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REFORMING THE DELIVERY SYSTEM: THE CENTER FOR MEDICARE AND MEDICAID INNOVATION

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

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REFORMING THE DELIVERY SYSTEM: THE CENTER FOR MEDICARE AND MEDICAID INNOVATION

WEDNESDAY, MARCH 20, 2013

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

The hearing was convened, pursuant to notice, at 9:35 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Carper, Casey, Hatch, Grassley, Crapo, Roberts, Thune, and Isakson.

Also present: Democratic Staff: Mac Campbell, General Counsel; David Schwartz, Chief Health Counsel; Tony Clapsis, Professional Staff; and Karen Fisher, Professional Staff. Republican Staff: Kimberly Brandt, Chief Healthcare Investigative Counsel.

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

The CHAIRMAN. The committee will come to order.

The great American inventor Thomas Edison often liked to challenge his colleagues by saying, "There is a way to do it better: find it." Edison always looked to inspire fresh ideas to overcome any challenge.

Today we are in need of new and innovative ideas for America's health care system. We know there is a better way to deliver health care and to lower costs. We created the Center for Medicare and Medicaid Innovation to find it.

Known simply as the Innovation Center, the Affordable Care Act established a national facility to inject government health care programs with some of the flexibility and creativity that the private sector enjoys.

The Center comes with a simple mission: lower costs and improve quality. It does so by testing new payment incentives and employing creative methods of delivering care. If the Center develops a successful idea, Medicare and Medicaid work to quickly replicate it nationwide. If an idea is not successful, they go back to the drawing board and develop something different.

In just a short time, the Innovation Center has produced results. According to the Congressional Budget Office, the investments in the Innovation Center are expected to generate a 13-percent return through 2019, and, in the decade after, the Center is expected to save taxpayers tens of billions of dollars.

The Innovation Center is already testing many promising ideas. These include Pioneer Accountable Care Organizations, groups of doctors across the United States who work together and coordinate their care to reduce costs.

From Minneapolis to Maine, from Nevada to New York, these doctors are sharing lessons learned and best practices in an effort to provide better patient care. This is just one of the more than 30 new programs that the Innovation Center has already introduced, impacting the lives of 5 million beneficiaries across all 50 States.

Health reform included specific ideas for the Innovation Center to test. We also knew that tapping into Americans' ingenuity and entrepreneurship could lead to ground-breaking ideas on how to improve the health care delivery system.

So we told the Center to ask Americans for their ideas on how to improve the quality of care without increasing costs, and, as an incentive, the Center would provide grants to test the most promising models. One company that answered the call is the online clinic, Health Link Now.

Recognizing the challenges that rural communities face in accessing mental health care, Health Link Now will partner with local hospitals and doctors in Montana and in Wyoming. They will provide mental health care through secure video-conferencing and interactive technology.

Patients in even the most rural areas, like Troy, MT, population 933, can now access quality care if needed. This initiative is expected to lower costs through reduced hospital admissions and emergency room visits while increasing access to care in rural communities. If proven successful, it will likely be replicated across rural America.

This is just one example of the type of revolutionary ideas the Innovation Center is supporting. Some of the tested models will be successful, others will not, but we cannot be afraid of missteps. We must continue trying new ideas, learning from mistakes, building on our successes. That is how we find what works.

We also need Medicare and Medicaid to develop programs faster than they have in the past. In 2003, Medicare partnered to create a demonstration project in which hospitals in 26 States, including St. James Healthcare in Butte, St. Vincent Healthcare in Billings, and Holy Rosary Healthcare in Miles City, MT, would receive bonus payments based on the quality of care delivered. From 2003 to 2009, the demonstration project is estimated to have saved thousands of lives, including 8,500 heart attack patients.

Seeing the success of this demonstration project, Congress used it as a model to create a program where Medicare rewards all hospitals across the Nation for high-quality care. It also penalizes hospitals that produce poor outcomes. That program began this year.

In many ways, the 2003 demonstration project set a new standard. It was developed in stages, with close public/private collaboration, but it took too long. We cannot wait a decade to develop a model and then implement it nationally. We need to cut through red tape much more quickly.

We need to allow proven ideas to ramp up and spread rapidly without waiting for Congress to act. That is what the vision of the

Center's task is. It can broadly deploy demonstration projects that are proven to reduce spending or increase quality.

This will allow us to test, evaluate, and then integrate new ideas nationwide in only a few years instead of a decade. I look forward to examining the progress that the Center has made. We are here to ask questions. We want to hear about different models tested, we want to hear which projects are the most promising, and we want to know when we are going to see results.

We are going to need a bold vision if we are going to get health care costs under control, so let us act boldly. Let us realize there is a way to do it better when it comes to health care costs, and, as Thomas Edison said, let us find it.

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

The CHAIRMAN. Senator Hatch is not here yet, so I will just introduce you, Dr. Gilfillan. Why don't you proceed? As most people know, you are the Director for the Center for Medicare and Medicaid Innovation. Doctor, your full statement will be in the record, and I would urge you to summarize and get to the point in about 5 minutes. We look forward to hearing from you.

I might say, I think you are doing great work. I would just encourage you to keep at it.

STATEMENT OF RICHARD J. GILFILLAN, M.D., DIRECTOR, CENTER FOR MEDICARE AND MEDICAID INNOVATION, CENTERS FOR MEDICARE AND MEDICAID SERVICES, BALTIMORE, MD

Dr. GILFILLAN. Chairman Baucus, Ranking Member Hatch, committee members, thank you for the opportunity to discuss the Innovation Center's progress. I am a family physician by background, and I practiced in rural Massachusetts and urban New Jersey. Before joining CMS, I was an executive at the Geisinger Health System in Pennsylvania. While there, I worked with colleagues to develop new primary care and episode-based payment models and tools for ACO development.

During that experience, I saw how innovative approaches to delivering high-quality care at a lower cost can make a real difference for patients and their families. Marie, a high-risk patient in a medical home program there, had previously been hospitalized frequently. Through that model, Marie gained access to a case manager who helped her better manage her medical conditions and avoid frequent trips to the ER.

Marie described the program simply by saying, "The idea of the program is to keep me healthy, keep me out of the hospital, and keep costs down. I don't think I would still be here without this program. It has been my lifeline."

Care like this is the promise of delivery system reform and the potential answer to the challenging problems we face in our health care system. In all of our work at the Center, we are focused on creating care models that improve outcomes, as this one did for Marie, because that is the way to make care more affordable and accessible for all Americans.

We must find new care and payment models that reward and support providers in delivering high-quality, coordinated, and efficient care, not simply for providing more services. Today, I am

pleased to report on our progress at the Center for Medicare and Medicaid Innovation.

Our job is to test new models of care delivery and payment that reduce costs and improve quality by changing the incentive structure of our payment systems to emphasize care coordination, improved quality outcomes, and reduced total cost of care.

In short, to accelerate our movement to a health care system with better outcomes and lower costs, we must accelerate the movement of CMS, and indirectly other payers, from being fee-for-service payers to becoming value-based purchasers of health care through the new models we are testing.

The resources provided in the Affordable Care Act have allowed us to build on the excellent existing CMS capabilities to test more models on a larger scale to get more rapid results. Right now we are working on three dozen models that support 50,000 health care providers who are serving more than 1 million Medicare, Medicaid, and CHIP beneficiaries, as well as many private patients. We believe these models will result in better coordinated care, improved quality outcomes, and reduced total costs of care.

Examples of these new service and payment models that reward providers for delivering high-quality, coordinated care and improved outcomes include our Comprehensive Primary Care Initiative, a multi-payer test of care management expenses to primary care physicians; our Pioneer Accountable Care Organization model, a multi-payer test also testing advanced Shared Savings incentives for larger, experienced groups of providers; and our Bundled Payments for Care Improvement Initiative, which is a model to test payment of a global episode fee instead of fee-for-service payments for specific procedures and conditions. Each of these models is directly supporting the re-designing and the re-engineering of care to deliver these outcomes.

From our work on these and other models, we have already learned that providers and other stakeholders are eager to redesign care and participate in models that reward quality and coordination and decrease costs. States and private payers are committed to working with us as well.

We also know that there is no one simple solution. We must test a broad range of models. Of course we are all eager to see the results of these models, but we need to be realistic. This change is difficult. Some models will work, and some will not. It will take time to see the improvements we are after.

We will see signs of change in some metrics early on, but measures of broader impacts, such as the total cost of care, will take longer. To get accurate information, we must give each project sufficient time for claims to come in and quality outcomes to emerge.

We are currently analyzing the first year of data from two primary care projects, the Multi-Payer Advanced Primary Care Practice and the Federally Qualified Health Center Advanced Primary Care Practice Demonstration. We will also see first-tier results from the Pioneer ACO model this summer. We will be able to start sharing interim results with Congress within the year and start giving recommendations for payment or care changes within the next 2 years.

The good news is that providers are responding positively to the many portions of the Affordable Care Act that support these efforts to improve care, such as value-based purchasing. Delivery system transformation to a more sustainable, higher-quality system is clearly under way across the Nation, and it is coming from grassroots providers in their communities who understand the need, the imperative, to improve our system.

More than 250 ACOs, including the 32 ACOs in models developed by the Innovation Center, are now operating in the Medicare fee-for-service program, serving more than 4 million Medicare beneficiaries. Early national data is starting to show the effects of this focus on improving care coordination, improved quality of care, and the total cost of care.

After more than 5 years of holding steady, the rate of all-cause hospital readmissions is starting to trend downwards. In addition, the rate of growth in per capita Medicare spending has been at historic lows for 3 years in a row. We look forward to seeing which models and demonstrations will provide the results our health care system and the people we serve need. I am happy to answer your questions.

The CHAIRMAN. Thank you, Doctor.

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

The CHAIRMAN. The bottom line is, I think most of us—at least I am—are concerned about making sure we are getting value for our buck in terms of the Act, that is, that the Center actually does produce results. You mentioned that it takes time. That is true, it does take time.

But at the same time, people, at least in Congress, are going to be a little bit impatient. They are going to want results that are quantifiable, demonstrable, that you can identify, put your finger on, and see, not just grand goals and platitudes. So what can you tell us? You mentioned you would have some results in a year, other results in a couple of years.

What can you tell us here that kind of makes us more comfortable that we are actually going to get demonstrable results so this whole effort is worthwhile? It sounded good when we put it together in the Act, but now we are trying to find out whether in practice it makes sense. So give us some numbers that make us a little more comfortable that you can actually get the work done where these proposals will produce results.

Dr. GILFILLAN. Certainly, Chairman Baucus. We are, as I said, now looking at some of the first-year results from some of our early programs in primary care. It takes time for all of these programs to—number one, programs have to start putting new care models in place, then they need to start measuring results. We need to see results over time so that the information we receive and analyze is complete.

Typically, for models like this, it will take us 12 months of experience with the new model operating, and then 3 months after that 12-month period to get the claims in-house into the system so we can analyze them. That is what we are doing right now with the two models that I mentioned for primary care. We are starting to see some signs, and I can share with you a couple of data points.

We want to make sure though that, as we do this analysis, it produces complete and accurate, dependable information. We can see now, as we look at data from the State of Vermont, that it appears that the trend, the rate of increase in cost for the total cost of care, looks like it is below what was expected. So it does appear that there is some early evidence of bending the cost trend from the medical home program that we have there.

In the State of North Carolina, we are seeing some improvement in the rates of hospitalization, that is, the frequency with which Medicare beneficiaries are being admitted to the hospital and the frequency with which they are visiting the emergency room.

These are two types of data that we are looking at very closely in all of our models: high-level data looking at the total cost of care and looking at quality measures and outcomes, and then more granular, more detailed measures of the actual experience, such as how often people go to the emergency room of the hospital.

We are working hard. In each of our models, we have established a rapid-cycle evaluation group, Senator, that allows us to watch these results on a quarterly basis. As they become complete, as we get that data to a point where we feel it is accurate and complete, then we will share those results with you.

The CHAIRMAN. I appreciate that. I have another question that I am curious about. The premise behind the ACA was to move away from volume-based services, fee-for-service, and push toward reimbursement based more on quality.

One question is, do you think that, based upon your work, that premise, that assumption, is still valid, and should we still work in that direction? The second is, as you, I am sure, know, *Time* magazine published an article that is getting a lot of currency. I read it last weekend.

I am just curious of the degree to which some of these delivery system reforms and some of your work at the Center can get at some of the problems pointed out in that article, namely how charges are based on this Charge Master in hospitals, and how, at least according to the author, many people are over-paying because the Charge Master sets rates much higher than the actual costs of the devices, the Durable Medical Equipment, or whatnot. So the question is the degree to which your work will get at some of those problems mentioned in that article.

Dr. GILFILLAN. Thank you for that question, Chairman Baucus. It was quite an interesting and revealing article that talked about many of the issues those of us who have been in health care for a long time have been concerned about.

To your first question, we believe that the underlying ideas in the Affordable Care Act regarding the need to transition from fee-for-service-based payment approaches to more value-based payment approaches is still correct, and I think it has gained greater acceptance throughout the country. I think what we are seeing is a real commitment from providers to engage with CMS and with their private payers to pursue these alternative approaches to reimbursement.

The article in *Time* spoke largely about the effect of charges on either commercial payers and rates of premium that people end up

paying through private payers or, even more unfortunately, the impact that they have on individuals who may not have coverage.

I think we are seeing in our models, where we are working closely with other payers, that there is a real opportunity to change the way private payers are paying providers as well, and some engagement from providers and being willing to engage with them on that.

So, I would be hopeful that, with the increased coverage that we are likely to see in 2014, the ability for more people to access negotiated rates that are paid by commercial payers, or the rates paid by government payers, we will see less impact from charges and we will see the gradual move on the private sector side from payments based on charges, such as were referred to in the article, to payments based on value produced, as you have stated.

The CHAIRMAN. Thank you. My time has expired.

Senator CARPER. Mr. Chairman? Mr. Chairman? I need to go chair a hearing on Sandy recovery in Homeland Security and Governmental Affairs. Could I have just 30 seconds to say something very briefly?

The CHAIRMAN. Absolutely.

Senator CARPER. Would my colleagues indulge me?

The CHAIRMAN. I am sure they will for 30 seconds.

Senator CARPER. Dr. Gilfillan, thank you so much for assuming these responsibilities for our country. The work that you are doing, the work at the Innovation Center, is just so important. It is exciting, it is essential. We are going to be debating in the next 36 to 48 hours how to get better health care results for less money, especially with respect to Medicare and Medicaid, and what you and other folks are working on across the country is just critical.

Our neighbor to the north is Pennsylvania. You ran Geisinger up there. I have been up to visit your facility and was just really impressed with what you are doing there and some of the lessons that we can learn, so thank you for doing this work.

The chairman is trying to impart a sense of urgency, and that is a sense of urgency that I think we all share. Thank you.

Dr. GILFILLAN. Thank you, Senator. I think I can say for all of our team, it is a real honor and a privilege to be involved in the work here at CMS and throughout the administration and the health care system to build on the work that was done in the Affordable Care Act.

The CHAIRMAN. Thank you.

Senator Crapo?

Senator CRAPO. Thank you, Mr. Chairman.

Dr. Gilfillan, I appreciate your work and appreciate you being here. I also appreciate hearing that CMS is taking an innovative approach to dealing with our Medicare issues. As the chairman referenced, we regularly are told from many different sources that we have to get away from focusing on volume and on to focusing on quality. The problem is, how do we do that? You are here to give us those answers.

Physicians should be able to manage the care of their beneficiaries in a way that rewards them for quality, which is why I supported things like—well, various programs that promote flexi-

bility and quality rewards for health care experts, like the Accountable Care Organizations.

I was also pleased to see that the dialysis community also accessed this integrated care program with the new End-Stage Renal Disease Care Initiative formation. I am told that, under this model, the dialysis clinics and nephrologists can access more expensive patients, those with multiple diseases and co-morbidities, and the care in the Medicare program.

My question is, can you explain to me how these two models, the Accountable Care Organization on the one hand and the new ESRD Care Initiative, will work together and how new patients are attributed to each?

Dr. GILFILLAN. Senator, thank you for that question. Yes, that is a great question. One of the things that we are working on at CMS in pursuit of all these models is to build the operational infrastructure that is needed to operate in this new way, needed to operate in a value-based world.

This goes right to the heart of that question, and we have built the operational capacity and ability to distinguish patients who were aligned with one ACO or one program versus another. It has been something we have worked hard on over the past 2 years. There are rules that we will use to decide who the most likely provider of care to a particular patient is and, as were laid out actually in the Shared Savings regulations, we look at the experience of that patient to see who has provided the most care.

In this case, while some patients were aligned with Pioneer ACOs or Shared Savings ACOs, the vast majority of ESRD patients, End-Stage Renal Disease patients, were not aligned with those ACOs. We expect that we will be able to use our computer systems that we have built to actually identify a distinct set of patients for the ACOs and a distinct set of patients who will be obtaining most of their care from their dialysis provider or their nephrologist and actually align them appropriately with the provider of their care.

Senator CRAPO. Thank you. Will the beneficiaries with ESRD be assigned first to the new ESRD-specific program and then to the primary care ACOs?

Dr. GILFILLAN. Senator, they will not be. They will not be assigned to two of the programs; they will only be assigned to one. Those who are assigned already to the Pioneer or Shared Savings ACOs will remain with those. Those who will be aligned through our analysis with the dialysis provider will be assigned there and will not be eligible for assignment into ACOs.

Senator CRAPO. All right. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Isakson?

Senator ISAKSON. Thank you, Mr. Chairman.

Thank you for your work, Dr. Gilfillan. I appreciate it very much. I have a question that actually popped into my head while you were talking. I am one who talks about fee-for-service all the time, and I commend the movement away from that and the movement towards reimbursement based on quality. But it seems to me, in the debate on the Accountable Care Organizations and in some de-

cisions that have been made by CMS, there has been a total move away from home health care to drive people more to hospitals than home health care services.

I represent a State that has a major metropolitan area, Atlanta, but we also have a huge rural area where there is not a physician in the county, much less a hospital. Home health care, particularly for the elderly, but in long-term recovery, is a better environment and a less expensive environment for a patient to be healed in than a hospital is. Have you all done any analysis of some of the decisions that have been made to drive the reimbursement rates on fee-for-service for home health care way down to move people into hospitals, which are far more expensive?

Dr. GILFILLAN. Senator Isakson, thank you for that question. We could not agree more with you that it is always better for a patient to obtain care in the least restrictive, least clinical, intense setting as possible. So, whenever care can be provided in a home, we think that is a good thing to do, assuming it can be done safely and effectively.

We have established some models that emphasize more, we think, home care, certainly our ACO programs, our Comprehensive Primary Care Initiatives. All of our primary care initiatives are very much oriented to using home care services as much as possible, avoiding unnecessary hospital services, so there is great incentive to do that.

We also, in our Bundled Payments for Care Improvement Initiative, through the use of episode-based payments, have created conditions in which hospitals, other providers working closely with home care providers, and other post-acute providers, can design care in a way that is most effective and delivers the best outcomes. So we think, more and more, we will see services provided in the home as a result of the models that we are testing.

Senator ISAKSON. Well, I am glad to hear you say that, because I have had a personal experience with one of my children many years ago where they were recovering over an extensive period of time, and the home health care, from the standpoint of the mental health of the patient, is far superior to long-term hospitalization in many recoveries.

I think there are some people—some people; I am not speaking about you—who are driving people away from home health care and into hospitalization, which is less good for the patient's mental health and much more expensive in terms of reimbursement. So, thank you for that answer.

The second question. Ten billion dollars is a lot of money. That is your authorization over a decade. Last November, GAO reported that several programs funded through CMMI were potentially duplicative or overlapping with other initiatives that CMS is currently undertaking. What specific steps are you taking to ensure that work is coordinated and that duplication does not take place?

Dr. GILFILLAN. Thank you, Senator. The GAO report did speak to, I think, three areas where there may have been duplication, or they thought that it was possible. They identified the specific activities that we had put in place to ensure that there was coordination, and they ranged from daily interactions with the Innovation Center team, with the Centers for Medicare and Medicaid Services,

and with the Center for Clinical Quality Standards. So we are working throughout CMS to ensure that we coordinate well. The other area that was identified in the GAO report was the potential overlap with activities of the Quality Improvement Organizations, the QIO program. We have reviewed all of the potential overlap situations between our QIOs and the hospital engagement networks from our Partnership for Patients Program.

We have created plans for any hospital where both organizations could potentially overlap so that they are coordinating and ensuring that there is no duplication of services or payments. So it is something we pay attention to regularly. We meet at the highest levels of CMS to review potential duplication and avoid that and ensure that the programs are synergistic and complementary.

Senator ISAKSON. Well, that is very important. Quite frankly, Congress is guilty of the same type thing. We have far too many duplicative appropriations in different departments where we could find a lot of savings if we would take time to look, so I am glad you paid attention to that report and are taking a look at it. Thank you for your service.

Dr. GILFILLAN. Thank you, Senator.

Senator ISAKSON. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Grassley, you are next.

Senator GRASSLEY. Thank you very much.

I am sorry I did not hear your testimony. I had to be at another place.

I have a question about the GAO's November report raising questions about CMMI activity overlapping with the CMS offices. Specifically, the GAO identified three key examples of overlap between the 17 Innovation Center models and the efforts of other CMS offices. CMS's response to this overlap was calling the work complementary to each other. At the same time, CMMI has a designated funding stream of $10 billion between 2010 and 2019.

So, as everyone is acutely aware, we are in the middle of sequestration. Agencies have been told to scale back and be smarter with the dollars. So my first question to you is, do you think it is appropriate for CMMI to be operating models that clearly overlap with existing programs at CMS, and was there a good policy reason for choosing models that overlapped so closely with existing CMS initiatives?

Dr. GILFILLAN. Thank you, Senator Grassley. The GAO report identified those three areas to include ACO activity, possible overlaps with Medicaid activities, and possible overlap between the Quality Improvement Organizations and the Partnership for Patients' Hospital Engagement Networks.

As they pointed out in the report, we have established mechanisms to ensure that there is not duplication in each of those programs. We did improve the coordination and address the specifics of overlap in the QIO and Partnership for Patients programs, and completed the work that they suggested in December.

One of the things we have learned, Senator—and we have heard loud and clear from stakeholders around the country—is that not one model works for everyone, that there are provider organizations that are experienced in delivering more coordinated care, hav-

ing done it for years in Medicare Advantage programs, and they were interested in having a more advanced program. The Pioneer program was the result of that.

We had people from around the country come to us in the earliest days of the Innovation Center, asking for a more advanced, higher opportunity program for ACOs. So we developed that program specifically for that segment of the delivery system that was more advanced and was requesting it.

Similarly, we had heard input from other physicians in rural communities about their concerns about being able to participate in the Shared Savings Accountable Care Organization program, because they were concerned they did not have sufficient capital to make the investments.

So we established the Advanced Payment ACO program, which supports small physician Accountable Care Organizations and Accountable Care Organizations from rural communities. As a result of those activities, we ended up with 40 Advanced Payment ACOs, seven of which are actually from rural communities and 33 that are physician-based Accountable Care Organizations.

So, Senator, we think there is good reason for developing programs that sound initially like they might be overlapping or duplicative but really represent the attempt to mix or match the richness, the diversity of the delivery system, and the requests we have had from stakeholders to create paths to this new care model for all different types of providers.

Senator GRASSLEY. All right. Well, put me down for being a little cynical about it. I think that you have answered in good faith, so I do not question your intent. But, in 3 to 5 years, when you might be called back here to testify during an evaluation phase, are you comfortable that you will be able to justify that those $10 billion were spent in truly separable projects, because that is going to be a lot of taxpayers' money that we are wagering?

Dr. GILFILLAN. Senator, we take financial accountability very seriously. I spent a career in the private sector, where I learned how important it is to be accountable for, and responsible in, the handling of financial resources.

We appreciate the resources we have. We know there is a great deal of work to be done. We think every day about what the ultimate return on the investments will be, and we are confident that we will come back to you at some future time and be able to demonstrate that to you.

Senator GRASSLEY. All right. Thank you.

Senator Roberts, you are next. The chairman just handed me the gavel, and I am going to give it to you, because I have to go to the Judiciary.

Senator ROBERTS. That is a very dangerous proposition. [Laughter.]

Senator GRASSLEY. Yes. Do not abuse the privilege.

Senator ROBERTS. I could ask unanimous consent and then say "without objection." [Laughter.]

I hate to tell you this, but you may not have a job, just repeal and—never mind. [Laughter.]

We will go on from there. You will note that they really did not hand me the gavel.

Thank you very much for coming and taking time out of your schedule to come up. I do not think it comes as any surprise to anybody on the committee, and perhaps you, that I have some strong concerns with many of the provisions of the Affordable Health Care Act, what some call AHA or PPACA, or whatever way you want to describe it, most especially, those provisions that I believe gave the Department, and more especially CMS, authority—as I have determined in talking to many of my providers out in the rural health care delivery system, both in Kansas and all across the country—to ration care. Now, those are their words, not mine, but I think they are mine as well after listening to many of their concerns.

You stated in your testimony that Congress provided the Secretary with the authority to expand the scope and duration of a model being tested through rulemaking, including—and this is very important—the option of expanding on a nationwide basis.

I do not think I would have ever been comfortable with this, and we did not get an opportunity at the time, although we had many hearings in the HELP Committee and here in this committee, but the final product, we did not have much access to, so I could not offer an amendment.

But I have talked about this a lot on the floor of the Senate and every chance that I get, but I do not think I would have been very comfortable with allowing officials who are not elected the ability to bypass the Congress to implement policies that could impact Americans in every State, every region of the United States. But I can tell you that I have become even more alarmed watching the implementation.

Right off the bat, the Department and CMS began implementing the major portions through IFRs, interim final rules. I have a big problem with this in regards to—I remember the days when CMS actually went out and asked people if in fact a regulation made sense, if in fact it could be tweaked, changed, or many different kinds of suggestions. If enough people really complained about it during a 90-day period, 60-day period, there would be an additional 60 days. Well, you gave 30 days.

Basically, the stakeholders do not really have an opportunity to weigh in. We have seen regulations, even economically significant regulations—and that is a term that is hard to really define—implemented with, I think, little or no quantitative cost/benefit analysis, despite the fact that it is required by the President's executive order.

Then—and this is the one that has really got me riled most recently—regulations are being implemented with what we call sub-regulatory guidances. This was a problem for me in that I had a heck of a time trying to remember that sub-regulatory guidance is just the name of it to begin with, but we are talking about such things as FAQs—FAQs is Frequently Asked Questions—and then bulletins, then postings to the website, then guidances.

Now, aside from the fact that stakeholders can barely keep up with all the regulations now coming out of CMS, we cannot even guarantee that these folks know about sub-regulatory guidances, because no one ever let them know. I am talking about everybody within the provider system who is involved with Medicare payments.

Then, when actually implementing the regulations through notice and comment, the Department is giving stakeholders a minimum amount of time, 30 days, to review hundreds of pages of regulations, sometimes with multiple regulations being issued in the same day.

Throw in the holidays, and you have a perfect recipe to assure stakeholders will not be able to engage constructively, if at all. I do not know how many hospital administrators—or for that matter doctors, nurses, whatever—are overwhelmed with the regulatory situation. They just do not have time to pay attention to subregulatory guidance. They do not even know it is there to begin with.

Then you are going to have to have somebody whom they hire—I think it is a new growth industry: regulatory overkill 101, 102, 103—but our universities and others in the private sector just cannot really have people available to do that. There are not that many people to help out. Do not tell me to call a 1–800 number that does not answer or where somebody does not have the answer.

Some representatives from the administration have come before this committee, and I thank them for this. They have suggested that 60 days is a more appropriate time frame in regards to subregulatory guidance, again, if they even have the ability to know what that is.

I would tell my distinguished friend and colleague and the ranking member that I am over my time 10 seconds, but I am on a roll, so I am going to keep going, if you do not mind.

Senator HATCH [presiding]. Keep rolling if you want to.

Senator ROBERTS. All right. Thank you.

I ask unanimous consent to proceed for another 5 minutes, if I might.

Senator HATCH. Without objection.

Senator ROBERTS. And I know that I want to give the good doctor an opportunity to respond.

I think this attempt to circumvent the traditional regulatory process—again, what CMS used to do, not what they do now because there is an agenda out there with all the regulations—I know that there is a time frame here that the administration wants to follow, but you cannot just leave the entire health care delivery system behind in a fog of regulations.

At any rate, this becomes especially alarming when coupled with new authorities to allow CMS to expand the policies nationwide without accountability through any congressional review, which is what we are having today. I think there is a big storm coming. I am concerned, because whatever chance we have for this to really succeed, I think, is being endangered by a storm of regulatory overkill. I call it a Katrina of regulations; perhaps that is an overstatement.

The traditional regulatory process, as described in both statute and executive order, calls for notice, it calls for comment, it calls for review, and it calls for consideration of comments, and the issuing then of a final rule.

Again, I do not think I will ever be comfortable with the way this was done, but here is my question, finally, after this speech, or rant, or whatever you want to call it. Can you assure me today that

any policies CMMI expands, especially those that go nationwide, will be done through the traditional rulemaking process, including the notice, 60-day comment period, review and consideration of comments, clear and quantitative cost/benefit analysis, and issuance then of a final rule? I suppose you could say "yes" and that would be the end of it, but would you please comment?

Dr. GILFILLAN. Senator, as you point out, the Affordable Care Act, section 3021, does speak to the potential for the Secretary expanding the scope or duration of a particular model even to a national level, assuming that we can demonstrate to the satisfaction of the actuaries at CMS that there are cost savings, or at least the same costs and quality getting better and quality always being better—the same, or better. So there is that provision, and it is stated through regulations.

We have not gotten to that point at this time. We have not issued any regulations. I understand and hear your concerns about regulations. We have not confronted that, but our expectation is that we would follow the usual regulatory pathways and all of their levels, but we have not gotten to that point with any of our models at this point.

I would say that——

Senator ROBERTS. But you intend to do that, of course?

Dr. GILFILLAN. We certainly are expecting to find models that are successful that we would like to expand the duration and the scope of, and ideally some of them nationally, as we demonstrate the results of these different models. I would say that we have not been involved in regulation other than in the regulations for the Medicare Shared Savings Program for Accountable Care Organizations. That was, I think, a remarkable example of how we put an initial——

Senator ROBERTS. All right. Now, I am going to do something I do not like to do, and I do not want to interrupt you, but you mentioned it, and that gets to my next question. And I am still over time. Again, I will ask for another 5 minutes if I have to.

But the Advanced Payment ACOs, that is what you are talking about, the Accountable Care Organizations. One question is, what percentage of these are rural? My answer to that is, I have heard back from many rural providers that, due to the structural limitations of the ACOs, it is difficult, if not impossible, for a rural community or provider to initiate an ACO.

We just do not have the doctors, we do not have the professionals. Many times you have to drive 60 miles, 120 miles, whatever, to see a doctor or a nurse clinician, and maybe there is only one doctor. That doctor may circulate around in many different hospitals. We do have regional centers that provide very good care.

But can you speak to how many rural providers have initiated ACOs versus any participation in an ACO initiated by a health system for a more urban community? I think there is a tremendous bias here to have ACOs succeed in urban settings, but the criteria for the rural providers I think are such that it just does not match up.

Dr. GILFILLAN. Certainly, Senator, that is an excellent question, confronting the real challenges that we know providers in rural communities face. That is why, for our Pioneer ACO model, we cre-

ated a specific set of criteria for rural entities to participate, and it resulted in us having a rural ACO in Ft. Dodge, IA, at Trinity Health.

In our Advanced Payment program, we put additional funding in place for rural providers for small physician organizations or for hospitals in rural areas who lacked capital to become Accountable Care Organizations. We have seven of our 40 Advanced Payment Accountable Care Organizations that are from rural areas. One of them includes a hospital, but the others are physician-based.

We have also worked hard across our other activities to ensure that we get good representation and good opportunities for rural providers, Senator. About 16 percent of our health care innovation awards are specifically for providers, rural providers, and are getting at some of those difficulties you have mentioned.

Senator ROBERTS. All right. I am out of time, and I am taking way too much time, and I apologize to my colleagues. I am going to ask one more question if I might, and I apologize to Senator Casey and to the ranking member.

You addressed efforts to reduce inappropriate hospital admissions. Now, I do not know of anybody on the committee or anybody anywhere who is supportive of continuing to allow for inappropriate hospital readmissions, and I know that you have done a lot of work for CMS, HHS, and have certainly done a lot of work to cut down on hospital readmissions. It comes under the heading of cost savings and even fraud and abuse prevention.

However, can you speak to me about what work is being done to look into the unintended consequences of these policies? Specifically, I am referring to anecdotal examples I am being given that make this a real problem in rural areas with patients who need to be readmitted but are not because of this policy.

In rural areas, there is no other place to go. I know of a particular case of a very good friend of mine—and I am not going to mention the hospital or the area—but whose mother was in her 90s and had a sprained ankle. She went in to see the doctor and went out to the parking lot and had apparently, later, as we have determined, a stroke, but she could not get readmitted back in the hospital except to the emergency room.

The person there who gave the treatment indicated she was fine and went home. It was obvious that her son knew something was terribly wrong but could not get her readmitted back into the hospital. Now, I am not going to go into the details of what happened later, but unfortunately she died.

Now, that is just one anecdotal example that I am personally aware of and was involved with, and I could not believe it. In talking to the hospital administrator, he said, well, this is what we are operating under. Now, that is a problem. I hope—I hope—that that is not a common theme, but I think you have to really take a look at the rural areas and hospital admissions. Have you done that on the other side of it? You always wonder what lurks under the banner of reform and what you are trying to do, and the real world out there is something entirely different if we are not careful.

Dr. GILFILLAN. Thank you, Senator. We would be happy to work with your folks and with CMS to look into any specific concerns you have, certainly, but we know we have to ultimately—every hos-

pital, every doctor makes decisions about the right way to care for a patient, and there is nothing in the Affordable Care Act that says that people cannot do things, it just asks them to exercise judgment about whether the patients need to be in the hospital or can be cared for at home or in other settings.

So we will monitor patient satisfaction rates, patient concerns, hospital complications. The whole intent of value-based purchasing, of course, is to look at the combination of quality of care outcomes, whether they be for admissions to the hospital or readmissions to the hospital.

Senator ROBERTS. So you are going to take a look at the readmission policy and look at the law of unintended consequences and what really happens out in a rural health care delivery system, and that that hospital administrator who tells me that, well, it says right here under subsection C, paragraph 2, I am sorry, I cannot do this. Something is wrong here somewhere. There is a disconnect.

Dr. GILFILLAN. Senator, we would be happy to follow up on that directly.

Senator ROBERTS. I do not mean to target anybody individually. The last thing they want is for me to call them and say, guess what, I am going to have CMS or you folks give them a call and figure out what is wrong. They do not want to do that. I mean, nobody wants to get into that kind of situation.

To my distinguished ranking member and Senator Casey, I apologize for taking so much time, but these are concerns that are very real, and I appreciate the doctor answering to the best of his ability. Thank you, sir.

Senator HATCH. Well, thank you, Senator.

Senator Casey, I have not made my opening statement. I will make that and I will hold my questions, and then I will turn to you. Is that all right?

Senator CASEY. Yes.

Senator HATCH. All right.

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

Senator HATCH. I want to thank Senator Baucus for convening this timely and much-needed hearing this morning. It is no secret that for many reasons—and we want to welcome you, Dr. Gilfillan, and appreciate you being here—I did not support the President's health reform bill.

Despite my long-term interest in reforming our Nation's health care delivery system to reduce costs and of course improve quality, I was concerned with the creation of a new bureaucracy known as the Center for Medicare and Medicaid Innovation, CMMI, and giving them $10 billion in taxpayer funds with no strings attached.

We have now held two hearings in the committee where we have heard from the public and private sectors about interesting ways they are working to improve the delivery of care. I for one wholly support the private sector, working among payers, providers, and patients, to come up with solutions that best fit their communities in order to achieve more efficient and higher quality results.

I have heard repeatedly from my Democratic colleagues that CMMI is tasked with letting "a thousand flowers bloom." What I

really wonder is if this is simply a euphemism for "barely controlled chaos." Dr. Gilfillan, I do not envy you your job. The administration expects you and your staff to overhaul the way health care is delivered in this country and to do it quickly so that people begin to believe their claims that Obamacare will save money.

I will make a prediction: come the first part of next year, this is going to be utter chaos, and people are going to realize what a tragic mess we are in because of Obamacare. However, despite the claims that Obamacare will save money, I am quite confident that Obamacare will only increase the costs of health care in this country.

I believe the evidence overwhelmingly supports my position, and we will all find out at the beginning of next year when all of these things trigger, including 20,000 pages of regulations.

With that said, I do think there is merit to trying to change the delivery of care and to focus on greater coordination of care, reducing hospital admissions, and providing better outcomes to patients. I am concerned, though, that there is confusion and a clear lack of focus at CMMI.

The Government Accountability Office, GAO, reported in November of last year that, while you have taken steps to coordinate with other offices at CMS, more work needs to be done to make coordination more systemic. It seems to me that CMMI would function best if it would pick a few initiatives, such as Accountable Care Organizations or Bundled Payments and really devote the time to those initiatives to make sure they actually work and have the intended consequences of lowering costs and increasing quality and efficiency.

Instead, I hate to say this, but I fear that you are trying to do too much at one time. Coordination among initiatives that have similar goals is something the GAO has highlighted as a concern. For example, the Innovation Center's Partnership for Patients model and CMS's Quality Improvement Program have a similar goal: to reduce the rate of preventable hospital-acquired conditions and 30-day hospital readmissions. Both models contract with organizations to disseminate interventions to hospitals and perform virtually identical functions. That sounds like something that could be consolidated.

I hope that CMMI takes the time to really study the impact of initiatives, both while they are going on and at the end of demonstrations, so we know if they work and how well they work before the initiatives are offered to more providers and patients.

Since the GAO report indicated that, in most cases, it would be 3 to 5 years before CMMI and the taxpayers know if these initiatives achieved their anticipated savings, it is critical that they be reviewed to determine whether they meet their stated goals. As you know, in the past, the Congressional Budget Office has shown us that most demonstrations do not actually save the taxpayers any money.

Finally, I wanted to raise concerns about the number of high-salary staff who are employed by CMMI. In addition to spending billions on the CMMI projects, GAO noted that nearly half of the 184-plus members of the CMMI staff are paid at the highest levels of the Federal pay scale, which stands in stark contrast to other

areas within CMS. I have also heard that CMMI staffers have state-of-the-art workspaces, including very expensive treadmill desks.

In a post-sequester world where White House tours are being canceled and Easter egg hunts are being threatened, you can imagine why the American people would take a very cynical view about Federal employees being furnished with $1,000 treadmill desks.

The Federal Government absolutely cannot afford to pour money into things that do not work. Our priority must be very clear. We need to make government as efficient as possible, and we do not need bloated bureaucracies, we do not need duplication of efforts, and we do not need an increased morass of regulations and platitudes.

We do not need taxpayer dollars being spent so that staff can work at treadmill desks. What we do need is a clear strategic plan to improve quality and reduce costs. We need specific goals with specific direction to achieve those goals. We need the right people with expertise in these areas to develop targeted approaches that can be tried quickly, studied, and assessed for measures of success.

Now, Dr. Gilfillan, you know that last year I sent you a letter asking for an accounting of what your office has been working on, how much money has been spent and, more importantly, how that money was spent. It took you more than 6 months to reply to my request. Now, let me repeat that again: 6 months. That is, to me, entirely unacceptable. I hope I will have your commitment today that that type of behavior will not be repeated, and all members of this committee will be given timely and complete responses. I would hope that you would do that. Can I get a commitment on that?

Dr. GILFILLAN. Senator, we deeply regret the length of time it took to respond to your letter. It was the first such letter we received. It took us time to develop what we felt was an adequately comprehensive report addressing your questions. It certainly is our intent to be much more——

Senator HATCH. Then call me and say, "Look, we need a little more time here; we will be happy to give you a step-by-step approach in accordance with what we have worked on." But do not let us sit there for 6 months without having a response. We are getting too much of that in this administration, where they just ignore what people up here ask them to give. It is too pervasive in this administration, and we have to stop that or there is going to be just unholy war up here.

Well, as you can see, I have a number of concerns that I do not have time enough to go into right now, but I do want to thank the chairman for convening this hearing.

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

Senator HATCH. Let me turn to Senator Casey at this point.

Senator CASEY. I want to thank the ranking member. Doctor, I appreciate you being here, for your testimony and for your service. I know you have fond memories of Pennsylvania, and we appreciate your work that you did in our State.

Doctor, I want to ask you one question that relates to the work that has been done to date—with regard to the work of the Innova-

tion Center. I know a lot of the focus, attention, and work has been on payment or delivery system reforms as it relates to Medicare and Medicaid, and appropriately so. We need to find more and better ways to deliver good care, good quality care, and also save money.

My concern, though, is, I am not sure we are doing enough in terms of using those same approaches or strategies as it relates to children. I guess the basic question I would have is, can we, or how can we, and how does CMMI plan to invest in strategies for children that we can prove over time will result in better outcomes, and especially with regard to children that have the kind of complex medical needs.

You have heard the child advocates often say that, when it comes to children's health insurance—and you know this better than I do as a medical doctor and a practitioner—children are not small adults, and you cannot just impose health care strategies or approaches on them that you would on an adult. So, can you talk a little bit about that and whether or not there might be more opportunities to focus those same reforms on children?

Dr. GILFILLAN. Certainly, Senator. Thank you for that question. We are working closely with our colleagues at the Centers for Medicaid and CHIP Services on a variety of programs intended to improve care for all Medicaid and CHIP beneficiaries, and of course most particularly focusing on issues that affect children.

One of those programs, of course, is the Strong Start initiative, where we are working hard with the private sector, the March of Dimes, the American Congress of Obstetricians and Gynecologists, to find new ways to deliver prenatal care to give kids the best start, to get them off on the right foot by decreasing the incidences of prematurity. So, from a program standpoint, that program is certainly well-focused on children at the very beginning.

In our health care innovation awards, we have a number of projects focused directly on the needs of children, specifically the children with complex needs. We have, I believe, four different models actually looking at systems of care intended to address the needs of those patients. We have a program in Cleveland, a program in Akron, a program in Texas, and a program in North Carolina focused directly on that population and investigating new systems.

Now, these are innovation awards, small programs. We are learning a lot. We have the option as we learn to expand them, make them broader model tests, and we have met with the stakeholders from the Pediatric Hospital Association several times to talk about that. We are also focused on what is probably the most significant health problem, chronic health problem, for children in the treatment of asthma.

We have a number of initiatives that we are working on, again, in the health care innovation award space, to look at new ways of treating children with asthma to decrease exacerbations or complications and limit or decrease the frequency that they have to go to the emergency room.

Then we are working with States through our State Innovation Model, where we are asking them to work with us, work with the Centers for Medicaid and CHIP Services, work with the Innovation

Center, to design programs that will improve care for all of their populations, and these will include the pediatric populations as well.

So it is an important area. We are committed to working through it, to learning from the initial models, and looking for broader opportunities, Senator, to test in a more broad-based way new care systems for children across the country.

Senator CASEY. And I appreciate that. I am glad you mentioned Strong Start, because I was noting in your testimony at page 7 the description, and quoting the second sentence of that section in your testimony, "The first is a public/private partnership, an awareness campaign to reduce the rate of early elective delivery prior to 39 weeks for all populations." You then go on and talk about, "It is a persistent problem." You highlight the Strong Start awards, 27 of them most recently, and two of them, by the way, in Pennsylvania. We are happy whenever that occurs.

But what are you seeing with regard to the larger challenge of making sure that we are learning through these programs to deliver care better? I know it is early, but have any conclusions as to that been yielded from Strong Start?

Dr. GILFILLAN. Well, yes, Senator. The Strong Start strategy is one we have been working on for almost a year now. This is an initiative to work across the delivery system with private sector colleagues, the March of Dimes, the American Congress of OB–GYNs, and other private sector interested parties, to help support the enactment of policies across hospitals that are consistent with what the American Congress of Obstetricians and Gynecologists has advocated for 20 years. That is, that there should not be elective deliveries performed prior to 39 weeks gestation.

Now what that means, elective deliveries mean, is there is no medical reason for doing it, so it may be done for the convenience of the practice, the physician. At times people have said patients are interested, moms are interested in having early elective deliveries.

What we have learned is that, while people think the baby may be at-term, the reality is there is a great deal of development that goes on between 37 and 39 weeks, so it is important. About 8 percent of the time, babies who are delivered at that time actually end up being admitted to the NICU, the Neonatal Intensive Care Unit, for complications.

Senator CASEY. Before 39 weeks?

Dr. GILFILLAN. Before 39 weeks, even though people think it is at-term. So the experts have long supported avoiding doing that and not delivering babies early like that. So, through the Partnership for Patients, we have engaged their hospital network to talk with hospitals about putting policies in place that prevent that from happening, and we have seen remarkable improvement in the hospitals that are doing that.

Some hospitals had already started doing that themselves, but many—the vast majority of hospitals around the country—had not put a policy like that in place. Through our private/public partnership with the March of Dimes, the American Congress of Obstetricians and Gynecologists, hospital associations, and through the relationships we have in our Partnership for Patients, we have been

really, I think, able to raise the consciousness, the awareness of this problem nationally, and we are seeing major changes across health systems, across State hospital associations, in hospitals putting that in place.

What happens very dramatically is, we see early elective deliveries going from a rate that could be as high as 15, and in some cases over 20 percent, going down to 2, 3, or 4 percent with better outcomes, because babies are not being admitted to the Neonatal Intensive Care Unit. We think, but we do not have definite evidence of this, we are beginning to see a decreased frequency in use of Neonatal Intensive Care Units as a result of this. More to come on that as that information and data become more complete and mature.

Senator CASEY. Thanks very much. I now owe the ranking member 3 minutes and 47 seconds.

Senator HATCH. Well, I was happy to give that to you, especially after giving the distinguished Senator from Kansas 10 minutes. And, we were interested in your questions besides.

Senator Thune, you will be our last questioner.

Senator THUNE. Thank you, Mr. Chairman.

Dr. Gilfillan, thank you for being here today. On page 31 of the November 2012 GAO report on the early implementation efforts of the CMS Center for Innovation, GAO talked about how a centralization database would hep the Innovation Center make coordination of the new models more systematic.

One of the biggest goals of such a database would be to prevent duplicative payments to providers that participate in CMS efforts involving incentive payments for meeting quality and cost measures. At the time, CMS officials said that such a database would ensure that beneficiaries are not counted twice for the purposes of calculating incentive payments and that the database would be fully functional in September of 2012. Is that database operational?

Dr. GILFILLAN. Yes, Senator, it is operational.

Senator THUNE. And can you explain what happens when the database discovers a beneficiary is being counted twice?

Dr. GILFILLAN. Certainly, Senator. That is a great question. It goes to how we have had to build new operating capabilities within CMS to track patients in the different initiatives that we have, not just within the Innovation Center, but across CMS and the Shared Savings Program as well.

So we had to build the capability for our information systems to only align a patient once with any of these programs, and that is exactly what the system does. We have a series of dates where different programs present their physicians to the IS folks. They run the data through this database.

They look at all the visits a patient has had to a particular provider, and, as a result of that, they align a patient with only one set of providers so that we do not have any duplication. So that system has been operating now since last year. It is refined and continually upgraded, and it becomes faster to operate, frankly, as they refine it. But it is operating and producing the result that we were after: namely, avoiding duplicated payments for patients.

Senator THUNE. Thank you.

My understanding is that, in mid-2012, CMMI had started to work on 17 new models designed to test different approaches to health care delivery and payment in Medicare and Medicaid, and it has assumed responsibility for another 20 demonstration programs that were already in progress when the Center was created. GAO's report, again, from November of 2012, provided some valuable insight into how those 17 new models were functioning. Since the GAO report, has CMMI initiated any new models?

Dr. GILFILLAN. Since the final report, we have announced awardees for our Strong Start program, and we have announced our upcoming comprehensive End-Stage Renal Disease program that we are just in the solicitation phase for right now.

We also have announced awardees for our State Innovation Model program and have identified six States that are testing their innovation plan, and another 19 States that are testing or have received grants, awards, to do design work. I think those are the major additions we have had since then.

Senator THUNE. What was the review process for those models?

Dr. GILFILLAN. Sure. Well, we follow the standard CMS review processes for consideration of applications, and we convene typically panels of reviewers to look at applications to rate them according to the criteria that we have. Then we go through a standard review and approval process that is consistent with the overall grant and corporate agreement-making policy of CMS.

Senator THUNE. And is that process that you just described any different from the process that was noted in the GAO report?

Dr. GILFILLAN. No, I do not believe it is, Senator. We followed the standard grant-making and corporate agreement-making processes that other Federal agencies follow. So I would have to go back and look at the exact language, but I do not think it is different.

Senator THUNE. If it is not, if the review process has not changed from what was noted in their report, how then can you be sure that you do not end up repeating the same mistakes that were noted in their report, in the GAO report?

Dr. GILFILLAN. Well, Senator, we have continually improved our approach. We are exquisitely conscious of potential duplication in all of our models. We are working carefully to coordinate across CMS and across the Innovation Center with different models. I think we have been very conscious of the importance of avoiding overlap where there is no added advantage to starting another program.

Senator THUNE. All right. My time is up, Mr. Chairman. Thank you.

Senator HATCH. Well, thank you.

Dr. GILFILLAN. Thank you, sir.

Senator HATCH. Dr. Gilfillan, we appreciate you taking the time to be with us, and we look forward to working with you in the future. Hopefully, we can get some of these conflicts resolved. But thank you for being here.

With that, we will recess until further notice.

Dr. GILFILLAN. Thank you very much, Senator Hatch.

[Whereupon, at 10:49 a.m., the hearing was concluded.]

APPENDIX

Additional Material Submitted for the Record

Hearing Statement of Senator Max Baucus (D-Mont.)
Regarding the Center for Medicare and Medicaid Innovation and Improving America's Health Care System

The great American inventor, Thomas Edison, often liked to challenge his colleagues saying, "There's a way to do it better—find it."

Edison always looked to inspire fresh ideas to overcome any challenge.

Today, we are in need of new and innovative ideas for America's health care system. We know there's a better way to deliver quality health care and to lower costs. We created the Center for Medicare and Medicaid Innovation to find it.

Known simply as the Innovation Center, the Affordable Care Act established the national facility to inject government health care programs with some of the flexibility and creativity the private sector enjoys.

The center comes with a simple mission: lower costs, and improve quality. It does so by testing new payment incentives and employing creative methods of delivering care. If the center develops a successful idea, Medicare and Medicaid work to quickly replicate it nationwide. If an idea is not successful, they go back to the drawing board and develop something different.

In just a short time, the Innovation Center has produced real results. According to the Congressional Budget Office, the investments in the Innovation Center are expected to generate a 13 percent return through 2019. And in the decade after, the center is expected to save taxpayers tens of billions of dollars.

The Innovation Center is already testing many promising ideas. These include Pioneer Accountable Care Organizations, groups of doctors across the United States who work together and coordinate their care to reduce costs. From Minneapolis to Maine and Nevada to New York, these doctors are sharing lessons learned and best practices in an effort to provide better patient care. This is just one of the more than 30 new programs the Innovation Center has already introduced, impacting the lives of 5 million beneficiaries across all 50 states.

Health reform included specific ideas for the Innovation Center to test. But we also knew that tapping into Americans' ingenuity and entrepreneurship could lead to groundbreaking ideas on how to improve the health care delivery system.

So we told the center to ask Americans for their ideas on how to improve the quality of care without increasing costs. And as an incentive, the center would provide grants to test the most promising models.

One company that answered the call is the online clinic Health Link Now. Recognizing the challenges rural communities face accessing mental health care, Health Link Now will partner with local hospitals and doctors in Montana and Wyoming. They will provide mental health care through secure videoconferencing and interactive technology. Patients in even the most rural areas — like Troy, Montana, population 933 — can now access quality care if needed.

This initiative is expected to lower costs through reduced hospital admissions and emergency room visits, while increasing access to care in rural communities. If proven successful, it will likely be replicated across rural America. This is just one example of the type of revolutionary ideas the Innovation Center is supporting.

Some of the tested models will be successful and others won't, but we cannot be afraid of missteps. We must continue trying new ideas, learning from mistakes, and building on our successes. That's how we find what works. And we also need Medicare and Medicaid to develop programs faster than they have in the past.

In 2003, Medicare partnered to create a demonstration project in which hospitals in 26 states — including St. James Healthcare in Butte, St. Vincent Healthcare in Billings, and Holy Rosary Healthcare in Miles City, Montana — would receive bonus payments based on the quality of care delivered. From 2003 to 2009, the demonstration project is estimated to have saved thousands of lives, including 8,500 heart attack patients.

Seeing the success of this demonstration project, Congress used it as a model to create a program where Medicare rewards all hospitals across the nation for high quality care. It also penalizes hospitals that produce poor outcomes. That program began this year.

In many ways, the 2003 demonstration project set a new standard. It was developed in stages, with close public-private collaborations. But it took too long.

We can't wait a decade to develop a model, and then implement it nationally. We need to cut through the red tape and act quickly. We need to allow proven ideas to ramp up and spread rapidly without waiting for Congress to act. That is the Innovation Center's task.

It can broadly deploy demonstration projects that are proven to reduce spending or increase quality. This will allow us to test, evaluate, and then integrate new ideas nationwide in only a few years instead of a decade or more.

I look forward to examining the progress the Innovation Center has made to date. We are here today to ask tough questions. We want to hear about different models being tested, we want to hear which projects are most promising, and we want to know when we will see more results.

We are going to need a bold vision if we are going to get health care costs under control. So let us act boldly. Let us realize there is a way to do it better when it comes to health care costs, and as Thomas Edison said, let us find it.

STATEMENT OF

RICHARD J. GILFILLAN, MD

DIRECTOR,

CENTER FOR MEDICARE AND MEDICAID INNOVATION

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

REFORMING THE DELIVERY SYSTEM:

THE CENTER ON MEDICARE AND MEDICAID INNOVATION

BEFORE THE

U. S. SENATE COMMITTEE ON FINANCE

MARCH 20, 2013

Senate Committee on Finance
Hearing on "Reforming the Delivery System:
The Center for Medicare and Medicaid Innovation"
March 20, 2013

Chairman Baucus, Ranking Member Hatch, and Members of the Committee, thank you for the opportunity to discuss our work at the Center for Medicare and Medicaid Innovation (the Innovation Center) at the Centers for Medicare & Medicaid Services (CMS). In the nearly three years since the Affordable Care Act became law, CMS has established the Innovation Center and initiated testing of numerous innovative payment and delivery models, under Innovation Center authority. The Innovation Center has also assumed administrative responsibility for a range of other pre-existing and separate statutory initiatives.

The Innovation Center has harnessed the energy and enthusiasm of a wide variety of innovators to help us identify models that can drive significant improvements in health care for enrollees in Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP). What we have learned from our outreach – and it confirms my experience in the private sector – is that physicians and providers want and need reform that can allow them to provide sustainable, quality health care to their patients. We are currently working with more than 50,000 health care providers from every State in the country to test various models. Knowing that there is no one solution that will improve the health care system and reduce costs, the Innovation Center is casting a wide net through our broad portfolio to give options and opportunities to participate in testing models.

We are moving forward with a serious and rigorous process to monitor and evaluate the initiatives we have underway and to develop additional initiatives that build on these efforts. One of our goals is to create a solid business case for providers to engage in quality improvement. We have made significant progress in developing these models, and will continue to engage providers, payers, employers, States, and other stakeholders in our efforts. Medicare beneficiaries are already starting to enjoy better quality of care through innovative care delivery systems designed to improve their health outcomes and reduce costs. Affordable

Care Act reforms are contributing substantially to recent reductions in the growth rate of Medicare spending per beneficiary[1] without reducing benefits for beneficiaries. Growth in national health expenditures over the past three years was lower than any time over the last 50 years. Fraud recoveries have increased to a record $4.2 billion in 2012, and $14.9 billion over the last four years. Medicare beneficiaries have gained access to additional benefits, such as increased coverage of preventive services and lower cost-sharing for prescription drugs.

We are also observing a decrease in the rate of patients returning to the hospital after being discharged. After fluctuating between 18.5 percent and 19.5 percent for the past five years, the 30-day all cause readmission rate dropped to 17.8 percent in the final quarter of 2012. This decrease is an early sign that our payment and delivery reforms are having an impact.

Innovation Center Background

Congress created the Innovation Center to test "innovative payment and service delivery models to reduce program expenditures… while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or CHIP benefits. The Affordable Care Act appropriated $10 billion to support the Innovation Center's activities initiated from Fiscal Year (FY) 2011 to FY 2019.

Congress also defined – through both the Affordable Care Act and previous legislation – a number of specific CMS demonstrations. Some of these demonstrations test proposed improvements in care delivery and payment, such as the Independence at Home Initiative. The Innovation Center also assumed responsibility for several demonstrations that were initiated through CMS's former Office for Research Development and Information, which was brought into the Innovation Center.[2]

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[1] ASPE Issue Brief: "Growth In Medicare Spending Per Beneficiary Continues To Hit Historic Lows" for full report please visit http://aspe.hhs.gov/health/reports/2013/medicarespendinggrowth/ib.cfm.

[2] The Innovation Center staff managed 23 statutorily-prescribed active demonstrations during the period between January 1, 2011 and October 31, 2012. Note that while the Innovation Center has administrative responsibility for these statutory demonstrations, they are not funded out of the Innovation Center's appropriation.

In support of the mission that Congress assigned to us, we organize the Center's work, and the organization structure,[3] around four main priorities: identifying and stimulating the development of innovative ideas; developing and testing new payments and service delivery models; evaluating results; and spreading best practices.

While the Center has new authorities and responsibilities, we execute these priorities within CMS's well-established governance and oversight processes. The Innovation Center works closely with other CMS Centers and Offices, through daily, weekly, biweekly, and monthly interactions and meetings. In particular, the Innovation Center works closely with the Center for Medicaid and CHIP Services on initiatives involving Medicaid or CHIP beneficiaries, with the Center for Medicare on initiatives involving Medicare beneficiaries, and with the Medicare-Medicaid Coordination Office on initiatives involving beneficiaries enrolled in both Medicare and Medicaid.

Identifying and Stimulating the Development and Testing of Innovative Ideas

During the development of models, the Innovation Center receives ideas from stakeholders, and consults with clinical and analytical experts, as well as with representatives of relevant Federal agencies. The Innovation Center actively engages innovators through its website, social media outreach, and an email listserv that reaches an audience of over 30,000 people across the country who are interested in innovations in health care delivery and payment. Since its formation, the Innovation Center has held numerous regional meetings, listening sessions, and open-door forums to engage thousands of innovators from around the country. In addition, stakeholders have shared more than 500 ideas for improving health care through the Share Your Ideas section of the Innovation Center's website.[4]

For all models, the Innovation Center selects participating organizations through an open process. The process follows established protocols to ensure that it is fair and transparent,

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[3] The Innovation Center's organizational structure is available at http://innovation.cms.gov/about/Our-Team/index.html.

[4] http://innovation.cms.gov/Share-Your-Ideas/Submit/index.html.

provides opportunities for potential partners to ask questions regarding the Innovation Center's expectations, and relies on multi-stakeholder expertise to select the most qualified partners.

Current Innovation Center Models

The Innovation Center is currently responsible for numerous initiatives that test new payment or care delivery systems following the business and experimental processes described above.[5] Major examples of the Innovation Center's initiatives include:

- The *Pioneer Accountable Care Organization (ACO) and Advance Payment ACO models*, which aim to align incentives for organizations to promote higher quality care and better health outcomes for the population served and greater accountability for the total cost of care;
- The *Bundled Payments for Care Improvement Initiative*, which is a series of four models that will realign incentives for hospitals and post-acute care providers to promote quality and efficiency;
- The *Comprehensive Primary Care Initiative*, which provides support to transform primary care practices;
- The *Strong Start for Mothers and Newborns Initiative*, which is an effort to test and evaluate enhanced prenatal care interventions for women enrolled in Medicaid or CHIP who are at risk for having a preterm birth;
- The *State Innovation Model*, which makes awards to States to design and test multi-payer payment and delivery models that seek to deliver high-quality health care and improve health system performance; and
- The *Health Care Innovation Awards*, which funds projects in communities across the Nation that aim to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and CHIP.

Each model has been developed to create a business case for quality improvement, relying on innovation to reduce spending while improving patient experience and health outcomes, and rewarding quality and population health management rather than greater volume of care.

[5] A full list of the Innovation Center's initiatives is available at http://innovation.cms.gov/.

Accountable Care Organizations (ACOs)

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

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

The Advance Payment ACO model examines whether and how pre-paying a portion of future shared savings could increase participation in the Shared Savings Program from entities such as physician-owned and rural providers with less capital. Through this ACO model, selected participants receive upfront and monthly payments, which they can use to make important investments in their care coordination infrastructure. It is our expectation that the assistance the Advanced Payment model provides to smaller and rural practices will result in expanding access to this coordinated care effort to more fee-for-service Medicare beneficiaries. Thirty-five ACOs are participating in this model.

In just over a year, more than 250 ACOs in 47 States and territories have formed and are working to improve the care experience for more than four million Medicare fee-for-service beneficiaries nationwide, which represents approximately eight percent of all Medicare beneficiaries. That number will grow over time as existing ACOs choose to add providers and more organizations are approved for participation in the Medicare Shared Savings Program.

Bundled Payments for Care Improvement Initiative

Traditionally, Medicare makes separate payments to providers for each of the individual services they furnish to beneficiaries during a single illness or course of treatment. This approach can result in fragmented care and a lack of coordination across health care settings. Bundling payments to multiple providers can better align incentives to those providers – hospitals, post-acute care providers, physicians, and other practitioners– leading them to work closely together to redesign care and better coordinate across all specialties and settings.

The Bundled Payments for Care Improvement Initiative is composed of four broadly-defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Over the course of the three-year initiative, CMS will work with hundreds of organizations to assess whether the models being tested result in enhanced quality of care and lower costs to Medicare. In January 2013, the Innovation Center announced the participants in Model 1, which tests bundled payments for acute care hospital stays, as well as the participants in Phase One of Models 2 through 4 of the Bundled Payments for Care Improvement Initiative. Phase One is the initial period of the initiative where the participants and CMS prepare for implementation and assumption of financial risk by sharing data and information. Phase Two will begin this summer.

Comprehensive Primary Care

The Innovation Center is also supporting primary care providers interested in transforming their practice. Approximately 500 primary care practices[6] in seven markets are participating in the Comprehensive Primary Care initiative, which is a multi-payer model testing the effectiveness of enhanced payments to improve care coordination for people enrolled in Medicare and Medicaid. We consulted extensively with other payers to design a model that would be suitable for adoption by Medicare, commercial, and Medicaid payers.

Under the Comprehensive Primary Care initiative, Medicare will pay primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating

[6] For a full list of participating practices please visit https://data.cms.gov/Government/CPC-Initiative-Participating-Primary-Care-Practice/mw5h-fu5i.

commercial, State, and other Federal insurance plans are also offering an enhanced payment to primary care practices that provide high-quality primary care. In order to receive the new care management fee from Medicare and other payers, primary care practices must agree to provide enhanced services for their patients, deliver preventive care, coordinate care with patients' other health care providers, engage patients and caregivers in managing their own care, and provide individualized, enhanced care for patients living with multiple chronic diseases and higher needs. To simplify the model for practitioners, and to maximize its impact, CMS and other payers used a coordinated approach to transform how primary care is practiced and financially supported. CMS and other payers also agreed to align quality measures in the model.

Strong Start for Mothers and Newborns

The Strong Start for Mothers and Newborns initiative, launched in 2012, is a two-part strategy to reduce preterm births and improve outcomes for newborns and pregnant women. The first is a public-private partnership and awareness campaign to reduce the rate of early elective deliveries prior to 39 weeks for all populations. Avoiding elective deliveries prior to 39 weeks has been a medical best practice recommended by the American Congress of Obstetricians and Gynecologists (ACOG) for more than 20 years but remains a persistent problem. CMS partnered with the ACOG, the March of Dimes, State and local governments, and the private sector to focus on increasing public awareness of this issue. The other component of the Strong Start Initiative is a funding opportunity to test the effectiveness of specific enhanced prenatal care approaches to reduce the frequency of premature births among high-risk pregnant women enrolled in Medicaid or CHIP.

In February 2013, we announced the recipients of 27 Strong Start for Mothers and Newborns awards with a total of up to $41.4 million made available to States, providers, academic institutions, and others to test new ways to prevent significant, long-term health problems for high-risk pregnant women and newborns enrolled in Medicaid or CHIP. The Strong Start awardees are located in 32 States, the District of Columbia, and Puerto Rico, and will serve more than 80,000 women enrolled in Medicaid or CHIP over the three intervention years. The grants will support enhanced prenatal care through group visits, at birth centers, and at maternity medical homes. These approaches expand access to care, improve care coordination, and

provide psychosocial support to pregnant women. Strong Start awardees will be serving women in the areas with the highest preterm birth rates in the country, including areas that are among the top ten prematurity and infant mortality counties according the Centers for Disease Control and Prevention. The Innovation Center will administer these awards through cooperative agreements over four years.

State Innovation Model

The State Innovation Model initiative was developed for States that are prepared for or committed to planning, designing, and testing new payment and service delivery models in the context of larger health system transformation. The goal is to create multi-payer models with a broad mission to improve community health and reduce long-term health risks for beneficiaries of Medicare, Medicaid, and CHIP, and lower costs in these programs.

The Innovation Center recently announced 25 States are participating in the first round of funding. Six States have received model-testing awards that support the implementation of their State's Health Care Innovation Plan. The Plan is a proposal that describes a State's strategy to use all of the levers available to it to transform its health care delivery system through multi-payer payment reform and other State-led initiatives. Three States are receiving pre-testing awards that will allow them to continue work on their Health Care Innovation Plans, and sixteen States are receiving model design awards to develop Health Care Innovation Plans. We expect to award additional model-testing awards in the future and expect that States that were given design awards will apply for the next round of model-testing awards.

Health Care Innovation Awards

The Health Care Innovation Awards were awarded to 107 recipients who are testing innovative care delivery models that aim to improve outcomes and reduce costs. Awardees were chosen for their innovative solutions to the health care challenges facing their communities and for their focus on creating a well-trained health care workforce that is equipped to meet the Nation's needs in our 21st-century health system. The initiative supports innovators who can rapidly deploy care improvement models (within six months of award) through new ventures or expansion of existing efforts to new populations of patients, in conjunction (where possible) with

other public and private sector partners. Funding for these projects is for three years. The projects are located in urban and rural areas, all 50 States, the District of Columbia, and Puerto Rico.

Some examples of the projects include the Prosser Washington Community Paramedics Program in Washington State, which received an award for a program through which physicians can send a community paramedic to visit a patient of concern, providing in-home medical monitoring, follow-ups, basic lab work, and patient education. By expanding the role of the emergency medical services, community paramedics can increase access to primary and preventive care, provide wellness interventions, decrease emergency room utilization, and improve outcomes.

Another awardee is the Delta Dental Plan of South Dakota's project, "Improving the care and oral health of American Indian mothers and young children and American Indian people with diabetes on South Dakota reservations." Delta Dental Plan, which covers over thirty-thousand isolated, low-income, and underserved Medicaid beneficiaries and other American Indians on reservations throughout South Dakota, aims to improve oral health and health care for American Indian mothers, their young children, and American Indian people with diabetes. Providing preventive care will help avoid and arrest oral and dental diseases, repair damage, prevent recurrence, and ultimately, reduce the need for surgical care.

Other Innovation Center Models

Other Innovation Center initiatives include the *Independence at Home Demonstration,*[7] created by the Affordable Care Act, which uses home-based primary care teams designed to improve health outcomes and reduce expenditures for Medicare beneficiaries with multiple chronic conditions. Under the Independence at Home Demonstration, selected primary care practices will provide home-based primary care to targeted chronically ill beneficiaries for a three-year period. Participating practices will make in-home visits tailored to an individual patient's needs and preferences with the goal of keeping them from being hospitalized.

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[7] The Independence at Home Demonstration is funded and authorized by § 3024 of the Affordable Care Act – not § 3021, which established the Innovation Center.

Additionally, the Innovation Center and the Health Resources and Services Administration (HRSA) jointly manage the *Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration.* Approximately 500 FQHCs are testing whether achieving certification as a medical home can improve care, health, and reduce costs. In addition to the Innovation Center's payments of per beneficiary amounts to support the FQHC's investment in primary care, HRSA is providing technical assistance to the FQHCs.

Another initiative is the *Partnership for Patients*, which is a public-private partnership to support physicians, nurses, and other clinicians in reducing hospital-acquired conditions and improving transitions in care. It will test the effect of multiple strategies to improve patient safety in hospitals, including reducing preventable hospital-acquired conditions and reducing 30-day readmissions. Part of the Partnership for Patients is the *Community-based Care Transitions Program*, an initiative in which 102 participants are working with local hospitals and other service providers to support Medicare patients who are at increased risk of being readmitted to the hospital while transitioning from care settings.[8] The Community-based Care Transitions Program will provide care transition services to over 700,000 Medicare beneficiaries in 40 States across the country.

Other initiatives being tested by the Innovation Center are intended to improve care coordination for beneficiaries with end-stage renal disease (ESRD), support hospitals for the cost of providing clinical training to advanced practice registered nursing students,[9] and determine whether Medicaid can support higher quality care at a lower total cost by reimbursing private psychiatric hospitals for certain psychiatric services for which Medicaid reimbursement has historically been unavailable.[10] The Innovation Center also collaborates with the Medicare-Medicaid Coordination Office to improve the quality of care available to and better coordinate benefits and services for the Medicare-Medicaid enrollee population. This latter category includes initiatives

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[8] The Community-based Care Transitions Program is funded and authorized by § 3026 of the Affordable Care Act – not § 3021, which established the Innovation Center.
[9] The Graduate Nurse Education Demonstration is funded and authorized by § 5509 of the Affordable Care Act.
[10] The Medicaid Emergency Psychiatric Demonstration is funded and authorized by § 2707 of the Affordable Care Act.

focused on improving financial alignment between Medicare and Medicaid and reducing avoidable hospitalizations among nursing facility residents.

Evaluating Results and Actively Spreading Best Practices

Congress provided the Secretary of Health and Human Services (HHS) with the authority to expand the scope and duration of a model being tested through rulemaking, including the option of expanding on a nationwide basis. For the Secretary to exercise this authority, a model must reduce net spending (as certified by the CMS Chief Actuary) without reducing the quality of care. No model may deny or limit the coverage or provision of Medicare, Medicaid, or CHIP benefits.

The law also requires that models tested by the Innovation Center shall be modified or terminated, unless the Secretary determines (and the CMS Chief Actuary certifies, with respect to spending) after testing has begun that the model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. The Innovation Center, working in concert with the Office of the Actuary, continuously monitors progress and results in order to quickly identify successful and unsuccessful models and take necessary action.

To assess the success of initiatives, the Innovation Center has assembled the Rapid Cycle Evaluation Group, responsible for evaluating the impact of each payment and service delivery model on the cost and quality of care, and on health outcomes. The Innovation Center, when considering a model for testing, engages staff from the Rapid Cycle Evaluation Group and the Office of the Actuary. Early in the process of implementation, evaluation staff considers advanced statistical methods, carefully defines and selects comparison groups, and applies conservative evidence thresholds to assure that programs deemed successful represent high-value investments of taxpayer dollars.

Establishing effective metrics at the outset of each model is critical to defining success. The Innovation Center selects measures for those that are appropriate for each model. Innovation Center evaluators collaborate with other CMS components to ensure that the metrics we use are

consistent across our programs as appropriate, and that we can thoughtfully compare the results of different models.

The Rapid Cycle Evaluation Group assesses each model's impact regularly and frequently to identify successful programs as quickly as possible. The Rapid Cycle Evaluation Group also provides ongoing feedback to participating entities to support continuous quality improvement on a quarterly basis. To determine the cost impact of the model, the Office of the Actuary monitors Innovation Center initiatives, and, once testing begins, will use data from the evaluation and monitoring as well as other available sources to certify results. The testing period for most models is typically three to five years, but in some cases it may be clear from the data within one or two years whether a model should be recommended for testing more broadly in Medicare, Medicaid, or CHIP, or should be terminated or modified.

The Innovation Center's work reflects a core belief that effective health care system reform requires continuous learning and sharing of best practices. Using data from the Rapid Cycle Evaluation Group, the Innovation Center organizes learning collaboratives among model participants to share effective approaches and disseminate best practices. This close collaboration will help ensure that best practices are disseminated rapidly, and aims to generate a more cooperative community of providers working together to improve the quality of care.

Looking Forward

The Innovation Center initiatives complement other reforms made by the Affordable Care Act. Thanks to the law, the Innovation Center is moving toward a system that provides better care and better health, and through these improvements, reduced cost. We look forward to advancing models and demonstrations that will provide the results our health care system needs.

United States Senate Committee on Finance
Public Hearing
"Reforming the Delivery System: The Center for Medicare and Medicaid Innovation"
March 20, 2013

Questions Submitted for the Record for Richard Gilfillan

Senator Max Baucus:

Rural Health

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

1. **Can some of the demonstrations CMMI is currently conducting be adapted to work in rural areas?**

Answer: We know that we have to change the incentive structure of our payment systems to emphasize care coordination, improve quality, and reduce the total cost of care, especially in rural areas that are often underserved. The Innovation Center has worked very hard to ensure that its models have geographic distribution so that each model is tested in variety of communities nationwide.

For example, the Adams County Health Center in Idaho is one of several rural participants in the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration which is testing enhanced support to FQHCs to help them achieve medical homes. The Adams County Health Center is in a medically underserved rural area, with only about three thousand residents in a thousand square mile service area. Also, the Mountain Area Health Education Center, serving a rural area in Western North Carolina, received a Health Care Innovation Award to test team-based primary care for patients with chronic pain.

We developed the Advance Payment Accountable Care Organization (ACO) model specifically for entities such as physician-based and rural providers with less access to capital to help increase the participation in the Shared Savings Program by these groups.

2. **Is CMMI developing any ideas aimed at improving health care provided in frontier areas like Montana?**

Answer: We are currently developing the Frontier Community Health Integration Demonstration Program with input from the Health Resources and Services Administration. This demonstration is for very small critical access hospitals with an inpatient census of less than five in sparsely populated states.

We believe that medical homes may have the potential to improve health care provided in frontier areas. Several of the Health Care Innovation Awards are testing medical home models. For example, two awards were given to organizations to test medical homes that focus on integrating primary and behavioral health care. These medical homes are being tested in several frontier areas, including Montana, North Dakota, and South Dakota. The Health Care Innovation Awards are still in their early stages and we do not yet have any results, but we anticipate that the results may inform future Medicare and Medicaid payment policy.

In addition, we have heard from rural stakeholders that they have difficulty meeting some of the requirements of the initiatives. We have formed a Health and Human Services Workgroup to gather ideas from stakeholders to find new models that might be appropriate for rural communities.

Senator Orrin Hatch:

Evaluation Contractors

3. **Has CMMI finished hiring evaluation contractors for all of the models? What is the status on getting evaluation plans finalized for all of the models?**

Answer: Evaluation contractors have been selected for the following initiatives: the Comprehensive Primary Care initiative, the FQHC Advanced Primary Care Practice demonstration, the Financial Alignment Initiative for Medicare-Medicaid enrollees, the Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents, the Pioneer ACO model, the Advance Payment ACO model, Model 1 for Bundled Payments for Care Improvement, Strong Start for Mothers and Newborns (home visiting only), Medicaid Incentives for the Prevention of Chronic Disease, Complex Diagnostic Lab demonstration, Independence at Home demonstration, Medicaid Emergency Psychiatric demonstration, Graduate Nurse Education demonstration, and the Partnership for Patients model. Procurements are in process and evaluation contractors should be selected this fall for the following models: Strong Start for Mothers and Newborns (maternity care homes, group care, and birth center approaches), Models 2 through 4 for Bundled Payments for Care Improvement, the State Innovation Model, and the Health Care Innovation Awards. The evaluation of the Comprehensive ESRD Care model is in the development stage, but it is too soon to award the contract.

Data Collection

Although the models are expected to be done over 3-5 years, data are to be gathered on each model from its very start, with the potential to stop models that don't appear promising.

4. **Are data currently being collected to be able to understand how well models are working and if they should keep going?**

Answer: To assess the success of initiatives, the Innovation Center has assembled the Rapid Cycle Evaluation Group, responsible for evaluating the impact of each payment and service delivery model on the cost and quality of care, and on health outcomes. When the Innovation Center considers a model for testing, we immediately involve staff from the Rapid Cycle Evaluation Group and work with the Office of the Actuary throughout the creation of the model. At the outset of testing of every model, evaluation staff considers statistical methods, carefully defines and selects comparison groups, and applies conservative evidence thresholds to assure that programs deemed successful represent high-value investments of taxpayer dollars.

Establishing effective metrics at the outset of each model is critical to defining success. The Innovation Center regularly summarizes individual milestones and data for each model. Innovation Center evaluators work to ensure that the metrics we use are consistent across our programs as appropriate and that we can thoughtfully compare the results of different models.

The Rapid Cycle Evaluation Group assesses each model's impact regularly and frequently – without compromising the rigor of the model testing and evaluation process – to identify successful programs as quickly as possible. The Rapid Cycle Evaluation Group also provides ongoing feedback to participating entities to support continuous quality improvement on a quarterly basis.

5. **To what extent has CMMI started to receive evaluation reports for models?**

Answer: As of March 7, 2013, the Innovation Center has begun the rapid cycle process for four of its initiatives: the Pioneer ACO Model, Multi-payer Advanced Primary Care Practice demonstration, the FQHC Advanced Primary Care Practice demonstration, and the Partnership for Patients.

We are currently analyzing the first year of data from two primary care projects that started in 2011, the Multi-payer Advanced Primary Care Practice and the FQHC Advanced Primary Care Practice Demonstration. In addition to the primary care projects, we anticipate that we will see the first results from the Pioneer ACO Model in summer 2013. These results will include the amount of savings or losses for each Pioneer ACO.

Quality Improvement Organizations

Has CMMI completed its review of the 26 Hospital Engagement Network contracts to ensure there is no duplication with the efforts of the Quality Improvement Organizations?

6. **Has any duplication been found and, if so, has CMMI taken steps to address the duplication?**

Answer: The Partnership for Patients and the Quality Improvement Organizations (QIOs) are both chartered to work collaboratively to reduce hospital acquired conditions and readmissions. The Partnership for Patients was designed to maximize the respective strengths of the Hospital Engagement Contractors (HENs) and the QIOs. For example, QIOs have highly specialized expertise in data collection and analysis, while HENs (which are mostly hospital systems and

state or national hospital associations) have strong relationships with hospital administrators and can capitalize on these relationships. It is CMS's intention that QIOs and HENs capitalize on these and other distinct strengths in supporting the quality improvement work of hospitals.

When the Partnership for Patients awarded the HEN contracts in December 2011, the Secretary specifically charged QIOs and HENs, and their accountable CMS program offices, to collaborate to maximize the teamwork and synergy among these programs. To ensure appropriate management and oversight of both initiatives, CMS has completed its analysis of the activities of the HENs and QIOs as they relate to one another in the areas of hospital acquired conditions and hospital readmissions. Contracts were reviewed to determine if a contract should be modified, a mitigation strategy should be employed, or technical direction should be issued. All activities were reviewed by December 31, 2012 and no contract modifications were required. Monitoring plans are in place to regularly assess future changes in the work plans of HENs and QIOs and the relationships of QIOs and HENs in the field to avoid future duplication.

7. **Was the outside review of CMMI completed in November 2012 as anticipated? If so, were any gaps found related to the CMMI's efforts to coordinate with other offices and has CMMI taken steps to address these gaps?**

Answer: In 2012, the Innovation Center had two contracts for assistance in setting up its operations in the most efficient and effective manner. The first contract was with Booz Allen Hamilton for assistance in drafting an operations plan. Significant progress has been made on the operations plan thus far and the Innovation Center is currently reviewing its strategic operations to identify additional areas of improvement.

The Innovation Center also contracted with Grant Thornton to review our financial and programmatic operations, to identify gaps in financial and operational controls, and to recommend improved operating processes for the Innovation Center. Grant Thornton reported that the financial controls at the Innovation Center appeared to be effective and meeting the applicable federal financial management laws. The Innovation Center leverages many of the existing processes established by the CMS Office of Financial Management and operates under that authority. Grant Thornton also identified areas for additional control development, such as improved documentation of standard operating procedures. The Innovation Center is working to implement Grant Thornton's recommendations while maintaining its ongoing efforts to improve operations.

Partnership for Patients Model

Regarding the Partnership for Patients Model, the 11/2/12 response from HHS to GAO noted three steps that you would take to identify and eliminate duplication between the HENs and the QIOs. Please update us on the status.

8. **Did you find any duplicative payments?**

9. **How much money?**

10. How long did it continue?

11. Has it stopped?

Answer to Questions 8-11: All HEN and QIO activities have been carefully reviewed to identify potential duplication, and monitoring plans are in place to prevent duplication from occurring. During the reviews, no instances of duplicative payments were found. The HEN contracts were awarded in December 2011 and the review of the activities of the HENs and the QIOs was completed in December 2012.

12. Is there a mitigation strategy in place, and have any of the contracts been modified?

Answer: To ensure appropriate management and oversight of both initiatives, CMS has completed its analysis of the activities of the HENs and QIOs as they relate to one another in the areas of hospital acquired conditions and hospital readmissions. Contracts were reviewed to determine if a contract should be modified, a mitigation strategy should be employed, or technical direction should be issued. No contract modifications were required. All activities were reviewed by December 31, 2012 and monitoring plans are in place to regularly assess future changes in the work plans of HENs and QIOs and the relationships of QIOs and HENs in the field to avoid future duplication.

13. What steps is CMMI/CMS taking to prevent similar problems in the future?

Answer: All activities were reviewed by December 31, 2012, and monitoring plans are in place to regularly assess future changes in the work plans of HENs and QIOs and the relationships of QIOs and HENs in the field to avoid future duplication.

14. Since GAO's review concluded in the fall of 2012, has CMMI hired additional staff?

a. Please give a breakdown of grades and provide some idea of level of employee.

Answer: Yes, the Innovation Center has hired staff since the conclusion of the GAO study. Total FTEs have increased from 184 (March 31, 2012) to 223 (March 31, 2013). As in the GAO report, we exclude certain individuals subject to interagency personnel agreements or on temporary details paid from other offices. There were 10 such individuals as of March 31, 2013.

A breakdown of the grades of current staff is provided below.

Innovation Center Grade Distribution: March 31, 2013

Innovation Center FTEs		% of Total
Grades 1-8	4	1.8%
Grade 9	8	3.6%
Grade 11	28	12.6%
Grade 12	21	9.4%
Grade 13	78	35.0%
Grade 14	21	9.4%
Grade 15	44	19.7%
SES	5	2.2%
Others	14	6.3%
Total	223	100.0%

15. Regarding "rapid cycle" evaluation, have any of the contractors who are evaluating the models provided feedback yet?

b. [If not] Why not? When do you expect to receive feedback?

Answer: Yes, we are receiving feedback reports from the FQHC Advanced Primary Care Practice demonstration, the Pioneer ACO model, and the Multi-payer Advanced Primary Care Practice initiative. Beginning this fall, we expect to begin to receive additional feedback reports. For example, we expect to receive the first feedback report for the Comprehensive Primary Care initiative in the fall, and the first feedback reports for the Bundled Payment for Care Improvement models in the spring of 2014.

Senator Robert Casey:

Partnership for Patients

When Jon Blum was here a few weeks ago he said that Partnership for Patients aims to save 60,000 lives through reducing hospital acquired infections and readmissions.

16. What impact are you finding the CMMI initiatives are having in these areas already?

Answer: The 30-day, all-cause readmission rate is estimated to have dropped in the last half of 2012, to approximately 18 percent, after averaging 19 percent for the past five years. This translates to about 70,000 fewer hospital readmissions in 2012. CMS has focused on reducing preventable readmissions in the Partnership for Patients as well as several new programs finalized in 2012 that tie Medicare reimbursement for hospitals to their readmission rates. Additionally, as part of the efforts of Partnership for Patients and the public awareness campaign of the Strong Start for Mothers and Newborns initiative, clinicians at some hospitals have reduced their early elective deliveries to close to zero, meaning fewer at-risk newborns and fewer admissions to the neonatal intensive care unit (NICU). Among 135 hospitals reporting common measures, early elective delivery rates have fallen (improved) by 48 percent.

ACOs

A Pediatric Accountable Care Organization Demonstration program, similar to the Medicare ACO provisions that have been implemented, was authorized but not funded in the ACA.

17. Could CMS implement this demonstration program with existing Innovation Center or other ACA funding? If not, why?

Answer: We have a number of initiatives and programs that focus on improving the health and healthcare outcomes for pediatric populations, including the Health Care Innovation Awards and the Strong Start for Mothers and Newborns initiative.

The Innovation Center has awarded Health Care Innovation Awards to two initiatives in Ohio that enhance provider incentives for caring for pediatric beneficiaries, similar to the goals of accountable care organizations. One of these awards was given to the Research Institute at Nationwide Children's Hospital, in partnership with Akron Children's Hospital and its integrated physician group, to expand its Partners for Kids (PFK) program in Ohio, serving over 492,000 Medicaid children enrollees and 25,000 children with disabilities. PFK will enhance provider incentives and improve access for high risk rural and urban underserved populations through comprehensive medical home-based services and the rapid deployment of an expanded health care workforce focusing on behavioral health, complex care, and high risk pregnancy.

Another relevant Health Care Innovation Award went to University Hospitals (UH) Rainbow Babies and Children's Hospital at UH Case Medical Center to improve care for approximately 65,000 children with Medicaid with high rates of emergency room visits, complex chronic conditions, and significant behavioral health problems in several counties across northeastern Ohio. The intervention will offer health care advice, referrals, and care coordination services through telehealth and home nurse hotlines; provide practice-tailored facilitation for primary care providers; and provide financial incentives to primary care physicians who reach quality performance targets, agree to offer extended hours, and make themselves available to treat these vulnerable children.

The Strong Start initiative is an Innovation Center project focusing on reducing early elective deliveries and reducing the rate of preterm births among high-risk women in Medicaid and

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

Senator Jay Rockefeller:

Medicaid Initiatives

With the exception of a few demonstrations, CMMI is focusing the vast majority of its energy on testing new payment and delivery system models in the Medicare program.

18. Does CMMI plan to increase their focus on enhancing care coordination and delivery under Medicaid moving forward?

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

19. Can you inform us about any potential Medicaid initiatives or demonstrations under discussion?

Answer: As we do in all areas, we continue to look for opportunities to test promising models in the Medicaid program. We are working closely with our colleagues at the Center for Medicaid and CHIP Services to coordinate our collective efforts to identify new opportunities.

Financial Alignment Initiative Plans

Under the Affordable Care Act, the Secretary is only supposed to expand demonstration projects when evidence from the demonstration suggests that expansion would lower costs without reducing quality or when quality is improved without raising costs. However, the Financial Alignment Initiative plans to enroll millions of dually eligible beneficiaries into untested new models of care. Enrolling such a large number of people—many of whom are among the most vulnerable Medicare and Medicaid enrollees—into a demonstration without sufficient evidence violates the intention of the statute.

20. Can you explain CMMI's rationale for moving forward on such a large scale and fast pace without first collecting substantial evidence on the effects the demonstration will have on quality and health outcomes?

Answer: CMS and States are proceeding at a measured pace for each State, and implementing safeguards to protect and enhance beneficiaries' access to high quality care. To date, CMS has approved demonstrations in four States, including capitated models in Massachusetts, Ohio and Illinois, and the managed fee-for-service model in Washington. The earliest enrollment for any Demonstration model is expected in July of 2013 in Washington.

CMS has committed to a national cap of 2 million beneficiaries in the Demonstrations. We believe this is a reasonable limit to balance concerns with size and the ability to test models across the nation in different delivery systems, States, and target populations. This approach will allow CMS to provide Congress and others with information to scale and advance integrated care for this population. We are proceeding judiciously on a State-by-State basis and enrollment will be phased in to ensure it is carefully conducted. To that end, CMS has established oversight and monitoring mechanisms as well as operational and implementation milestones to ensure the Demonstration will preserve and strengthen Medicare-Medicaid enrollees' access to care, quality of care, and benefits. CMS ultimately controls how many beneficiaries will be approved to be enrolled in a given Demonstration.

21. Several demonstrations, including the Financial Alignment Initiative, will run over the course of several years. At the end of that time period, what specific steps will you go through to evaluate whether particular demonstration should continue or be expanded?

Answer: CMS is funding and managing the evaluation of each approved Demonstration and models. For the Financial Alignment Initiative, CMS has contracted with an external independent evaluator, RTI International, to measure, monitor, and evaluate the overall impact of the Demonstrations and models, including impacts on Medicare-Medicaid enrollees, expenditures, and service utilization. The evaluator will design unique, State-specific evaluation plans for each individual State participating in the Demonstration, as well as an aggregate analysis that will look at the Demonstration overall including Demonstration interventions and impact on key subpopulations within each State. The evaluation will use a mixed methods approach to capture and analyze quantitative and qualitative information.

The Memorandums of Understanding for Massachusetts, Ohio, Washington, and Illinois provide examples of the types of areas that will be measured in all Demonstrations, including beneficiary experience of care, care transitions, support of community living, access to services, and shifts in service utilization patterns, among many others. Additional quality measures, as well as qualitative evaluation components such as beneficiary focus groups and key informant interviews, will be included in the State-specific evaluation plans.

22. Will you commit to us that you will come back to brief Congress on the results of your demonstrations before continuing or expanding them?

Answer: We will continue to keep the Congress informed as to the results of our initiatives.

Emergency Psychiatric Demonstration

I am pleased that West Virginia was among the states included in the Emergency Psychiatric Demonstration. I have high hopes that this long overdue demonstration will help improve care for patients residing in institutes for mental disease, who are often among the most vulnerable in the Medicaid population.

23. Do you have any early results or findings related to quality or cost-savings from this demonstration that you are able to share?

Answer: The Medicaid Emergency Psychiatric Demonstration began on July 1, 2012. Not all of the states started at that time but all started before the end of 2012. We are in the process of collecting data from the states on enrollments, discharges, average length of stay, readmissions, and causes of readmissions back into the demonstration within a 30 day period. Right now, we have insufficient data to make any determinations regarding cost savings and quality of care; however, we are hopeful to have preliminary findings by the end of the year.

Project ECHO

I am also pleased that CMMI provided an innovation grant last year to Project Extension for Community Healthcare Outcomes (Project ECHO), as I believe this program is demonstrating how technology can be used both to continue medical education and to expand health care services available to rural populations.

24. What is CMMI doing to build on the initial successes of this important initiative?

Answer: Project Extension for Community Healthcare Outcomes (Project ECHO) seeks to address important disparities in health care services for rural populations in remote and underserved areas. The Project is designed to test an approach to improve access and care for rural populations through the use of a technology-based platform for in-service medical training. To date, Project ECHO has not yet provided services to patients as part of this award; they are currently refining their approach to identify the participants whose quality outcomes could be improved and Medicare expenditures could be reduced through comprehensive and coordinated care.

Senator Michael Bennet:

First of all, I want to say that I am supportive of the work of the Centers for Medicare and Medicaid Innovation Center (CMMI) because part of tackling the high costs of health care is exploring and implementing these models that have the potential to bend the cost curve.

I understand and appreciate that it is difficult to design models that ensure that Medicare will see savings, but do not reduce access for patients.

Payment Reforms

The Affordable Care Act (ACA) directs you to test specific payment reforms, but also authorizes you to test any others as CMMI believes finds merit.

25. **Would you please share the most promising example of a payment test not specifically described in the ACA?**

Answer: One example of a model not specifically described in the Affordable Care Act is the Advance Payment ACO model developed by the Innovation Center for organizations participating as ACOs in the Shared Savings Program. Through the Advance Payment ACO model, selected participants in the Shared Savings Program receive advance payments that will be repaid from the future shared savings they earn.

The Advance Payment ACO model is testing:

- Whether providing an advance payment (in the form of up-front and monthly payments to be repaid in the future) increases participation in the Shared Savings Program, and
- Whether advance payments allow ACOs to improve care for beneficiaries and generate Medicare savings more quickly, and increase the amount of Medicare savings.

The Advance Payment ACO model is restricted to entities with less access to capital, to help smaller practices and rural providers participate in the Shared Savings Program.

26. **For providers in my state with payment reform ideas of their own, how does HHS select new ideas for testing consideration?**

Answer: We know that clinicians, health systems, community leaders, and other innovators throughout the country are developing new models of payment and service delivery that provide better health and better health care at lower costs. The Innovation Center is seeking those ideas on how care can be furnished in ways that will lower the total expenditures while improving the quality of care.

The Innovation Center solicits ideas from stakeholders thorough a web portal available at: http://innovation.cms.gov/Share-Your-Ideas/index.html. Once ideas are received, the Innovation Center considers the idea, along with other ideas received through the portal, to help improve and shape the Innovation Center's work on an ongoing basis. Ideas may be utilized within CMS to develop requests for proposals, applications, studies, models to be tested, or for other purposes.

27. **How do you ensure these payment reform ideas work with in a geographically diverse population, such as in a state like Colorado?**

a. **For example, a provider group may wish to propose a new payment model to reward providers who adopt the "Choosing Wisely" program; is CMS prepared to accept such as request?**

Answer: The Innovation Center is interested in testing new models of payment and service delivery. Once ideas are received, the Innovation Center considers the idea, along with other ideas received through the portal to help improve and shape the Innovation Center's work on an ongoing basis. If an idea is developed into a model the Innovation Center then selects participants. Generally, CMS uses a competitive application process to select participants to allow many providers to participate so that we can learn from the model in different areas. The Innovation Center's process is to test models in as many geographically diverse areas as possible when applicable to the model.

28. **Is CMMI planning to integrate the future of its payment models with the results from the winners of the recently announced Health Care Innovation Challenge. If so, how?**

Answer: Health Care Innovation Awards may inform future payment models. One area with potential to inform the future payment models are medical homes. Several of the Health Care Innovation Awards are testing medical home models, including specialized medical home models. For example, the Innovation Center is testing medical homes for individuals with disabilities and complex health conditions, high-risk chronically ill children, and individuals with breast, lung, or colorectal cancer. We believe these medical home models have the promise to improve quality and reduce expenditures. The Health Care Innovation Awards are still in their early stages and we do not yet have any results, but we anticipate that the results may inform future Medicare and Medicaid payment policy.

Health IT

As you know, our state is home to many health IT innovators, including iTriage and others.

29. **Are you engaging such firms to be possible partners with providers actively testing new payment methods?**

a. **If so, how are you monitoring and reporting on what works and what doesn't?**

Answer: The Innovation Center is testing innovative payment and service delivery models that have the potential to reduce program expenditures or preserving or enhancing the quality of care provided to program beneficiaries. Participants in the testing of all of the models are encouraged to use health information technology (IT) and we understand they are using a variety of different technologies. We would welcome ideas from health IT innovators for new payment and service delivery models to more effectively use health IT.

Medicare Fee-for-Service

For years, Congress has been looking for bipartisan ways to replace the Medicare fee-for-service system with a new payment reform that pays for quality not quantity of service.

30. While we wait for the results of various demonstrations and pilot projects, is CMMI planning to release a comprehensive path suggesting how we can structure a new payment design model to replace the Medicare fee-for-service system?

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

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

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

Community-Based Care Transition Programs

31. What are the latest results of the Community-based Care Transitions Program, Section 3026 of the Affordable Care Act?

a. Are the early rounds of awardees on track to meet their savings target?

Answer: Preliminary results are encouraging, demonstrating a downward trend in 30-day readmission rates. However, due to the inherent lag in claims data, we only have two quarters of data for the first seven sites and one quarter for the next eight that were approved. These decreasing 30-day readmission rates apply to the sites' target population and to unadjusted all-cause readmission rates among the participating hospitals.

In addition, we have substantially increased the number of approved sites: 59 new agreements finalized since the beginning of this year, increasing the number of participating program sites to a total of 102. All newly-awarded sites are expected to fully implement their programs within 90 days of award.

ESRD

The End Stage Renal Disease demonstration project has the potential to provide a better quality of life for ESRD patients and better manage their care. The initial offering resulted in feedback from stakeholders that could provide insight for ways to improve the design of this project and increase the integrity of the model long term.

32. Can you give us a sense of where you are in the revision process? When we can expect the revisions to be displayed?

Answer: We have received feedback from stakeholders that additional time was needed to prepare an application. On March 13, we announced an extension of the deadline for letters of intent and applications for the Comprehensive ESRD Care initiative. The letter of intent deadline was extended to May 15, 2013, and the application deadline was extended to July 1, 2013. CMS is always interested in stakeholder feedback and is considering feedback received on this model.

One particular issue from the ESRD community deals with the participation of patients who may already be attributed to a traditional Medicare ACO.

33. Is there value in allowing these patients the opportunity to also participate in a program designed specifically for their condition?

a. Could this program offer additional benefits to this vulnerable population?

Answer: The Affordable Care Act created many opportunities for reforming the delivery and financing of health care. The interventions supported through this model must complement and support other health reform efforts, while still maintaining sufficient independence to isolate the effects of this initiative. To avoid duplication between shared savings initiatives, Medicare beneficiaries will not be matched to more than one shared savings program. The beneficiary population living with ESRD has complex health care needs, typically with comorbid conditions and disease complications, requiring extensive care coordination services.

We believe the ESRD Seamless Care Organizations (ESCOs) that will participate in the Comprehensive ESRD Care model will be well qualified to care for beneficiaries with ESRD. Beneficiaries will continue to be free to choose the provider and dialysis facility they wish to use. However, in order to properly assign financial responsibility among ACOs and ESCOs, and to promote continuity of care, beneficiaries that are already assigned to ACOs will continue to be assigned to ACOs as long as the beneficiaries meet the criteria for assignment.

b. Is CMS willing to consider changes to the current ESRD Seamless Care Organizations (ESCO) attribution framework?

Answer: CMS is always interested in stakeholder feedback to improve initiatives.

On the provider side, our office has heard some concerns about the new program, as proposed, requiring that a third "other Medicare provider" join with doctors and dialysis providers in the formation of these new integrated care models. We have heard that this is an extremely difficult requirement to meet.

34. Is there a concern that those providers unfamiliar with the day-to-day treatment of ESRD may not be willing to sign up for the risk that ESCOs must undertake?

Answer: The purpose of the Comprehensive ESRD Care model is to ensure that the beneficiary with ESRD receives the full continuum of care beyond dialysis treatment. This model will align financial incentives for dialysis facilities, nephrologists, and other Medicare providers and suppliers to improve the care provided to beneficiaries with ESRD, while also guarding against unwarranted market consolidation.

35. Would CMS be willing to consider other options to ensure provider participation in a way that will still allow ESCOs to meet the requirements of the program?

Answer: CMS is always interested in stakeholder feedback to improve initiatives.

Senator Mike Crapo:

ACOs

Your testimony highlighted the breadth and scope of your Pioneer and Advance Payment ACO models. However, none of the models or quality measures focus directly on the issue of obesity. Obesity costs are estimated at more than $147 billion annually.

36. What flexibility can you give ACO providers to more aggressively address this significant economic and public health issue?

Answer: ACOs are accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. ACOs have significant flexibility to invest in redesigned care processes for high quality and efficient service delivery, including efforts to target obesity.

CMS has undertaken a range of initiatives to educate providers and beneficiaries about Medicare coverage of important preventive services, many of which are now available without part B cost-sharing for beneficiaries. These include coverage of Intensive Behavioral Therapy for Obesity, which was established through CMS' national coverage determination process in November 2011. This benefit includes screening for obesity in adults and, for those who qualify (with a body mass index (BMI) $\geq$ 30 kg/m2), a nutritional assessment and up to 12 months of intensive counseling to promote sustained weight loss through diet and exercise.

Other Medicare-covered preventive services include a one-time "Welcome to Medicare" visit for new beneficiaries followed by annual "wellness visits" to develop and update a personalized prevention plan focused on each beneficiary's medical history, risk factors, and individual needs. These visits (also available without cost-sharing) include a BMI measurement and, if needed, referrals for education, counseling, or other community-based interventions aimed at reducing risk factors and promoting wellness, including through weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

37. Would ACO participants and providers have the opportunity to create demonstration projects related to obesity if they could demonstrate better health outcomes and savings?

Answer: We know that ACO participants are redesigning care delivery to promote better health and better health care at lower costs. We encourage ACO participants to implement activities related to obesity that will enhance quality and reduce expenditures. The ACO models allows the organizing physicians and other participants to undertake activities to reduce the burden of obesity or other indicators of poor health and to share in any savings generated as a result of those interventions.

The Innovation Center is always seeking ideas on how care can be furnished in ways that will lower the total expenditures while improving the quality of care. ACOs with ideas for a demonstration project related to obesity should send their ideas to the Innovation Center through the web portal available at: http://innovation.cms.gov/Share-Your-Ideas/index.html. Once ideas are received, the Innovation Center considers the idea along with other ideas received through the portal to help improve and shape the Innovation Center's work on an ongoing basis.

38. Could these demonstrations include access to and coverage of FDA-approved therapies for obesity?

Answer: We have not heard from ACO participants that alternative coverage policies of FDA-approved therapies for obesity are needed. We would be happy to review any additional information available.

Comprehensive Primary Care Initiative

Under your Comprehensive Primary Care initiative, you note the desire to provide "individualized, enhanced care for patients living with multiple chronic diseases and higher needs".

39. In your opinion, would decreasing the prevalence of chronic conditions produce savings in Medicare?

Answer: The goal of the Comprehensive Primary Care initiative is to test whether a set of comprehensive primary care functions, coupled with payment reform, use of data to guide improvement, and meaningful use of health information technology can enhance quality and reduce expenditures. We think that improving care coordination for beneficiaries with chronic conditions could lead to Medicare savings.

40. Given the strong correlation between obesity and many chronic conditions, would CMMI allow access to a full range of treatment options for these Medicare beneficiaries?

Answer: We have not heard from Comprehensive Primary Care initiative practices that alternative coverage policies for treatment options for obesity are needed. However, we would be happy to review any additional information available.

Quality Standards

There are huge gaps in ACO quality measures to fully assess care. There are no quality standards for cancer treatment (only cancer screening). There are no quality standards for stroke. There are no quality standards for Alzheimer's disease, for Parkinson's disease, or for any neurological condition. There are no standards for arthritis. There are other areas where quality standards are lacking.

41. What steps are you taking to improve your agency's ability to measure quality of care provided in ACOs?

Answer: The quality metrics proposed for ACOs and finalized after consideration of public comments were a careful balance between ensuring that quality of care is maintained while avoiding imposing an excessive reporting burden on ACOs. In addition to the quality metrics that must be reported by the ACOs, CMS is also monitoring other data, including measures of utilization of services, to ensure that ACOs are not avoiding at-risk beneficiaries. In future rulemaking for the Medicare Shared Savings Program, we anticipate reviewing the selected quality measures and seeking public comment on other measures that could be used to assess ACO performance.

Additionally, under the Hospital Inpatient Quality Reporting (IQR) program, there are a wide variety of measures that hospitals, including hospitals participating in ACOs, must report in order to receive the full payment update each year. The measure set for the IQR program has grown as the science of quality measurement has evolved, and some of the measures in the program include: a stroke measure set, a venous thromboembolism measure set, certain healthcare-associated infection measures, mortality measures, readmission measures, surgical care measures, and patient experience of care measures.

42. Will you include an independent assessment by clinical experts?

Answer: The Shared Savings Program final rule describes our efforts to monitor ACOs for avoidance of at-risk beneficiaries as well as our methods to enforce compliance with the quality performance standards. Medicare fee-for-service beneficiaries will be surveyed to determine their satisfaction with ACOs and may also raise issues related to their care to 1–800 Medicare, the Medicare ombudsman's office, or quality improvement organizations. In addition, the Pioneer ACO model will be evaluated to assess the ability of the Pioneer ACOs to enhance quality and reduce expenditures.

ACE Demonstration

The CMS Acute Care Episode (ACE) Demonstration project has been underway since 2009, and I understand that it has served as the basis for many of the features of the Bundling Initiative. I am very interested in understanding how this program has had an impact on the quality of care, access to care and cost for patients participating in this demonstration.

43. What has CMS learned now that the project has been underway since 2009?

Answer: CMS has learned a number of things since the start of the ACE Demonstration. Working closely with the Medicare Administrative Contractor, we have developed and tested an electronic claims processing system for bundled payments which has nationwide applicability. We have learned that bundling Part A and Part B payments does encourage hospitals and physicians to work together to improve coordination of care and to increase efficiencies in service delivery.

44. When will we see some results from the 4-year old ACE bundling demo and the outstanding gain sharing demos?

Answer: The evaluation of the ACE Demonstration is being completed. Results are expected to be available later this year. In addition, the evaluation of the Medicare Hospital Gainsharing and Physician Hospital Collaboration demonstrations are underway. Results are expected late next year.

45. What impact have these demos had on quality, cost and beneficiary access to technologies/treatments/procedures?

Answer: While we are seeing reductions in costs for both Medicare and participating providers claim they have reduced their operating costs in the ACE demonstration, standards of care are being maintained or improved. Physician and beneficiary access to technologies, treatments, and procedures remains unchanged.

46. Have you evaluated patient access to new treatments in the demonstrations?

Answer: We have no indication that access has in any way been curtailed. Despite the change in the payment methodology, decisions regarding medical treatment remain the sole responsibility of the patient's physician.

STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER U.S. SENATE COMMITTEE ON FINANCE HEARING OF MARCH 20, 2013 REFORMING THE DELIVERY SYSTEM: THE CENTER FOR MEDICARE AND MEDICAID INNOVATION

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, delivered the following opening statement at a committee hearing examining the role and progress of the new Center for Medicare and Medicaid Innovation (CMMI) within the Center for Medicare and Medicaid Services (CMS):

I want to thank Senator Baucus for convening this timely and much needed hearing this morning.

It is no secret that, for many reasons, I did not support the President's health reform bill. Despite my long-time interest in reforming our nation's health care delivery system to reduce costs and improve quality, I was concerned with the creation of a new bureaucracy known as the Centers for Medicare and Medicaid Innovation (CMMI) and giving them $10 billion in taxpayer funds with no strings attached.

We have now held two hearings in the committee where we have heard from the public and private sectors about interesting ways they are working to improve the delivery of care.

I, for one, wholly support the private sector working among payers, providers, and patients to come up with solutions that best fit their communities in order to achieve more efficient and higher quality results.

I have heard repeatedly from my Democratic colleagues that CMMI is tasked with letting "a thousand flowers bloom." What I really wonder is if this is simply a euphemism for *barely controlled chaos*.

Dr. Gilfillan, I don't envy your job.

The administration expects you and your staff to overhaul the way health care is delivered in this country and to do it quickly so that people begin to believe their claims that Obamacare will save money. However, despite these claims, I am quite confident that Obamacare will only increase the cost of health care in this country, and I believe the evidence overwhelmingly supports my position.

With that said, I do think there is merit to trying to change the delivery of care and to focus on greater coordination of care, reducing hospital admissions, and providing better outcomes to patients. I am concerned, though, that there is confusion and a clear lack focus at CMMI.

The Government Accountability Office (GAO) reported in November of last year that, while you have taken steps to coordinate with other offices at CMS, more work needs to be done to make coordination more systemic. It seems to me that CMMI would function best if it would pick a few initiatives – such as accountable care organizations (ACOs) or bundled payments – and really devote the time to those initiatives to make sure they actually work and have the intended consequences of lowering costs and increasing quality and efficiency.

Instead, I fear you are trying to do too much at one time.

Coordination among initiatives that have similar goals is something the GAO has highlighted as a concern.

For example, the Innovation Center's Partnership for Patients model and CMS's Quality Improvement program have a similar goal: to reduce the rate of preventable hospital acquired conditions and 30-day hospital readmissions. Both models contract with organizations to disseminate interventions to hospitals and perform virtually identical functions.

That sounds like something that could be consolidated.

I hope that CMMI takes the time to really study the impact of initiatives both while they are going on and at the end of demonstrations so that we know if they work – and how well they work – before the initiatives are offered to more providers and patients.

Since the GAO report indicated that, in most cases, it will be three to five years before CMMI and the taxpayers know if these initiatives achieve their anticipated savings, it is critical that they be reviewed to determine whether they meet their stated goals. As you know, in the past, the Congressional Budget Office has shown us that most demonstrations don't actually save the taxpayers any money.

Finally, I wanted to raise concerns about the number of high salary staff that are employed by CMMI.

In addition to spending billions on the CMMI projects, GAO noted that nearly half of the 184-plus members of the CMMI staff are paid at the highest levels of the federal pay scale, which stands in stark contrast to other areas within CMS. I have also heard that CMMI staffers have state-of-the-art workspaces, including very expensive treadmill desks.

In a post sequester world, where White House tours are being cancelled and Easter egg hunts are being threatened, you can imagine why American people would take a very cynical view about federal employees being furnished with thousand dollar treadmill desks.

The federal government absolutely cannot afford to pour money into things that don't work. Our priority must be very clear: we need to make government as efficient as possible.

We do not need bloated bureaucracies.

We do not need duplication of efforts.

We do not need an increased morass of regulation and platitudes.

And, we do not need taxpayer dollars being spent so that staff can work at treadmill desks.

What we do need is a clear strategic plan to improve quality and reduce costs.

We need specific goals with specific direction to achieve those goals.

We need the right people with expertise in these areas to develop targeted approaches that can be tried quickly, studied, and assessed for measures of success.

Dr. Gilfillan, you know that last year, I sent you a letter asking for an accounting of what your office has been working on, how much money had been spent, and, more importantly, how that money was spent. It took you more than six months to reply.

Let me repeat that again – six months.

This is entirely unacceptable.

I hope I will have your commitment today that this behavior will not be repeated and all members of this committee will be given timely and complete responses.

As you can see, I have a number of concerns that I hope can be addressed during today's hearing. I want to once again thank the Chairman for convening this hearing today and I look forward to a robust and informative discussion.

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COMMUNICATIONS

United States Senate Committee on Finance
Hearing on "Reforming the Delivery System:
The Center for Medicare and Medicaid Innovation
Delivery System Reform: Progress Report from CMS"
March 20, 2013

Testimony for the Record
Submitted by:
The Roundtable on Critical Care Policy
Stephanie Silverman, President

Chairman Baucus, Ranking Member Hatch, and other Members of the Committee, we thank you for holding this important hearing and appreciate the opportunity to submit a statement for the record. The Roundtable on Critical Care Policy supports the Committee's commitment to ensuring that the reforms authorized by the Patient Protection and Affordable Care Act (PPACA) will be implemented in a way that improves 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.

Critical care medicine is the care of patients whose illnesses or injuries present a significant danger to life, limb, or organ function and encompasses a wide array of diseases and health issues including respiratory failure, shock, severe infection, traumatic injury, burns, neurological emergencies, and multi-system organ failure. The care provided in the intensive care unit (ICU) is highly specialized and complex due to the extreme severity of illness of its patient population, often involving multiple disease processes in different organ systems at the same time. Each year, five million Americans are admitted into adult medical, surgical, pediatric, or neo-natal ICUs.[i] Providers of critical care require specialized training because the care delivered in the ICU is technology-intensive and the outcomes have life or death consequences. The high resource usage inherent in the ICU often makes care delivery costly, with critical care representing 17 percent of all hospital costs and total costs of critical care services in the U.S. exceeding $121 billion annually.[ii]

The Center for Medicare and Medicaid Innovation (CMI) was created to facilitate health system improvements to ensure better health care, better health and reduced costs for beneficiaries. The Roundtable strongly supports these goals and believes that the engagement of the critical care community is essential towards achieving them.

As the Committee moves forward with overseeing the implementation of CMI's activities and considers 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.

According to the Government Accountability Office, between 2010 and 2012, CMI distributed approximately $3.667 billion in demonstration funding.[iii] While during this time frame several important critical care initiatives—such as those aimed at expanding telemedicine in the ICU— received funding under the *Health Innovation Awards,* it appears that less than 1 percent of the funding was directed at critical care or ICU-focused projects. Given the impact that critical care medicine has on the health care system, we believe that additional critical care-focused efforts, including CMI-sponsored demonstration programs, are necessary to achieve additional improvements in the quality and efficiency of this area of medicine.

Towards that end, we encourage CMI to support a specific initiative focused on testing models of care aimed at improving the quality and efficiency of care provided to critically ill and injured patients receiving treatment in the ICU. For instance, demonstrations directed at incorporating value-based purchasing methodologies, novel informatics, monitoring or other methodologies could improve patient outcomes and reduce inefficiencies in the delivery of critical care. Advancement of prediction models could help providers and hospitals to identify patients at high risk for requiring critical care services and streamline care delivery to prevent unexpected admissions for critical illnesses. The testing and adoption of new organizational models in some communities, such as the regionalization of critical care, could improve triaging to ensure patients are being referred to the hospital and ICU that is most appropriate.

Moreover, workforce issues continue to challenge the critical care sector. A new study published in the *JAMA-Pediatrics* found that "the health of critically ill newborns is endangered by insufficient nurse staffing,"[iv] and a national survey reported in the *Archives of Internal Medicine* found that critical care was one of two specialties with the highest percentage of physician burnout.[v] Testing of new staffing models and ways to deliver high quality, team-based care could lead to improvements in patient care.

Lastly, recognizing that the ICU is one of the primary delivery centers for palliative and end-of-life care, the Roundtable believes that policy and structural improvements are needed to ensure that at the end of a patient's life, he or she receives appropriate care and support. Aligning advanced care with the goals of patients and family members will improve population health and individual patients' care. We strongly support CMI sponsoring projects aimed at delivery models of care that seek to provide individuals and their families with access to tools, resources and services that best meet their advanced care needs, as well as projects designed to improve transitions and care coordination to and from the ICU. The Roundtable also supports demonstration projects that facilitate the clear communication of advanced directives and similar plans, which enunciate and enable a patient's desired course or level of treatment. We believe that projects aimed at establishing programs such as the Physician Orders for Life Sustaining Treatment program (POST) would make great strides towards ensuring that patients are provided with the care that meets their values, goals and preferences.

With the aging of the baby boomer generation and the escalating costs of health care, now more than ever it is essential that we seek reforms that will ensure that the critical care system is structured to provide the highest quality, most efficient care. The Roundtable on Critical Care Policy strongly believes that investments made by CMI—particularly demonstrations aimed at the critically ill and injured—will not only improve health outcomes, but will also result in significant overall savings to the health care system. We thank you for your consideration.

[i] Society of Critical Care Medicine. Critical care statistics in the United States. http://www.sccm.org/AboutSCCM/Public%20Relations/Pages/Statistics.aspx

[ii] 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)

[iii] Government Accountability Office, CMS Innovation Center: Early Implementation Efforts Suggest Need for Additional Actions to Help Ensure Coordination with Other CMS Offices, GAO-13-12, Nov 15, 2012

[iv] Robert Wood Johnson Foundation, "Not Enough Nurses in Neonatal Intensive Care Units: New Study Reveals Striking Understaffing for Critically Ill Babies Compared with National Guidelines", Press Release, March 19, 2013

[v] TD Shanafelt, S. Boone, L Tan et al. "Burnout and satisfaction with work-life balance among US physicians relative to the general U.S. population," Arch Internal Medicine, 2012; 172: 1377-1385.

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March 15, 2013

Senate Committee on Finance
Attention: Editorial and Document Section
Rm. SD-219
Dirksen Senate Office Building
Washington, DC 20510-6200b

Re: Reforming the Delivery System – The Center on Medicare and Medicaid Innovation
Wednesday, March 20, 2013, 10:00 AM (STATEMENT)

Mr. Chairman:

As reported by the Centers for Medicare and Medicaid Services[1], through specific transformative programs in the Affordable Care Act (ACA) and program launched by the Innovation Center, Health and Human Services (HHS) and CMS are working hard to support physicians, nurses, hospital systems, and others who have accepted the challenge to develop a new, sustainable health care system with engaged patients and are rewarded for keeping people well, not simply delivering more services.

According to CMS[2], the Innovation Center was established by section 115A of the Social Security Act (as added by section 3021 of the ACA). They [1]state that Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits.

CMS also state that Congress provided the Secretary of HHS with the authority to expand the scope and duration of a model being tested through rulemaking, including the option of testing on a nationwide basis. They state that in order for the Secretary to exercise this authority, a model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits. Innovation Center is currently focused on the following priorities:

- Developing and testing new payment and service delivery models
- Effectively developing and managing congressionally mandated and authorized demonstrations and related initiatives,
- Rapidly evaluating results and advancing best practices, and

[1] Centers for Medicaid and Medicare Services. (2012). One Year of Innovation: Taking Action to Improve Care and Reduce Costs. Retrieved from: http://innovation.cms.gov/Files/reports/Innovation-Center-Year-One-Summary-document.pdf

[2] Centers for Medicaid and Medicare Services. (2013). About the CMS Innovation Center. Retrieved from: http://innovation.cms.gov/About/index.html

[3] Centers for Medicaid and Medicare Services. (2012). Report to Congress December 2012. Retrieved from: http://innovation.cms.gov/Files/reports/RTC-12-2012.pdf

- Engaging a broad range of stakeholders to develop additional models of testing.

According to CMS[3], the statute requires that the Secretary of HHS submit to Congress a report on the Innovation Center's activities at least once every other year, beginning in 2012. This report should cover activities between January 1, 2011 and October 31, 2012. According to CMS, during that time the Innovation Center announced 14 initiatives under the authority of section 115A of the SSA. Interest in these initiatives has been significant and the level of public and private engagement has been high. Hundreds of ideas for improvement in care delivery and payment have been shared with the Innovation Center through its web site. They report that one initiative, the Health Care Innovation Awards, received almost 3,000 applications.

A written report was submitted to Congress in December of 2012. It is my understanding the Senate Committee on Finance will now hear testimony from Dr. Richard J. Gilfillan, Director, Center for Medicare and Medicaid Innovation, Centers for Medicare and Medicaid Services.

Although there is very broad support for the innovation interventions, my hope is that the Committee will constantly ask the question does innovation make us better off. I urge the Committee to explicitly define how the benefits and costs will be measured in the innovation interventions, so that cost-effectiveness research can be considered when determining if the interventions should be disseminated nationwide.

There are times when increased benefits can also coincide with increased costs. However, in this case, CMS required an improved quality of care without an increased cost of care, and a rapid evaluation of results. The Committee should remember that rapid financial innovations can lead to systematic risk and when programs without a track record expand rapidly, investors and implementers tend to minimize or underestimate the risks involved. With this, the Committee also should guard against tightening the regulations in ways that slow innovation. This Committee indeed faces a balancing act. I applaud your efforts and look forward to witnessing this hearing and testimony.

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