you and I look forward to hearing your testimony.

Senator Jay Rockefeller
Statement for the Record
Senate Finance Committee
Hearing on Strengthening Medicare and Medicaid
(Witness: Dr. Donald Berwick)

November 17, 2010

Dr. Berwick, thank you for coming before the committee for this important hearing on how health reform will modernize America's health care system and strengthen our Medicare and Medicaid programs, which provide vital health care to millions of Americans every day.

I want to state upfront that I believe reform was the right decision for our country, and especially for my home state of West Virginia – at precisely the right time.

The Status Quo is Unsustainable

Our country has always had naysayers of health reform – that's why it took so long to get it done. And not surprisingly, the naysayers are still here today, and they want to continue with business as usual.

It is time for Americans to understand what will happen if we give in to the naysayers of reform.

The subject of health care is extraordinarily complex. There are no easy solutions to tackling the interwoven problems of poor access, high cost, and inadequate quality.

Until the passage of this year's health reform law, none of the fundamental problems that have plagued our system for the last hundred years had ever been addressed in a meaningful way.

And, until health reform is fully implemented, these problems will not begin to go away.

So today, I look forward to shining a light on these issues, and hearing how our seniors, children, and most vulnerable Americans will benefit from a 21st-century health care system that provides high-quality care at an affordable cost.

Today I want to be very specific about what my fellow West Virginians will lose if we do not move forward with the transformational changes in the health reform law.

No state has more to gain from a reformed health care system than West Virginia. But, the converse is also true – no state has more to lose if the implementation of comprehensive health reform does not go forward.

Without health reform, health care costs will continue to skyrocket, quality of care will suffer, and 55 million Americans will be uninsured by 2019.

First, it is important to recognize that Medicaid and CHIP are absolutely the foundation of health care coverage for working families. During this difficult recession, the uninsured rate for children has not increased, despite rising poverty levels and fewer employers offering coverage. From 2008-2009, the growth in the number of uninsured would have been more than double what it was without these two programs.

That is why it is so essential that we commit to making Medicaid and CHIP even stronger under health reform. The Medicaid expansion could reduce the uninsured rate among low-income adults by up to 70 percent, and states will have new options to improve the quality of care, reduce costs, and improve population health through new payment reform and medical home demonstration projects. And, the federal government will finance, on average, over 95% of the expansion from 2014-2019, making this an extremely cost-effective investment for states. The truth is that, without Medicaid, low-income families simply have no place else to turn.

Second, without health reform, the long-term sustainability of Medicare will be in grave danger. Before reform, the Medicare trustees told us the Medicare trust fund would be bankrupt by 2017. Thanks to health reform, Medicare is sustainable much farther into the future, for 12 additional years through 2029 – and we are moving the program into the 21st Century, giving states and health care providers an unprecedented opportunity to transform health care for the better.

The fact is that health reform will finally begin to change how we pay for health care in this country. It will move us from a system that pays health providers based on the quantity of services they provide to a new system that pays providers based on quality of care they provide.

Many people do not understand exactly what we mean when we talk about health care quality. What we mean is that, as Americans, we pay far too much for health care and get far too little in terms of good health outcomes. Patient safety problems, like hospital-acquired infections and medication errors, are rampant. In most cases, doctors and hospitals that provide inferior care get the same payment as doctors and hospitals that provide excellent care. This is not good for patients and it is not sustainable.

The bottom line is that health reform will protect patients and save taxpayers money. Under health reform, hospitals not meeting basic standards for care will have the opportunity and technical assistance to improve, but Medicare will not continue to pay for sub-standard care, medical errors, poor health outcomes, operating on the wrong body part, unnecessary readmissions, or hospital acquired infections.

The only way to get better value for our health care, in the judgment of many health care experts, is to get away from fee-for-service medicine. Fee-for-service medicine is like paying for all the different car parts, from multiple retailers, but there is no guarantee

that you're buying a complete car, and it's anybody's guess whether you'll actually be able to drive the car once it's put together.

And yet this fragmented model has become the norm in health care. Medicare beneficiaries with five or more chronic conditions see an average of 14 different physicians per year. Their doctors are all too frequently paid just for their individual work, and nobody is looking at the whole picture of this person's care. The health reform law changes that, with new ways of paying for care that focus on outcomes.

The new health reform law requires, for the first time, that a National Quality Strategy be put into place. It provides funding for important demonstration projects so we can learn how to improve patient care and contain the growth of health care costs. There is no one-size-fits-all answer, but we must move forward and we must learn how to do better. Finally, health reform includes an Independent Payment Advisory Board – or IPAB. I authored this provision because I so firmly believe we need an independent authority to get Medicare payment decisions back in the hands of experts and out of the hands of lobbyists. With IPAB, we finally have a way to take special interests out of the process and create an independent entity with the sole mission of protecting Medicare's long-term quality and solvency while helping to accelerate the adoption of innovative payment reforms.

It can be done. Doctors, nurses, and hospitals must lead the way. And the beauty of the health reform law is that it gives states the flexibility to do what is right for their people.

For example, in Maryland, the state established an innovative approach to hospital payment in 1971. By harmonizing payments, aligning incentives for providers, and testing new models of delivery system reform over time, Maryland's approach has saved the state approximately $43 billion, and has resulted in the 2nd lowest rate of hospital cost growth of any state in the country.

Health reform gives health care professionals all across the country the opportunity to take on innovative new approaches that are tailored to their populations and their states. The new Center for Medicare and Medicaid Innovation will help catalyze the next generation of improvements to our health care system – testing new approaches to delivering better care at a more affordable cost.

The simple truth is, if we do not implement health reform, we will squander the opportunity to save lives and save our country billions of dollars. Without this law health insurance premiums will continue to skyrocket and eat up more and more of family budgets. Without this law, small businesses will continue to drop coverage for their employees, because they simply cannot afford the rising costs.

Without health reform, many Americans will lose important benefits

Unfortunately, some Americans have been misled into thinking that health reform will somehow decrease their choices or take away access to their doctors.

But in fact, it is the naysayers of reform who would like to take away Medicare benefits. The new law actually increases seniors' ability to get the services they need: starting next year, seniors will no longer have to pay any out-of-pocket costs for most preventive services, like mammograms, cholesterol tests, and bone mass tests. Medicare will cover the cost of an annual wellness visit. And, the law completely eliminates the Medicare prescription drug doughnut hole by 2020, and provides seniors and individuals with disabilities significant help with the cost of brand name prescriptions along the way.

Ultimately, this new law will extend Medicare's solvency for an additional 12 years, from 2017 to 2029. This is enormously significant.

Once it is fully implemented, this legislation will cover 32 million Americans – and that will strengthen Medicare as well, because people will have had the chance to get the health care they need before they become Medicare-eligible.

It is simple common sense. We know doctors recommend that many preventive tests, like colon cancer screenings, should start when people are in their fifties. We know that heart attacks and complications of diabetes can be prevented with access to good preventive care. As a result, Medicare spending is significantly higher for adults who were previously uninsured, compared to adults who could access the care they needed before signing up for Medicare.

The health care law is already taking steps to address this problem. Preventive care is now fully covered in new insurance plans. There is a new Pre-Existing Condition Insurance Program for people who have been denied coverage. And, we invested $5 billion in an Early Retiree Reinsurance Program to help companies keep coverage for their early retirees, ages 55 to 64. Thirteen companies and three cities in West Virginia are taking advantage of the program, and our state employees' program is going to save $10 million annually.

Without health reform, population health will continue to suffer

Finally, if we do not move forward health reform, we squander the opportunity to improve the health of our most vulnerable residents. Sadly, West Virginia has among the worst health outcomes in the nation. In 2009, West Virginia had more preventable hospitalizations, heart attacks, and diabetes than any other state. We suffered some of the highest rates of death from cancer and infant mortality. West Virginia was ranked among the three lowest states for both access to dental care and poor mental health. We have the most smokers and among the highest rates of obesity of any state. And West Virginia is not alone in our poor population health status.

That is why the prevention and health promotion initiatives in the health reform law are so fundamentally important to improving Americans' health and getting costs under control. Health reform improves coverage for preventive services in Medicaid, Medicare, and private insurance. It will make it easier for seniors to create a personalized prevention plan with their physicians and take away financial barriers for important preventive screenings. Health reform will promote better coordination of care for people with chronic diseases, and it will finally help Americans fight back against the preventable illnesses that devastate so many lives.

This law is just the beginning. The problems are longstanding and the solutions will not happen overnight. And I look forward to hearing from Dr. Berwick about the role a stronger Medicare and Medicaid will play in our health care system.

Statement for the Finance Committee Hearing
Strengthening Medicare and Medicaid:
Taking Steps to Modernize America's Health Care System
Senator Olympia J. Snowe
November 17, 2010

Thank you, Mr. Chairman for holding this hearing today. Before I begin, I would like to echo the sentiment of many of my Republican colleagues and express my deep concerns with the President's use of the recess appointment process rather than following traditional nomination procedures with Dr. Berwick. Nomination hearings give the Senate and public at large an invaluable opportunity to learn more about the nominee and the direction they will take with the agency. These hearings are indispensable to open and transparent government and should not be circumvented. Process matters—and I fear that lately, we have been looking for shortcuts rather than systematically working through issues.

Without question, CMS has an enormous task ahead in implementing health reform . . . yet we also have great challenges in what the new law leaves out. One of the glaring omissions from the health reform bill was the failure to include the true cost of a solution to problems caused by the Medicare sustainable growth rate formula, which threatens to cut physician payments by 21 percent on November 30th. Addressing the true cost of Medicare should have been the starting point for health reform, rather than simply an afterthought. In fact, the $210 billion in new Medicare taxes contained in the health reform law would have generated enough revenue to solve the reimbursement problems caused by the SGR formula for nearly *ten years*. Unfortunately, we have no clear path forward on a funding source for a long term solution, and I look forward to learning more about how the Administration prefers to pay for the cost.

At the same time, the CMS Actuary reports that some of the Medicare cuts in the health reform bill are "unrealistic" and that "*15 percent of Part A providers would become unprofitable within the 10-year projection period*." Not only does this have a detrimental impact on access, but it is also completely at odds with the claim that health reform will result in an increase in jobs. I hope that the Administration is paying close attention to these warnings even though it doesn't necessarily paint a rosy picture of health reform.

In terms of more specific aspects of implementation, one of my key concerns is how to reward efficient providers in an environment where there is every financial incentive to drive up volume. Dr. Berwick, last year, you led an effort with Dr. Atul Gawande, Dr. Mark McClellan, and Dr. Elliott Fisher that recognized Portland, Maine as one of ten communities providing high quality, low cost care. Maine's hospitals are rated 3rd in the country as cited in the Agency on Healthcare Research & Quality's 2008 National Healthcare Quality & Disparities Reports.

Yet when considering overall hospital reimbursement to the cost of providing care, Maine has the second lowest reimbursement in the country. Maine's Medicare hospital payment to cost ratio is 79.1 percent while the national Medicare hospital payment to cost ratio average is 90.6

percent. This leaves Maine especially vulnerable to across the board cuts. In the health reform law, there is currently a patchwork of temporary payment adjustments, as well as the requirement to include efficiency measures in value based purchasing by FY2014. I am interested to learn what you see as the key opportunities as well as the challenges ahead in implementing these changes.

I also continue to have serious concerns with the inequity that exists in the treatment of states with generous Medicaid programs under the new health reform law. In the short term, Maine will be forced to maintain a *much* more generous program than states that have expanded minimally due to the maintenance of effort requirement . . . all during the worst recession in a generation. And over the long term, Maine will have to shoulder a larger share of the cost of parent coverage than states that chose to spend their budget dollars elsewhere. This policy assumes that because Maine has already made the investment in parent coverage, then the state can afford these costs in perpetuity and shouldn't receive any more assistance. This is absolutely ridiculous considering that Maine ranks 30th in the country in per-capita income, yet has the second highest rate of Medicaid eligibility for parents in the country. *The bottom line is that federally mandated coverage levels should be reimbursed equitably—and that is not the case under current law*.

Throughout my tenure in Congress, ensuring the viability and sustainability of Medicare has been a top priority of mine, especially representing a state that is ranked second in the percentage of citizens who rely on Medicare benefits. And though I was not able to support the health reform law, I look forward to working with you to find ways to improve Medicare and Medicaid wherever possible.

Thank you, Mr. Chairman.

COMMUNICATION

United States Senate Committee on Finance
Hearing on "Strengthening Medicare and Medicaid:
Taking Steps to Modernize America's Health Care System"
November 17, 2010
Statement for the Record
Submitted by:
The Roundtable on Critical Care Policy's
Executive Director Stephanie Silverman

Chairman Baucus and Ranking Member Grassley and other Members of the Committee, we thank you for holding this important hearing to learn of Acting Administrator for the Centers for Medicare and Medicaid Don Berwick's plan for implementation of the Patient Protection and Affordable Care Act (PPACA). The Roundtable on Critical Care Policy supports the Committee's commitment to ensuring that the reforms authorized by PPACA will be implemented in a way to improve the efficiency and effectiveness of our health care system by transforming the way health care is delivered in this country.

Established in 2009, the Roundtable on Critical Care Policy provides a collaborative forum for leaders in critical care and public health to forge and advance a common federal policy agenda to improve the quality, delivery, and efficiency of critical care in the United States.

The Roundtable is supportive of Acting Administrator Berwick's simultaneous pursuit of the "Triple Aim": improving the experience of care, improving the health of populations, and reducing per capita costs of health care. However, as the Committee moves forward with overseeing the implementation of these goals and develops additional policies to strengthen and modernize Medicare and Medicaid, the Roundtable encourages the Committee to consider proposals focused on improving the delivery of critical care.

Each year, over five million Americans are admitted into traditional, surgical, pediatric, or neo-natal intensive care units (ICUs).[1] The ICU is one of the most costly areas in the hospital,

[1] Society of Critical Care Medicine. Critical care statistics in the United States. http://www.sccm.org/AboutSCCM/Public%20Relations/Pages/Statistics.aspx.

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representing 13% of all hospital costs, with the total costs of critical care services in the U.S. exceeding $80 billion annually.[2] Providers of critical care require specialized training, the care delivered in the ICU is technology-intensive, treatment is unusually complex due to what may be a patient's system—or multiple system—challenges or failures, and outcomes have life or death consequences. Approximately 540,000 individuals die each year after admission to the ICU, and almost 20% of all deaths in the U.S. occur during a hospitalization that involves care in the ICU.[3]

Despite the significant role critical care medicine plays in providing high-quality health care, the PPACA did little to address the challenges that plague the critical care delivery system. A failure to address these challenges could jeopardize patient safety as well as the nation's ability to respond effectively to a national disaster or pandemic—such as H1N1—that demands a strong and adaptable critical care infrastructure.

The ability to respond quickly and effectively to a health incident requires responders and decision-makers to have immediate access to essential resource information. In 2009, the Department of Health and Human Services in the *National Health Security Strategy* identified that "the nation lacks a comprehensive coordinated national health information system that can quickly provide health care data in the early stages of an incident".[4] As the Strategy noted the federal government—not to mention the critical care community—lacks a coordinated, reliable, and consistent national health information system that can quickly assess the state of existing critical care capacity and resources in the United States on a regional or local basis. The Roundtable believes that a better understanding or our critical care infrastructure would help identify areas that need to be strengthened, and inform decision making during a disaster on how to optimize critical care resources.

A lack of knowledge regarding available critical care resources and capacity in the U.S. is not the only limiting factor facing the delivery of critical care. To be sure, multiple studies have documented that the demands on the critical care workforce—including doctors, nurses, and respiratory therapists—are outpacing the supply of qualified critical care practitioners. A 2006, study by the Health Resources & Services Administration found that the current demand for intensivists will continue to exceed the available supply, due largely to the growing elderly population, as individuals over the age of 65 consume a large percentage of critical care services.[5]

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[2] Halpern Na, Pastores SM. "Critical Care Medicine in the United States 2000-2005: An analysis of bed number, occupancy rates, payer mix and costs," *Critical Care Medicine* 37 no.1 (2010)

[3] Angus DC, Barnato AE, Linde-Zwirble WT, et al. "Use of Intensive care at the end of life in the United States: an epidemiologic study" *Critical Care Medicine* 32 (2004)

[4] U.S. Department of Health and Human Services, *National Health Security Strategy* (December 2009,)6.

[5] Health Resources and Services Administration Report to Congress: The Critical Care Workforce: A Study of the Supply and Demand for Critical Care Physicians. Requested by: Senate Report 108-81. Available at: http://bhpr.hrsa.gov/healthworkforce/reports/criticalcare/default.htm. Accessed November 2010.

The current and projected critical care workforce shortage pose significant patient safety concerns. While PPACA included several initiatives to expand the health care workforce, they were largely focused on expanding primary care. However, a solution cannot be reached solely by adding to the workforce; we must also find ways to improve the efficiency of the existing workforce. That is why the Roundtable enthusiastically supports a provision included in PPACA that prioritizes within the newly established Centers for Medicare and Medicaid the testing of models that make use of electronic monitoring—specifically by intensivists and critical care specialists— to improve inpatient care.

Another challenge facing critical care medicine is the notable absence of research on the availability, appropriateness, and effectiveness of a wide array of medical treatments and modalities for the critically ill or injured. At present, many of the current, high-cost treatments delivered in the ICU lack comparative effectiveness data, yet in 2009 when the Institute of Medicine released its mandated report recommending 100 topics to be given priority for comparative effectiveness research funding, few related to critical care. Moreover, current federal research efforts are partitioned and scattered across the government and throughout that National Institutes of Health's (NIH) 27 institutes, making it difficult to coordinate existing research and identify gaps.

As the Committee looks to address these issues in the future, we hope that you will consider some of the reforms included in the "Critical Care Assessment and Improvement Act of 2010 (H.R. 6306) introduced by Representative Tammy Baldwin in late September. This legislation would authorize a much needed assessment of the current state of the critical care delivery system, including its capacity, capabilities, and economic impact. In addition, the bill would establish a Critical Care Coordinating Council within the NIH to coordinate the collection and analysis of information on current critical care research, identify gaps in such research, and strengthen partnerships. Lastly, the bill authorizes a number of initiatives to bolster federal disaster preparedness efforts to care for the critically ill or injured.

The Roundtable on Critical Care Policy appreciates the opportunity to submit a statement for the record and looks forward to working with the Committee to strengthen our health care delivery system.

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