

**PRESIDENT'S FISCAL YEAR 2012
HEALTH CARE PROPOSALS**

HEARING
BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ONE HUNDRED TWELFTH CONGRESS
FIRST SESSION

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FEBRUARY 15, 2011
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PRESIDENT'S FISCAL YEAR 2012 HEALTH CARE PROPOSALS

TUESDAY, FEBRUARY 15, 2011

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

The hearing was convened, pursuant to notice, at 2:56 p.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Bingaman, Wyden, Cantwell, Nelson, Menendez, Carper, Cardin, Hatch, Grassley, Snowe, Kyl, Roberts, Coburn, and Thune.

Also present: Democratic Staff: Russ Sullivan, Staff Director; David Schwartz, Acting Chief Health Counsel; Chris Dawe, Professional Staff; and Kelly Whitener, Professional Staff. Republican Staff: Chris Campbell, Republican Staff Director; Jay Khosla, Chief Health Counsel; Stephanie Carlton, Health Policy Advisor; and Kristin Welsh, Health Policy Advisor.

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

The CHAIRMAN. The committee will come to order.

President Harry Truman once said, "The health of all its citizens deserves the help of all the Nation." Today we welcome Secretary Kathleen Sebelius to the Finance Committee to discuss the President's budget and the health of our citizens.

Last year, Madam Secretary, you appeared before this committee to discuss the President's budget under much different circumstances. Today, our circumstances are much improved because of the new health care law. We consider what other areas of your Department, particularly human services, need to be addressed this year.

Last year, seniors with Medicare drug benefits had a gap in coverage that made their prescriptions unaffordable. This year, seniors in this coverage gap received a 50-percent discount on their prescription drugs. Last year, small businesses struggled to afford health benefits for their employees. This year, 4 million small businesses could be eligible for a tax credit to help curb the cost of coverage. Last year, billions of taxpayer dollars were lost to fraud, and law enforcement officials were stuck with antiquated tools to fight scams. This year, tough new laws keep criminals out of Federal health care programs.

This morning we turn our attention to the President's budget proposal for the Department of Health and Human Services. We

are all concerned about our country's deficit and its impact on future generations. We know that the main driver of our long-term deficit is the rapid growth of health care costs. That is the main driver. I think it is important for people to think about that for a while. Without a solution to these runaway costs, we will not reign in our deficits.

So why do health care costs continue to grow so quickly? Our system pays health care providers based on the quantity of care they deliver rather than the quality of care patients receive. This imbalance is particularly problematic because one in four Americans has at least two chronic conditions. These patients are often treated by multiple doctors. Each provides care in his or her own specialty, and coordination among these doctors is all too rare.

What are the consequences of this lack of coordination? Duplicative tests and procedures, medicines that counteract each other, frustrated patients. In the end, care is still too expensive, but patients are not necessarily any healthier.

Health reform changes all this. Medicare payments to hospitals will now be based in part on the health of their patients rather than on the number of tests performed. Medicare providers who work together and coordinate care will be rewarded by sharing in program savings. These changes will not only improve the lives of patients, they will improve the government's bottom line.

The independent, nonpartisan experts at the Congressional Budget Office have said that the Affordable Care Act reduces the deficit by \$210 billion in the first 10 years, and by more than a trillion dollars in the 10 years that follow. Despite this progress, some oppose health care reform and want to move backward. But repealing health reform will strip away critical protections for people in need and will add to the deficit.

Protections for people like David Hutchins and his son Elijah, from Missoula, MT. They are persons who would be affected by repealing the health care law. Elijah suffers from leukemia and was born with Down's Syndrome. Because of the new health care law, insurance companies are now prohibited from denying Elijah coverage just because he is sick. Repealing health reform would bring us back to the days when insurance company bureaucrats would be allowed to turn Elijah away.

Beyond health care, Congress must also reauthorize the Temporary Assistance to Needy Families, otherwise known as TANF. It must be reauthorized this year. Our economy is moving in the right direction, but the recession has taught us that TANF must do a better job at responding during economic downturns. Reauthorization is an opportunity to address TANF's potential to train American workers for professions currently experiencing a shortage of workers.

I hear from business owners in Montana that professions like nursing, trucking, data processing, for example, would benefit from training of a skilled workforce. We also have more work to do to improve our child welfare system. In particular, the Safe and Stable Families Program needs to be reauthorized. I look forward to working with Senator Hatch and the many child welfare champions on this committee to build on the groundbreaking work when we last reauthorized this program. Let us remember the need to en-

courage fathers more effectively in our strategies to prevent poverty.

We look forward to improving these programs with compassion and common sense. There is much more I would like to have said, but time is short. Madam Secretary, thank you for being here. We look forward to your testimony, especially as you comment on the President's budget.

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

The CHAIRMAN. Senator Hatch?

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

Senator HATCH. Thank you, Mr. Chairman. Welcome, Madam Secretary. We appreciate you being here. Thank you for joining us today.

We have a lot to talk about. As you may have heard, the President released his fiscal year 2012 budget yesterday. As you may have also heard, it has not received the warmest of receptions. It is one thing to have Republicans criticizing you for failing to outline meaningful deficit reduction, but you know you have a problem when even the mainstream media outlets voice skepticism about this budget's ability to right our fiscal ship.

Even before the President released his budget, members of this committee were eager to hear from you.

Congress is a co-equal branch of government, endowed by the Constitution with the entirety of the legislative power. This committee in particular has oversight of your Department's operations and application of the laws that we pass. Yet, since you were here last year, almost a year ago, your agency has been responsible for thousands of pages of regulations implementing the 2,700-page health care law with next to no opportunity for public oversight by this committee.

We can all agree that the implementation process would have benefitted from some careful oversight. The process of implementing the health care bill has at times been chaotic, due in no small part to the decision to delegate so much rulemaking authority to a sprawling Federal bureaucracy and the fast-tracking of implementation timelines.

The result has not been only a rush to promulgate rules, but a need to issue subsequent subregulatory guidance in the form of releases, notices, frequently asked questions on model notice language samples that clarify and revise previously issued rules. Now, I know that many on this committee have questions about both the process and the substance of this implementation process.

This committee's questions for you have increased exponentially with the release of the President's budget. Last fall, it was clear that the people in my State of Utah—and I think every State in the Union—voiced a desire for smaller government and less spending. The citizens of this Nation spoke, but they were not given a voice in this particular budget.

The President sent us a budget that promises \$1.1 trillion in deficit reduction over 10 years. That might sound like a lot of money until you consider that this year's deficit alone is over \$1.6 trillion.

Judging from the reaction of even the mainstream media this morning, I do not think there is any way that these numbers could be spun into a good story. So, I look forward to a forthright conversation with you today.

Here are just a few of the items that need to be addressed. First, there is almost no effort in this budget to deal with the existing and ever-growing crisis of Medicaid financing. While the budget acknowledges the \$111 billion collective shortfall that States are facing in 2011 alone, it fails to give flexibility to States in managing the nearly one-quarter of their budgets which is being spent on Medicaid. Specifically, it fails to respond to requests from Governors for relief from the health law's onerous Medicaid maintenance of effort restrictions.

Second, this budget increases the size of the Department of Health and Human Services by more than 4,700 bureaucrats just in the next 2 years, largely to implement this partisan \$2.6 trillion health care law. It is important to note that just last week CBO, the Congressional Budget Office, said that this new health law will be responsible for the loss of as many as 800,000 jobs, at a time when our unemployment rate continues to stagnate north of 9 percent. Americans have said over and over again, they want smaller government and more private sector jobs, not the other way around.

Third, there is some real smoke and mirrors in this budget. Just take a look at the physician payment fix, or doc fix. By your own estimates, the 10-year cost of a doc fix, simply with a zero-percent update, stands at an astonishing \$370 billion. Although the health care law cut more than \$529 billion out of an insolvent Medicare program to fund new entitlement spending, it did not even attempt to address this fundamental flaw in the program itself.

At the end of this year alone, physicians will face a 28-percent cut in their payments, seriously threatening access for millions of seniors. The SGR, the Sustainable Growth Rate, in my opinion, should have been permanently fixed in so-called comprehensive health care reform. I suspect that the desire to spin that legislation as saving money had something to do with leaving out a fix that everyone knows will cost hundreds of billions of dollars.

Although this budget attempts to provide a 2-year doc fix, the largest single piece of savings outlined in the budget to pay for it is \$18 billion from the reduction in Medicaid provider taxes, placing a further strain on State budgets that are already struggling under the burdensome unfunded mandates of this new law.

The budget also calls for nearly \$13 billion in savings by reducing the exclusivity periods for follow-on biologics and challenges to so-called "pay-for-delay" arrangements. These proposals not only fly in the face of bipartisan arrangements made in Congress, but more importantly will significantly harm incentives for innovation of life-saving medical treatments.

The problem with this budget is not just the failure to make meaningful cuts. It is also that the failure to reduce government expenditures requires damaging revenue raisers. Investments in new medicines cost billions of dollars and years of effort. If businesses are going to invest in these life-changing and lifesaving

medicines, they need to have some expectation that they will recoup those investments.

Yet, the proposal to reduce the period of data exclusivity unnecessarily undermines this crucial industry in order to generate revenue that will go toward financing wasteful government spending. We all know that biologics is one of our real hopes for the future, along with a number of other matters, including stem cell research and personalized medicine, just to name three of the top ones.

I will have more to say on this issue with your colleague, Secretary Geithner, tomorrow. But the assumption that the tax rates will expire in 2012 will have far-reaching consequences for small business owners, who account for half of all small business flow-through income. These small business owners would see their marginal tax rates hiked by 17 percent, to 24 percent, under this budget. I find it hard to believe that this revenue raiser will not adversely impact the ability of small businesses to hire more workers and provide meaningful health benefits to their employees.

I am curious what analysis has been done by the Office of Management and Budget or the Department of Health and Human Services about the impact of these tax hikes on the cost of the new entitlements in the health law. If we are making it harder for businesses to provide health benefits to their employees, more employees are going to get their health coverage from the Federal Government. Maybe that is the plan here.

Finally, I would be remiss if I failed to address the growing red elephant in the room, the fact that our broken entitlements are pushing our country closer to bankruptcy with every passing day. The President's Fiscal Commission recommended serious reforms to our entitlements, but to borrow from one liberal blogger's analysis of this budget, it is almost like the Fiscal Commission never happened. The President has the responsibility and the charge to lead on entitlement reform. There is no bypassing this responsibility. This budget, unfortunately, shows a real lack of leadership on this critical matter.

Now, here is what the *Washington Post* had to say: "Having been given the chance, the cover, and the push by the Fiscal Commission he created to take bold steps to raise revenue and curb entitlement spending, President Obama, in his fiscal 2012 budget proposal, chose instead to duck and to mask some of the ducking with the sort of budgetary gimmicks he once derided."

Madam Secretary, thank you for coming here today. Under the best of circumstances, testifying before Congress can be like going into the lion's den. In this case, since it has been so long since you have testified, it is like you are going into a den where the lions have not been fed for a few weeks.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hatch.

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

The CHAIRMAN. I might say, I think the President's budget is a good start. Much more needs to be done. I do not think there is much disagreement about that, but I think there is agreement that it is also a start. We have days and weeks and months ahead of us, and I hope we make significant progress.

Secretary Sebelius, thank you very much for coming. As is our custom, and you know it, your prepared statement will be included in the record. Feel free to speak for however long you want; let discretion be your guide. Proceed.

STATEMENT OF HON. KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary SEBELIUS. Thank you, Chairman Baucus and Senator Hatch, members of the committee. It is good to be here with the Finance Committee to discuss the 2012 budget for the Department of Health and Human Services.

In the President's State of the Union address, he outlined his vision of how the United States can win the future by out-educating, out-building, and out-innovating the world so we can give every family and business the chance to thrive. Our 2012 budget is a blueprint for putting that vision into action and for making the investments that will grow the economy and create jobs.

Our budget also recognizes that we cannot build lasting prosperity on a mountain of debt. Years of deficits have put us in a position where we need to make tough choices. We cannot invest for the future unless we also live within our means. So in developing the budget, we looked closely at every program in our Department. When we found waste, we cut it. If programs were not working well enough, we redesigned them to put a new focus on results. In some cases, we had to cut programs that we would not have cut if we were in better fiscal times. So, I look forward to answering your questions.

First, I just want to share a few of the highlights. Over the last 10½ months, we have worked around the clock with our partners in Congress and in States throughout the country to deliver the promise of the Affordable Care Act to the American people.

The budget builds on that progress by supporting innovative new models of care that will improve patient safety and quality while reducing the burden of rising health costs on families, businesses, cities, and States. It makes new investments in our health care workforce and community health centers to make quality, affordable care available to millions more Americans and create hundreds of thousands of new jobs across the country.

At the same time, the budget includes proposals that will strengthen program integrity in Medicare, promote lower pharmaceutical costs, improve Medicare program operations, and reform the Quality Improvement Organizations program, which helps providers improve care. It includes savings proposals to strengthen Medicaid, and funding for the Transitional Medical Assistance program and Medicare Part B premium assistance for low-income beneficiaries program, which keep down health costs for low-income individuals and help them keep their coverage.

To make sure America continues to lead the world in innovation, our budget also increases funding for the National Institutes of Health. New frontiers of research, like cell-based therapies and genomics, have the promise to unlock revolutionary treatments and cures from diseases ranging from Alzheimer's to cancer to autism. Our budget will allow the world's leading scientists to pursue these

discoveries while keeping America at the forefront of biomedical research.

We know there is nothing more important to our future than the healthy development of all our children, so the HHS budget includes significant increases in funding for childcare and Head Start. Science shows that success in school is significantly enhanced by high-quality early-learning opportunities, which makes these investments some of the wisest we can make.

But our budget does more than provide additional resources. It aims to raise the bar on quality child care programs, supporting key reforms to transform the Nation's child care system into one that fosters both healthy development and gets children ready for school.

The budget proposes a new early-learning challenge fund, a partnership with the Department of Education that promotes State innovation in early education. These initiatives, combined with the quality efforts already underway in Head Start, are an important part of the President's education agenda, designed to help every child reach his or her academic potential and make the country more competitive.

The budget also supports a child support and fatherhood initiative that will promote strong family relationships by encouraging fathers to take responsibility for their children, changing policies so that more of that support reaches the children, and maintains a commitment to vigorous enforcement and promoting relationships between fathers and their children.

There are funds for new performance-driven incentives for States to improve outcomes for children in foster care, such as reducing long-term foster care stays and the rate of child maltreatment recurrence. These children deserve to be part of a better future.

Our budget also recognizes that, at a time when so many Americans are making every dollar count, we need to do the same. That is why this budget provides new support for President Obama's unprecedented push to stamp out waste, fraud, and abuse in the health care system, an effort that more than pays for itself, returning a record \$4 billion to taxpayers in 2010 alone.

In addition, the budget provides a robust package of administrative improvements that will deliver \$32.3 billion over the next 10 years in Medicare and Medicaid savings. The proposals enhance prepayment scrutiny, expanded auditing, increasing penalties for improper action, and strengthening CMS's ability to implement corrective actions. In closing, Mr. Chairman, we have made eliminating waste, fraud, and abuse a priority across our entire Department, but we know that is not enough.

So, over the last few months we have also gone through our Department's budget program by program to find additional savings and opportunities where we can make our resources go further. For example, in 2009, Congress created a grant program to expand health coverage in 13 States. The work we are doing right now under the health law to expand the Affordable Care Act allows this program to be cut so we do not duplicate our efforts.

Another example is CDC funding to help States reduce chronic disease. Previously, the funding was split between different diseases: one grant for heart disease, another grant for diabetes. It did

not make sense, since those conditions often have the same risk factors, like smoking and obesity. Now States will get one comprehensive grant that allows them the flexibility to address chronic disease more effectively.

So the 2012 budget we are releasing makes tough choices and smart, targeted investments today so we can have a stronger, healthier, more competitive America tomorrow. That is what it will take to win the future, and that is what we are determined to do. Again, thank you, Mr. Chairman. I look forward to answering your questions.

The CHAIRMAN. Thank you, Madam Secretary.

[The prepared statement of Secretary Sebelius appears in the appendix.]

The CHAIRMAN. CBO estimates that the health care law will reduce the labor used in the economy by about a half percent to 1 percent. Some have interpreted this to mean that the law itself requires a reduction in the workforce, where in fact the point of that CBO analysis is that people will no longer have to keep their job in order to have health insurance.

Some people might voluntarily retire early. Others might seek other employment someplace because they do not have to stay with their current employer. They are not locked into their employer because of health insurance. Could you address that point, that is, the assertion that some people make that CBO's statistic really is a bit misleading, and clarify what it really means?

Secretary SEBELIUS. Thank you, Mr. Chairman. Mr. Chairman, I think we have seen what has happened in the 10½ months since the Affordable Care Act was signed into law, which is about a million private sector jobs growing. There are also estimates of about 250,000 additional jobs created over the future, with everything from building health care centers, to more workforce training, to the health IT personnel we are going to need.

The statistic I think you are referring to with CBO deals exactly with the ability—finally, the freedom—for Americans who might choose to retire, to retire because they will no longer be tied to their employment, the so-called job lock for insurance.

Once there are competitive available marketplaces set up, we know a particularly vulnerable population is the 55- to 65-year-olds who now often have very few choices that are affordable, and sometimes none at all with a preexisting health condition, before they are Medicare-eligible.

The CHAIRMAN. I appreciate that.

Secretary SEBELIUS. So indeed, that is retirement.

The CHAIRMAN. Good.

Could you address SGR? I think we need a permanent solution. It makes no sense for Congress, every year, to address the SGR. It comes up; we know we are not going to let it lapse. We try to figure out ways to pay for it. We waste a lot of time reinventing the wheel. I did not come here to be a maintenance Senator, or a continuance Senator, or an extending Senator. I came here to do things.

So one way to accomplish that objective is to reduce the amount of these extenders, and one is the SGR. I know in your budget you talk about a 2-year provision, paid for with various measures. I just

would like a strong commitment from you—and I am sure most members of the committee would agree—that we need a permanent fix. We need a permanent solution. We need an honest, permanent solution. Your thoughts, please?

Secretary SEBELIUS. Well, Mr. Chairman, I could not agree more. I assure you, the President agrees. As you know, the SGR predates, by a lot, the debate about any kind of comprehensive health reform. It dates back to the late 1990s and has been fixed a year at a time by Congress, and in fact twice was not fixed in time, so doctors actually saw a cut. The President's budget has a proposed 2-plus years of offsets. He looks forward to working with Congress for the 10-year proposal that he has put forward every year since he became President, and I look forward to that discussion.

The CHAIRMAN. I urge you to think very seriously, very deeply. We have a chance here. We have an opportunity. To be honest, and some people have said this—I have heard Senator Carper say this, I have heard many people say this—one reason unemployment is not coming down as fast as it should as we come out of this recession is because of uncertainty, it is unpredictability.

People, businesses and consumers, just do not know what the future holds for them. There are many examples of this, and one is this SGR provision. It is unpredictable. Doctors do not know, Congress does not know, people do not know. That is just one of many, many, many examples.

So I would really urge you to very, very seriously take this problem under consideration. I am trying to emphasize how serious this really is. We have an opportunity here with each of these extenders, one by one, to figure out a solution. Either they are permanent or we repeal them. Let us find a solution here because we are spending too much of our time here in the Congress just trying to extend something that is a law, with gnashing of teeth. We know what the outcome is probably going to be anyway, but it is how we get there.

One final point here, and that is, the most important part of health care reform which I do not think enough attention is given to, is delivery system reform. That is the real key. That is the stealth sleeper in this legislation which, over time, is going to start cutting down unnecessary health care costs. We have a problem, as you know. Both CBO and OMB do not score it the way I think it should be scored and the way most of us who really, presumptuously, understand this stuff think it should be scored.

So I would like you—and I think I speak for most—to just really light a fire under all those working on delivery system reform and give yourself benchmarks, give yourself data sets and points and so forth—what you accomplish by a certain period of time, et cetera—because I am just giving you advance notice that this is something that I am going to be focused on very heavily, because I want this to work.

I think most people want this to work, that is, delivery system reform. After a while, it is going to pay huge dividends, and that is a basic way, over time, to address the Medicare trust fund cost overrun. So my time is up, but I urge you and will be asking you a lot about that in the future.

Secretary SEBELIUS. Thank you.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Madam Secretary, I think we need to find a responsible way to pay the SGR and make it permanent. I think we should have fixed it with all the Medicare cuts we have in the bill. I do not think it is too late to do it. What I see is 500-some-odd billion dollars taken out to be used for another unsustainable entitlement program when we could have paid for it then. But I think we have to do that, and I hope that you will work with us to find a way to do it.

Now, Secretary Sebelius, the President's budget acknowledges that the States are facing a collective budget shortfall of \$111 billion in 2011 alone. As you know, Medicaid spending consumes nearly a quarter of the State budgets on average, and the new health care law's maintenance of effort restrictions limit State flexibility in lowering Medicaid spending. While I realize that the President's budget proposes a few minor program integrity provisions, given the \$111 billion fiscal crisis States are facing, I am concerned that the President's budget fails to contain the flexibility necessary for States to balance their budgets. I know you are Secretary of Health and Human Services, but, if you were still the Governor of Kansas, what would you be asking the Secretary of HHS for now? Do you agree with the request made by both Democratic and Republican Governors regarding flexibility from the maintenance of effort restrictions?

Secretary SEBELIUS. Well, Senator, we do not have the authority to blanket-waive what is a congressional law, and signed into law by the President. We are diligently working with Governors around the country, and it is a commitment that I take very seriously because these are my former colleagues, and I know exactly what they are facing.

As you know, there was an enormous influx of revenue from the Federal Government to States that is about to expire at the end of June, dealing with an enhanced FMAP. They also have a lot of flexibility, frankly, that a number of States are not taking advantage of. So we are sending teams around the country, we are helping to analyze the budget, we are looking at ways that Medicaid can certainly serve more people at a lower cost, and there are lots of strategies that I think we look forward to working on with States. We have granted waivers in a very timely fashion and are trying to be very hands-on with States, trying to analyze where their problem areas are and what the future looks like.

Senator HATCH. Well, both Democratic and Republican Governors are up in arms about it. You sent out a letter to States on February 3, 2011, but I am pretty sure that does not even come close in solving the problem. To quote Governor Haley Barbour, "Secretary Sebelius's letter fails to provide solutions that immediately address the exploding State budget problems posed by the Medicaid program." So I am very concerned about it, as are the Governors.

Secretary SEBELIUS. Senator, one of the features of the new Affordable Care Act is, for the first time, we have an office dedicated to the dual-eligibles, those citizens who are over 65 and eligible for Medicare, but also because of their income, eligible for Medicaid. It

is the biggest cost driver in any State budget. I looked at the numbers the other day. It is about 15 percent in terms of enrollment in Medicaid and responsible for about 40 percent of the costs.

So for the first time, we really have a chance to work with States around chronically ill, disabled, serious illnesses that, frankly, right now navigate two very complicated and cumbersome systems. I think that, just for example, the reduction of readmissions—if you can keep one disabled Medicaid patient from being readmitted inadvertently to the hospital through a medical home strategy or follow-up care, that would take care of the cost of three non-disabled Medicaid clients for an entire year. So there are some strategies which we think can have big pay-offs for States, and we are eager to work with them.

Senator HATCH. Well, you do have the authority to waive the MOE under section 1115 of the Social Security Act.

Secretary SEBELIUS. We do 1115 waivers, and we are doing those on a regular basis, Senator.

Senator HATCH. All right. I think my time is up.

The CHAIRMAN. Thank you, Senator.

Next, Senator Grassley.

Senator GRASSLEY. Thank you.

Madam Secretary, I opposed—

The CHAIRMAN. Excuse me, Senator.

Senator GRASSLEY. I am sorry.

The CHAIRMAN. I have to leave, but I would like Senator Bingaman to chair the hearing, and he will recognize you.

Senator GRASSLEY. All right. Thank you.

The CHAIRMAN. Senator Bingaman? I mean, Senator Grassley.

Senator GRASSLEY. Madam Secretary, I opposed placing a maintenance of eligibility requirement on States for Medicaid. I proposed an amendment during the 2009 stimulus bill debate to strike the provision. The only exception to maintenance of effort requirement in the Affordable Care Act was an amendment that I authored. It is a mistake for the Federal Government to pick and choose which tools States have available to deal with trying budget times.

That said, I am concerned about what actions States might take if maintenance of effort is removed. I am particularly concerned about what actions might be taken towards the developmentally disabled. In the Family Opportunity Act, we promoted Medicaid expansion for the disabled to alleviate the perverse incentives families had to not make more money, lest they lose benefits. States should be mindful of the impact that cutting the disabled could have on recipients.

Still, Madam Secretary, I am baffled by how much the administration has dug into this issue. Your efforts to protect eligibility for higher-income Medicaid recipients threatens the care provided for people with far less income. In your letter to the State of Arizona, you discussed optional benefits, noting that much of Medicaid's long-term care benefits are optional. Are you really suggesting that States cut long-term care?

Before you answer, let me go on. Your letter talks about States better managing prescription drugs. This, after the Affordable Care Act increased Medicaid drug rebates and kept all the savings for

the Federal Government. In the budget proposal yesterday, the administration proposed cutting back on Medicaid provider taxes, money that comes straight out of Medicaid providers. If a State cuts providers to a degree that they no longer participate, access is threatened for people with no income.

So my question to you: have you considered that your efforts to protect eligibility for higher-income optional Medicaid recipients is causing damage to the quality of care and access available to mandatory Medicaid recipients, people with far lower incomes than the people you are trying to protect?

Secretary SEBELIUS. Well, Senator, as I was explaining to Senator Hatch, we are very concerned about the State fiscal situation and the Medicaid issues that they are facing as a portion of the budget crisis, and particularly as the enhanced Federal match, the FMAP, will cease to exist at the end of June of this year. So we are aggressively working with States around a variety of strategies.

Recently in conversation with Governor Brewer of Arizona, the letter you referred to, Governor Brewer actually has a waiver that has put in place some coverage options that actually expire this fall. So part of her request to me is really not even necessary because there is no mandatory effort to keep that waiver in place. So we are trying a State at a time. Each State is in a slightly different situation.

States have insured optional populations, or raised eligibility criteria, or done a variety of things, and we are aggressively working to try to figure out how you can cover, particularly, the most vulnerable population with the maximum resources available and figure out what flexibility we can make available to Governors. There is extensive flexibility.

Senator GRASSLEY. Do you have agreement with me, though, that this can work against lower-income people, what you are trying to do in protecting people of higher income?

Secretary SEBELIUS. Well, Senator, I am not quite sure what we are talking about in protecting people with higher income, but certainly the most vulnerable populations are the ones that I think have the greatest attention. Some of them are the so-called optional populations, though, by law. That is the way Congress set up the Medicaid program, and optional populations are ones, as you know, Senator, that States either choose to pick up or not pick up.

Senator GRASSLEY. Let me finish with another point on a different issue. This is really just asking you for information, not for an answer right now. This would be in the interest of transparency and accountability. I asked that your Department direct the Center for Consumer Information and Insurance Oversight to post the following information on its websites: (1) the criteria each entity met to obtain a waiver; (2) a list of entities that applied but were denied a waiver; and (3) and last, the reason for each denial. Would you agree to do that?

Secretary SEBELIUS. Senator, I know that information is being compiled right now, and we will certainly get you the information as fast as possible. I can tell you, about 97 percent of the waivers have been granted that have applied, but we will follow up on that

request. I assume that request has been sent in, or is this by way of sending it?

Senator GRASSLEY. This is a way of sending it.

Secretary SEBELIUS. All right. Thank you.

Senator GRASSLEY. Thank you.

Thank you, Mr. Chairman.

Senator BINGAMAN. Thank you.

According to the list I was given here, I am next, and then Senator Wyden, Senator Coburn, and Senator Menendez, in that order. Then we have a whole long list after that.

So, Madam Secretary, thank you for being here. Let me ask about this issue of State flexibility under the law, and particularly in relation to health insurance exchanges. I know one of the issues that Governors have been writing to you about—I have a letter here signed by, I think, 21 Republican Governors, complaining about various aspects of the law, urging you to waive provisions in the law, which you do not have authority to waive, at least as I understand the law, and then saying that, if you do not agree to do this, HHS should begin making plans to run exchanges under its own auspices. That is their suggestion.

My understanding when we were doing health care reform was that we built a lot of flexibility into the law so that States could design these health insurance exchanges to meet their own requirements and to accommodate the concerns that they had. It seems to me very short-sighted for a State to be urging you to take that responsibility.

I do not know if you have any comments about how you are doing in getting States on track to set up these health insurance exchanges, what advantages there are to them doing that, what disadvantages there might be to you stepping in and taking over that responsibility. So, that is the question.

Secretary SEBELIUS. Well, Senator, you are absolutely right. The way the law is designed is that in 2014 there will be a new State-based exchange marketplace, primarily for small business owners and individuals who are currently purchasing coverage without any leverage of large numbers, and often with lots of rules and restrictions on preexisting conditions. They pay about 25 percent more than their colleagues in a large firm. The opportunity to pool people in a State-based exchange with private insurers offering competitive programs is one feature of the new law.

I think this is the letter that Governor Daniels signed, if I am correct, dealing with the State-based exchange issues. We are in the process of giving Governor Daniels and his colleagues an answer, but virtually everything he raises as a possible problem in terms of State flexibility is indeed built into the law. States will choose which programs, which carriers offer coverage. They will choose benefit packages, they will have the flexibility of designing an exchange at the State level.

We have 48 States right now that have planning grants around building an exchange. We are providing a lot of technical assistance, and I think that States are looking, in my experience, very much forward to having the opportunity to put together a marketplace which many of them do not have available currently. They also have the option, Senator, of doing this on a regional level or

a multi-State level, because we know some States have small enough marketplaces that they really cannot provide that coverage and competition within their own boundaries. So there is an enormous amount of State-based flexibility around the new exchanges.

Senator BINGAMAN. Let me ask on this regional issue—I know we did have that option in the law. Are there States that are seriously looking at that that might actually join together in setting up these exchanges?

Secretary SEBELIUS. Yes. I think right now there are a number of States beginning to explore that. As you know, the exchanges are not designed to be up and running until 2014, so we are beginning the conversations and the build-out. We have some States that want to move ahead pretty aggressively and design enrollment systems and IT systems that could be used as models for others. But I know conversations are going on among a number of the northeast States, I know they are going on in the Midwest about ways that there could be a larger pooling arrangement, or having another State run your exchange for you. So those conversations are very much under way.

Senator BINGAMAN. Thank you.

Senator Wyden?

Secretary WYDEN. Thank you, Mr. Chairman.

Welcome to you, Secretary Sebelius. As you know, one area where there is significant bipartisan support is payment reform. What I am concerned about is that the Department seems to be moving ahead now with a rule for coding, the billing process, which looks to me like it is moving in exactly the opposite direction, that it is moving, in effect, to prop up fee-for-service. I have heard from providers and a whole host of people that they are up in arms about it. There are estimates that this could cost \$30–40 billion. Their argument is essentially that it is like using World War II military hardware for today's threat.

Now, there are 150,000 of these codes. It is something called ICD-10. I do not want to get into all the root canal-type discussions that you are going to have to have for billing codes. But my question to you is, why not junk this process that has generated so much hostility, save the money—and I gather from experts it could be like \$30–40 billion—and move on to payment reform, which you are for and there is strong bipartisan support for?

Now, my understanding is that there has been some discussion about this in the past. This could be done by rule, so you would not have to come to the Congress. I think it would have bipartisan support. I think it could save a lot of money. I wonder what your thoughts are on it.

Secretary SEBELIUS. Well, Senator, as you know, and you have already referred to, I share your passion and interest in payment reform. There are an enormous number of features in the Affordable Care Act that move us in a very new direction, much to the, I think, delight of not only the private sector employers who have been trying to move aggressively in this direction for a while, but also health providers who see real opportunities for innovation.

I am not totally familiar with the coding process, but I assure you that I will take a strong look at it and would love to follow up with you on—

Senator WYDEN. Would you?

Secretary SEBELIUS [continuing]. Ways that that could fit into the new system.

Senator WYDEN. It was a rule essentially that began during the Bush administration. Throughout the last few years, people have sensed that this would be locking in exactly the kind of philosophy that both political parties are trying to move away from. Here is a chance to save huge sums of money, \$30–40 billion, and get to where I believe you want to be, which is the bundling, the payment reform, the prospective approach, and away from fee-for-service. So can you all get back to me about that?

Secretary SEBELIUS. Absolutely.

Senator WYDEN. All right.

The second question I want to ask you is a philosophical one. As you know, I have also been very interested in this waiver issue. We were able to get into the bill section 1332, which in effect says that States could get a waiver in 2017 as long as they met the major provisions of the bill, the provisions on coverage and affordability.

What the States are now saying is, why can we not do this in 2014, because we are going to have to do one thing for 2014 and then we would really like to do something else for 2017. Why are we spending all this time, bureaucracy, and red tape? What, philosophically—let us set aside all of the legislation and the like. What, philosophically, is wrong with the idea of just moving up from 2017 to 2014 this waiver process so that States do not have to go out and spend all this time, money, and hassle doing it twice?

Secretary SEBELIUS. Well, Senator, I know that you have a piece of legislation that would do just that, and that there are lots of conversations going on not only in our office, but that I have had with Governors who would like an opportunity to look at a whole-State approach, including your new Governor, Governor Kitzhaber, who is eager to get going. So we are very much engaged in that conversation, and I think that, depending on what the future looks like—flexibility is clearly something States would very much like to have, and it may well be one of the pieces of the puzzle.

Senator WYDEN. I hope we can talk some more about it. I mean, I think the point really is, the way to make this work most effectively now is to take the core provisions that are in the bill and see what we can do to improve on them in a bipartisan way.

Secretary SEBELIUS. You bet.

Senator WYDEN. What I am struck by is, when I listen to Governors, they say, why in the world would we have to do it twice? I mean, this is not about this bill, my bill, somebody else's bill. But philosophically, if you are going to get to do something you really want to do in 2017, why can we not all work together in a bipartisan way to let them jump-start it in 2014 so they do not have to spend all the time and money? So, let us talk about that some more.

Secretary SEBELIUS. Thank you.

Senator WYDEN. Thank you.

Senator BINGAMAN. Senator Coburn?

Senator COBURN. Thank you, and welcome.

I was interested in your comments on the strategies that States can use in terms of their Medicaid problems: medical homes, de-

crease readmissions, take people out of chronic long-term care, give them back their lives, decreasing hospital readmissions, decreasing utilizations. Do you all have a strategy within this budget to encourage that?

Secretary SEBELIUS. Yes, sir.

Senator COBURN. And what is it?

Secretary SEBELIUS. Well, there are a whole series of delivery system reforms that, for the first time, I think are part of the directive to CMS. So we have everything from resources in the innovation center, which will encourage modeling of various kinds of care strategies that we know are more effective and less expensive because they are happening in various parts of the country, to the Accountable Care Organization structures that are coming together. What we very much anticipate, both through the new Office of Dual Eligibles, but also with very close coordination with States, is using the Medicare strategies for the first time also in encouraging States to pick up those same strategies in their Medicaid budgets.

Senator COBURN. With the Accountable Care Organizations, there is a thought out there that it is going to accomplish the opposite of what you had hoped, in other words, reduce efficiency, increase the cost, and increase the utilization. The theory behind this conclusion goes: all these hospitals are buying all the practices and, in fact, there will be less competition, not more. Do you have any concerns about that?

Secretary SEBELIUS. Yes. I do think that is a concern, Senator, and one that I think is shared by some of the providers in communities across this country. There is a feature in the Accountable Care Organization that is a determinant that it cannot be an entity that spends more money. At a minimum, you have to spend the same money and increase quality, but ideally you spend less money and increase quality.

What we see, what I have been really encouraged by, is provider groups who very much are eager to become an Accountable Care Organization, provider groups combined with community health centers. We do not see a hospital-dominated model being the only strategy that can work. I think there is a concern that anti-competitive moves that drive a monopoly pricing system are just, as you say, the opposite of what is beneficial.

Senator COBURN. Well, that is exactly what is happening out there right now.

Let me go back to Medicaid for a minute. You outlined strategies where you are actually putting resources into your budget to enhance these strategies. In 2009, Rhode Island was given a waiver. They were given a 5-year waiver and a block grant. The strategies you just outlined putting resources behind, they have already achieved a 16-percent savings, increased their coverage. They have medical homes, decreased ER utilization by 30 percent, and are saving a significant amount over what was block-granted, which was actually going to be less than what we would have spent.

So does the administration have a position? We are trying to do this from Washington, and Rhode Island has already proven that, if we will let the States do it, they will do it. We said, here is the minimum you have to do, and they have done it. What is the administration's position on the success of Rhode Island?

Secretary SEBELIUS. Well, Senator, as you know, Rhode Island was able to get engaged in that strategy, and several other States have similar strategies. There is a North Carolina program.

Senator COBURN. But none of them has a complete block grant like Rhode Island. There is no other State that has that, correct?

Secretary SEBELIUS. I cannot answer that question.

Senator COBURN. No, there is not. If I am wrong—

Secretary SEBELIUS. But I am saying we are eager to work with States. They were given that authority under the Medicaid system. They came in with a program. We are doing that all over the country.

Senator COBURN. Well, my question for you is, if Rhode Island can save 15.8 percent, why do we not just block-grant every State, let them take the rules off, and let them do these strategies that you are outlining rather than spending money in Washington telling them what to do? Rhode Island obviously has figured it out. Why would we not do that?

Secretary SEBELIUS. Well, Senator, I think the block grant also has features that can be very damaging to the population that Senator Grassley just identified. In this latest recessionary period, if States had had block-granted funds, I think what we would have seen is millions of people losing coverage, being dropped out of the program.

Senator COBURN. But there is a minimum requirement. Rhode Island cannot drop coverage.

Secretary SEBELIUS. I do not know what the—I mean, I would be happy to follow up on that and see what Rhode Island is doing.

Senator COBURN. I would love to have that discussion with you.

Secretary SEBELIUS. All right. Thank you.

Senator COBURN. Because we are creating an environment here to do what Rhode Island has already proved the States will do on their own if we will untangle them, and we are going to spend \$155 million to get minimal savings through this on what the States have already proven they can do.

My time is gone, and I yield back.

Senator BINGAMAN. Senator Menendez is not here, so the next three are: Senator Carper, then Senator Cardin, then Senator Snowe.

Senator Carper?

Senator CARPER. Thanks, Mr. Chairman.

Madam Secretary, welcome. It is very nice to see you.

Secretary SEBELIUS. Thank you.

Senator CARPER. Thank you for your good efforts and the efforts of the team that you are leading.

A couple of statements, and then I have a question. The question I am going to ask you is on defensive medicine: what is in the President's budget with respect to defensive medicine, and what are we doing already, what would we do under his proposal?

But before we get to that, a couple of people sat at this table 2 years ago. The chairman had an extensive series, as you know, of hearings where we focused on, among other things, how we get better outcomes for less money. That continues to be the focus of my efforts, not only in crafting of health care legislation, but as we try to implement it and go forward. It is all well and good that we talk

about extending coverage to people who do not have it; God knows we need to do that. But unless we find ways to get better outcomes for less money, we are not going to be able to extend that coverage for long.

But they sat at this table a year and a half, 2 years ago, and they said if we could make progress on four fronts—(1) obesity/overweight; (2) tobacco; (3) reducing high blood pressure; (4) addressing cholesterol—if we could do those four things, we would do more in terms of getting better outcomes for less money than anything else they could think of. I have not talked to too many people since then who have actually disagreed with that.

There is an effort going on on obesity, led by the First Lady, but a lot of other folks are involved in it. I would just say, my hope is that we will look to the best that you can in your job, in your Department, for ways to get better outcomes by encouraging young people and old people, incentivizing young people and older people, to lose weight.

We are on the way to 30–40 percent obesity in this country, and it is a killer in more ways than one. In terms of Medicaid costs, finding ways, especially with young people and folks who are on Medicaid, that is almost a captive population. That is a group that we really, really need to focus on. So, I would lay that at your feet.

The thing I want to talk about is defensive medicine. My focus on defensive medicine has been, how do we reduce the incidence of defensive medicine? We know it drives health care costs because doctors are doing it, nurses, hospitals are doing all kinds of things to try to, in what we said in Naval aviation, cover their 6 o'clock so they will not get sued. In Naval aviation, you cover your 6 o'clock so you will not get shot down.

But a lot of stuff is going on in defensive medicine to reduce the likelihood that people will get sued. It runs up our costs, as we know. We have been working on—in fact, we include it in the health care bill—provisions that say, let us use \$50 million, authorize \$50 million, for these demonstration projects to robustly demonstrate what is working in States to reduce the incidence of defensive medicine, reduce the incidence of lawsuits, and improve outcomes—those three goals. I do not think they are mutually exclusive.

Would you just share with us what the President is calling for in his budget? I think instead of \$50 million, it should be \$250 million, and I think you are actually doing something with about \$25 million in a bunch of States. But could you just talk to us about it?

Secretary SEBELIUS. Sure. Senator, right now underway we have grants out around the country to States and to health systems, seven 3-year demonstration grants and 13 1-year planning grants that are looking at ways to improve patient safety, reduce preventable injuries, ensure patients are compensated, reduce frivolous lawsuits, and reduce liability premiums. So, the kind of goals that you outlined.

Examples underway: a judge-directed New York State negotiation program, which seems to be promising. All these are up and running only about 6 months, so we are 6 months into the 3 years. In Oregon, in Senator Wyden's State, a medical liability and pa-

tients' guidelines project that is looking at a safe harbor, how to develop the kind of guidelines that would give doctors actually a safe harbor from being sued. Those projects are underway with a very rigorous evaluation criteria.

This year in the President's 2012 budget, in the Department of Justice he has suggested 250 million additional dollars administered by the Bureau of Justice to go into four areas, again, around the same principles; health courts, which are available in some areas; and rapidly settle safe harbors, the kind of Oregon project that is underway; early disclosure and offer; and then a series of other legal strategies and reforms.

So I think the President is very serious about following up on this. He wants to actually use the authority that we have right now to move these projects out. As soon as we find ones that actually pay off and work, we can implement them.

Senator CARPER. Good.

Mr. Chairman, at our caucus lunch today I mentioned that there is pretty good reason to believe that there is \$30–40 billion, maybe more, in terms of fraud in Medicare every year. I think you and the Department of Justice just announced a week or two ago \$4 billion in fraud recovered, which is a high-water mark.

Secretary SEBELIUS. For 2010.

Senator CARPER. For the last year. That is good. But we know the number, the bogey out there, is like \$40 billion, maybe more. I would say, let us use everything, every tool we have in the toolbox, to go out and get more of that money.

And finally, we have this program called Senior Medicare Patrol.

Secretary SEBELIUS. Yes.

Senator CARPER. We have probably fewer than 200 people, 200 seniors in my State who are signed up to actually be the folks out there helping us to watchdog this stuff, to watchdog the fraud. One of the things we may want to do is really grow that, grow the awareness of that program and list a lot of our seniors. They are the ones who see the fraud. I really just urge us to take that on as a charge. We are going to do it in my State, and I hope we do it in all the States.

Secretary SEBELIUS. We could not agree more. Actually, the charge the President gave us last year as part of this Justice-HHS fraud effort was to double the size of the Senior Medicare Patrol, and we are actively recruiting seniors. The best boots on the ground against fraudulent activity are the seniors themselves, talking to their neighbors, talking to their friends, reading their Medicare billing and turning folks in.

We used to not even take fraud calls at the 1–800–Medicare line. That has changed. Everybody is sort of involved in the anti-fraud activities, and we are taking it very seriously.

Senator CARPER. Maybe if we are doing that, Mr. Chairman, what we could do is offer them a discount to memberships in gyms across the country, and take care of two birds with one stone. Thank you very much.

Senator BINGAMAN. Senator Cardin?

Senator CARDIN. Well, thank you very much.

I want to follow up on the chairman's point about how we can bring down costs in health care. As I have traveled through my

State, a lot of the provisions that have been put into the Affordable Care Act will bring down costs even more than CBO has scored. I think the wellness exam for our seniors will pay off dividends as they understand what they can do to lower their risk of serious illness. Filling in the prescription drug coverage gap will also help, because we know that taking proper medicines can absolutely reduce cost.

Yesterday I was at the Greater Baden Health Center which is located about 6 or 7 miles from here in Prince George's County, Maryland. We were doing an event where that center has expanded, expanded over grants that the Federal Government had given under the Recovery Act. But it also is now expanding into prenatal care. The State of Maryland ranks 39th in infant mortality, a record that we are not proud of. The numbers are much, much higher in the minority community—260 percent higher.

I have a couple of questions related to the qualified health centers. First, part of the Affordable Care Act provides attention to minority health and disparities. I am concerned as to how that is going to be implemented. If we can bring down the infant mortality rate in the minority community, if we can bring better parity in this Nation for those who suffer from diabetes or heart disease, we can bring down health care costs in America. That is the reason why Congress adopted the amendments that put a spotlight on minority health and disparities. I am interested in hearing about your strategy to implement those provisions within HHS.

Secretary SEBELIUS. Well, Senator, I could not agree more. I think the Affordable Care Act has some huge pieces of that puzzle. One is, for the first time, having affordable health coverage for everyone so people will have a health home and a way to get regular check-ups before they show up in the emergency room with acute illness. That is a big step forward, and it is a particularly big step forward in minority communities where the level of uninsured is significantly higher than in white communities.

The doubling of the number of community health centers is a second big piece of the puzzle so that, not only would there be more accessible available providers in under-served areas, but there is a portion of the provider increase in the workforce increase which is specifically aimed at getting culturally competent providers into neighborhoods, making sure that we are recruiting doctors from communities where they will practice for a long period of time.

Third, we have a very significant effort under way on health disparities, looking at all of the programs we operate across HHS and seeing, what do we need to put in place so, by the time 2014 comes along and we have expanded access to coverage, that we actually have maximized the opportunities that people have to not only get appropriate health care, but as you say, deal with their chronic conditions.

I think, finally, the wellness efforts are, again, aimed often at strategies which will have a huge impact in minority communities. Often people are living in food deserts where they do not have access to fresh fruits and vegetables. That hopefully will change over time with community projects. More attention paid to school breakfasts and lunches, where a lot of our kids eat their meals on a regular basis—not only more nutrition, but making sure that we lower

fats and salts and cholesterol out of those meals; more physical education. So I think there is a range of strategies which get at the issues you have identified.

Senator CARDIN. And I agree with all of that.

I want to emphasize the importance of the federally qualified health centers. We did that last year by providing a substantial increase in resources.

Secretary SEBELIUS. Right.

Senator CARDIN. If we are going to get families to use their community centers and not the emergency room, we need to have community centers.

Secretary SEBELIUS. You bet.

Senator CARDIN. Part of the new law will change the way in which communities are determined to be in need or underserved with facilities and health care professionals. This is particularly important in my State, where Prince George's County has had a hard time qualifying and competing for the dollars because of the way an area's eligibility was determined, even though there is clearly a shortage of professionals in that area. I believe you have rulemaking to deal with that. How is that coming along?

Secretary SEBELIUS. Well, Senator, there is a kind of new mapping effort under way because we heard a lot of complaints from folks who said the old methodology was not accurately demonstrating where the needs were and matching the needs. So Mary Wakefield, who leads the Center for Health Resources and Services, is undertaking that. There also is a new Workforce Commission looking at strategies not only to recruit more folks to underserved areas, but also the cultural competency of providers. So I think we intend to move aggressively to get the right match between what areas really are under-served and where those resources go.

Senator CARDIN. Well, I hope you will work with us on that, because I can tell you, the old way it was allocated did discriminate against areas that clearly were in desperate need. I hope you can get this right, and I hope that we can work together on it.

Secretary SEBELIUS. I look forward to it.

Senator BINGAMAN. Next would be Senator Menendez, then Senator Snowe.

Senator MENENDEZ. Thank you, Mr. Chairman.

Madam Secretary, thank you for your service. I appreciate a great deal what you are doing.

I am concerned about the Children's Health Insurance Program and the question of Medicaid in general. In New Jersey, Medicaid and the Children's Health Insurance Program, which we call New Jersey Family Care, serves over 800,000 children who would otherwise not have access to regular medical care. We have seen that number grow by 8 percent since 2009.

Now, I am hearing a series of Governors say that they want relief from the requirement for keeping Medicaid enrollment eligibility as is, and that would mean to me, when I hear relief, is translated into cutting eligibility, which means to cut children, pregnant women, sometimes seniors, none of which feels like a really great way to balance a budget in terms of choices.

It seems to me that people without coverage still get sick without Medicaid or with lower Medicaid eligibility levels, that the cost of providing these necessary services will shift to hospitals—which is entirely opposite the focus that we tried to do in the Affordable Care Act, to get people out of the emergency room as their form of primary health care—and we will shift it to hospitals and clinics that are required to help people in need. That cost shift does not stop there, because hospitals and clinics will have to make up the difference somehow, and they will charge higher rates to private insurers, and that ultimately means people with insurance will ultimately pay the cost of higher premiums.

So I would love to hear from you as to what is your Department's and this administration's response to this request and the concerns that I have of what it means in terms of a cutting and cost shift to some of the most vulnerable in our society?

Secretary SEBELIUS. Well, Senator, I think we share the concerns that cutting health care for potentially millions of Americans is not a strategy that helps us win the future, if you want to use the President's terminology that we need a healthy, prosperous Nation and a healthy, prosperous workforce. We understand that budget struggle States are in, particularly in this window between 2011 and 2014 when there is additional Federal help.

So what we have done very aggressively is try to work a State at a time to look at the issues and look at the situations and share with them strategies. I mean, you heard Senator Coburn talk about what Rhode Island is doing around a waiver that actually guaranteed that they would not drop eligibility, but used their flexibility to lower costs and enhance quality. That kind of strategy, I think, is available to States, and is one that we look forward to working on.

The irony, I think, Senator, as you well know in the Medicaid budget, the largest cost driver of any State is often the dual-eligible population who are in nursing homes. That has become an explosive population, and frankly kind of shifted onto States. Having some longer-term strategies and conversations with Governors, I think, is appropriate. But children are often not only very vulnerable to not having health care, but also very inexpensive. So it is kind of a lose-lose situation. If they are cut off the program, they can be damaged for a long period of time, and yet a State basically does not save money.

Senator MENENDEZ. I appreciate that. What I am concerned with is, I hear many of my colleagues who talk about family values. I hear them talk about the sanctity of life. It seems to me that, when we have that life born into the world, that value does not get diminished. It actually has a greater societal responsibility. So, I am afraid of where we are headed in that respect, so I appreciate your answer.

Finally, Senator Grassley and I have legislation called the Save Act, which is about child support. I am thrilled to see that you are committed to enhancing funding for child support enforcement. Our bill requires a lot better tracking mechanism through a centralized lien process to ensure that information about child support in one State is available to other States, which from everyone I have

talked to, from judges to welfare departments to others who administer this, tell me this is one of the critical challenges they have.

I hope that both Senator Grassley and I can work with you as you are incentivizing States to look at how we incentivize this mechanism for a central lien process that I think will reverberate to the benefit of the taxpayers, and most importantly to children who should be getting those support payments.

Secretary SEBELIUS. I look forward to that.

Senator MENENDEZ. Thank you, Mr. Chairman.

Senator BINGAMAN. Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

Welcome, Secretary Sebelius, to the committee. I want to start out with the health care reform law because I think, as we look forward in terms of implementation, which obviously you are going to play a central role in given the fact that you are invoked more than 1,700 times in this 2,700-page bill, which speaks to the issue as to why we on this side of the aisle voted for, and support, repeal of this legislation that has become law that represents a massive government overreach, frankly. The more that we proceed on implementation of this law, the more it becomes, I think, abundantly clear that it is on a collision course with job creators, with small businesses who are struggling to emerge from the worst recession since the Great Depression.

As Senator Hatch noted, 800,000 jobs will be lost—that was based on the Congressional Budget Office's estimate—between now and 2020. Just looking at more immediately what is happening, first of all, with the grandfather clause, I know the administration made a promise that, if you like your current health insurance plan, you can keep it. Well, not exactly, after 121 pages of regulations just with respect to that particular provision in the law.

In many of the changes that were included in that regulation, it really draws the grandfather clause very broadly so that many businesses are not going to be able to retain that health insurance plan for their employees. So it is not exactly the way it has been described. If you just look at the numerous requirements based on grandfather status, if you eliminate your benefits, increase co-insurance, increase deductibles, increase co-payments, decrease employee share of the premium by more than 5 percent, there is only one that was in statute and that is adding an annual limit and decreasing lifetime of annual limits. So the list goes on in terms of what the impact is going to be on job creation.

Then you look at the employer mandate. That has been drafted to include part-time employees in the calculation of that mandate that will require and impose a penalty on businesses. So a business of 50, if you can include part-time employees as those who are working 30 hours a week, that ultimately can impose a severe penalty on that employer of \$2,000. So you are capturing more and more small businesses.

Then it comes to waivers. I have not figured out exactly what the fairness is involved in how you are making determinations on waivers. We know that for big companies like McDonald's and unions and so on that are getting these waivers for minimal medical coverage plans, I gather, that is one thing. But our State, for example, has been trying to get one under the minimum medical ratio loss

that was submitted by the State back in July, and we have yet to receive a response. Without that response, we lose one of the two insurers in our State that insures 14,000 people. So, obviously, this represents a significant and serious hardship. In fact, the Maine Bureau of Insurance said it is going to have a destabilizing force, and we have yet to receive an answer from your Department with respect to this issue.

So I would like to have you address that. Overall, on the issue of jobs, I think that that is a reality. We can sit here and talk about all that is going to happen, but we are looking at a collision course in terms of the intersection between the thousands and thousands of pages of regulations that are going to come out of your Department and the other agencies in administering this plan, and those on the ground are going to have to live by those regulations and by the law itself.

Secretary SEBELIUS. Well, Senator, with regard to the Maine application for a waiver of the medical loss ratio, part of the requirement of the application is to develop some data. We are working with the Maine Department on that data. The requirement for data collection just started in January, but the application is very much underway. The letter was written well before the rule was even out.

As you know, Senator, the rule for the MLR did not even come out until November, so we received a letter in July asking for a waiver of an application that was not even developed into a final recommendation by the National Association of Insurance Commissioners. So part of that time delay was, we did not even know what she was asking to waive. But we are working with her and taking a very strong look at it.

Senator SNOWE. Well, I understand what you are saying. But on the other hand, why can this not be examined very quickly? How did you—

Secretary SEBELIUS. Because there is a data requirement as part of the application of market destabilization, and that data requirement was not even available to start until she knew what the rule was.

Senator SNOWE. All right.

And on the other waivers then of more than 900 for all these other companies and organizations, you had the rule issued and all of that was out there, so they were able to make that many determinations.

Secretary SEBELIUS. The 900 waivers deal with one provision of the Act, which is a \$750,000 annual benefit limit. They had to submit data. Most plans have a January 1 start time, so we got the bulk of the applications in the October–December period and looked at market disruption and rate increases. Those determinations—as I said, I think about 96 percent of the people who came in were granted a waiver.

Senator SNOWE. I bet it is pretty straightforward. We only have two insurers in Maine for all practical purposes, and 14,000 people depend on them. If you lose one of the insurers, we do not have it. I mean, that is the bottom line in terms of the facts and what is going to affect the people of Maine.

Secretary SEBELIUS. And we are taking it very seriously. I just want to tell you that the application was made well before there was even a determination of what the medical loss ratio would require.

Senator SNOWE. All right.

Senator BINGAMAN. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Secretary Sebelius, thank you for being with us today. I want to focus a little bit on something that was noted by the President's bipartisan Fiscal Commission having to do with the CLASS Act, which was a part of one of the offsets, the pay-fors, for the health care bill. It was viewed as financially unsound by many experts, and the Commission recommended significantly reforming or repealing the CLASS program.

I am concerned that the budget did not propose changes to the CLASS Act. I guess my question is, do you agree with your actuary—your own actuary, the CMS chief actuary—that the program is at a significant risk of failure and with the Fiscal Commission's recommendations to either reform it or repeal it?

Secretary SEBELIUS. Yes, Senator, I do agree with reform or repeal, which is why we were pleased to have been given administrative flexibility in the law. While the law outlined a framework for the CLASS Act, we determined pretty quickly that it would not meet the requirement that the Act be self-sustaining and not rely on taxpayer investment. So we have made a series of program changes already in terms of eligibility requirements, the wage possibilities.

We are modeling very carefully what will exist, starting with the principle rule that the program will not start unless we can absolutely be certain that it will be solvent and self-sustaining into the future. But we do have flexibility. I would be happy to provide you with the details of at least what is being outlined so far, which is significantly different than the framework that the law itself describes.

Senator THUNE. Well, I am really concerned. I offered an amendment, that at the time was debated, to repeal that provision simply because it does show, in the near term, some revenues because you have some premium dollars coming in. But almost everybody who has looked at it says in the out-years this becomes a major liability.

Secretary SEBELIUS. And, if you would take a snapshot of what was written as the criteria of how many years someone would have to work, what the wage would have to be to enter the program, if there would be any indexing of benefits, the snapshot in the bill, I would absolutely agree, is totally unsustainable. We do have administrative flexibility, though, and I have a team together, including the actuary who was with Genworth, which is probably the largest provider of any kind of long-term services. We are modeling things.

This will not be a program that starts collecting until 2012. Our goal is both to try to deliver the benefits that I think a lot of Americans feel make a huge difference between their ability to live long-term in their own homes or own communities or be forced into a nursing home, and making sure that this is not a program that is

unsustainable absent massive taxpayer infusion. That is a principle which we believe very strongly.

Senator THUNE. Would you support requiring that premiums be indexed for inflation?

Secretary SEBELIUS. Senator, that is currently part of our plan. Yes, sir.

Senator THUNE. All right.

How about, there has been some discussion—in fact, there was a study that was done by the Center for Retirement Research at Boston College that highlighted the need for broad participation in order to achieve solvency. Would you support a mandate on participation?

Secretary SEBELIUS. I cannot tell you about the mandate, but I know that the modeling—if you are at the 2- to 3-percent participation rate, you have a barely sustainable program. If you move closer to 5 or 6 percent, you have a much more sustainable program. That is one of the issues that is being very carefully looked at: what the framework is, can you have a flexible benefit package, what other ways are there.

But I think increasing the work requirement to 5 full years, having some anti-gaming provisions so people cannot opt in and out of the system—which was possible under the original strategy—raising dramatically the threshold from a \$1,200 a year work requirement to a \$12,000 a year work requirement, and having premiums that are indexed are all part of the framework of what could make this program sustainable.

Senator THUNE. Now, as it is written today, the CLASS Act must provide an average benefit of at least \$50 a day, which is about \$1,500 a month, or \$18,000 a year, in a cash debit card. How will HHS ensure that the funds that are spent are spent on methods that provide care? I mean, what type of compliance audits do you expect to have in place on something like this?

Secretary SEBELIUS. Well, I think there would be a very significant program integrity feature to the bill, and also probably some very specific design of benefits about what it is that actually could be purchased along the way, that could verify the fact that it is going to supporting home services.

As you know, the program is designed for people to set aside their own money and then draw out their own money with no taxpayer support, so the framework is not perhaps designed to mandate that only a few options could be available, since people are basically spending their own money. But a defined benefit package with some revenue streams that make sure we are supported on into the future is part of the program design.

Senator THUNE. There is a clock here. Am I over my time, Mr. Chairman?

Senator BINGAMAN. Yes.

Senator THUNE. I am sorry. All right. I would keep going, but I do not have it down here on the small table end.

Senator BINGAMAN. We need to expand our clocks around this place.

Senator Hatch, did you have additional questions?

Senator HATCH. No, I am happy.

Senator BINGAMAN. Well then, Senator Thune, why don't you go ahead?

Senator THUNE. I just had one more, Mr. Chairman, if it is all right. I want to explore this a little bit further. If the premiums have to support a 75-year actuarial balance, at what level are the premiums too high to be affordable? Have you given thought to what happens when you run into an adverse selection problem and you push premiums into the so-called "death spiral" where they are no longer affordable?

Secretary SEBELIUS. Yes. I think there are two forms of death spirals. One is, as you say, an immediately adversely selected pool so that you have an expensive population and a narrow take-up rate. The other is that premiums are so high that, compared to other possibilities on the marketplace, no one takes it up. So it is both a premium issue and a selectivity issue that we are looking at, neither of which is impossible to solve, but both of which take some real work.

I will tell you, Senator, that we have a number, I think, of skilled folks who come out of the industry. One of the challenges of this program is, in the private sector right now there is not such a product available. There are residential services available as an addendum to a long-term care policy, but the ability to buy really just home health services, services that would allow people to stay and age in place, are really not available in the private sector market right now.

So we are tapping some of the best minds in the private sector, looking at strategies to make sure this works long-term. But certainly adverse selection, solvency, and making good on the commitment that people would have these flexible accounts in the future is the strategy that we have moving forward.

Senator THUNE. I appreciate your responses, Madam Secretary, and I would only suggest that my preferred solution to this is still repeal of this program.

Thank you, Mr. Chairman.

Senator HATCH. Mr. Chairman?

Senator BINGAMAN. Senator Hatch?

Senator HATCH. Madam Secretary, a number of people do have questions that they will submit in writing. I also would hope that you could answer them as quickly as possible and send them back to us.

Secretary SEBELIUS. Certainly.

Senator HATCH. Thank you.

Thank you, Mr. Chairman.

Senator BINGAMAN. We will try to leave the record open here for a week for members to file any additional questions they might have.

Madam Secretary, thank you very much for your time. You have been very generous with your time, and we appreciate your service.

Secretary SEBELIUS. Sure. Thank you.

Senator BINGAMAN. That will conclude the hearing.

[Whereupon, at 4:26 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

**Hearing Statement of Senator Max Baucus
Regarding the President's Fiscal Year 2012 Health Care Budget Proposals
*As prepared for delivery***

President Harry Truman once said:

"...The health of all its citizens deserves the help of all the nation."

Today we welcome Secretary Kathleen Sebelius to the Finance Committee to discuss the President's Budget – and the health of our citizens.

Last year, Madam Secretary, you appeared before this Committee to discuss the President's Budget under much different circumstances.

Today our circumstances are much improved because of the new health care law. And we consider what other areas of your department – particularly human services – need to be addressed this year.

Last year, insurance companies were free to deny care or drop coverage.

This year, insurance companies are barred from imposing lifetime limits on benefits. They can no longer arbitrarily end coverage for those who need it most. And they can't turn away a child because of a pre-existing condition.

Last year, seniors with Medicare drug benefits had a gap in coverage that made their prescriptions unaffordable.

This year, seniors in this coverage gap will receive a 50 percent discount on their prescription drugs.

Last year, small businesses struggled to afford health benefits for their employees.

This year, four million small businesses could be eligible for a tax credit to help curb the cost of coverage.

Last year, billions of taxpayer dollars were lost to fraud, and law enforcement officials were stuck with antiquated tools to fight scams.

This year, tough new laws keep criminals out of federal health care programs.

Last year, our health care system was on an unsustainable path. One in six Americans was uninsured. Health care spending accounted for nearly 20 percent of our economy, and costs were rising.

Today, we are moving toward a system that contains costs, a system that modernizes care and a system that provides affordable coverage options to millions more Americans.

This afternoon, we turn our attention to the President's budget proposal for the Department of Health and Human Services.

We are all concerned about our country's deficit and its impact on future generations. We know that the main driver of our long term-deficit is the rapid growth of health care costs. Without a solution to these runaway costs, we will not rein in our deficits.

Why do health care costs continue growing so quickly? Our system pays health care providers based on the quantity of care they deliver, rather than the quality of care patients receive.

This imbalance is particularly problematic because one in four Americans has at least two chronic conditions. These patients are often treated by multiple doctors. Each provides care in his or her own specialty, and coordination among these doctors is all too rare.

What are the consequences of this lack of coordination? Duplicative tests and procedures. Medicines that counteract each other. Frustrated patients.

In the end, care is still too expensive, but patients are not necessarily any healthier.

Health reform changes all of this. Medicare payments to hospitals will now be based, in part, on the health of their patients, rather than on the number of tests performed. Medicare providers who work together and coordinate care will be rewarded by sharing in program savings.

These changes will not only improve the lives of patients. They will improve the government's bottom line.

Health care reform reduces the deficit by modernizing the way we deliver care to patients and rooting out waste.

The independent, non-partisan experts at the Congressional Budget Office have said the Affordable Care Act reduces the deficit by \$230 billion in the first ten years and by more than a trillion dollars in the ten years that follow. Despite this progress, some oppose health reform and want to move backward.

But repealing health reform will strip away critical protections from people in need - protections for people like David Hutchins and his son Elijah from Missoula, Montana. Elijah suffers from leukemia and was born with Down Syndrome.

Because of the new health care law, insurance companies are now prohibited from denying Elijah coverage just because he's sick.

Repealing health reform would bring us back to the days when insurance company bureaucrats would be allowed to turn Elijah away.

Repealing health reform would add nearly a quarter of a trillion dollars to our deficit in the next ten years and another trillion dollars in the following decade. Our kids and grandkids would be saddled with that heavy burden.

Beyond health care, Congress must also reauthorize the Temporary Assistance to Needy Families, or TANF, program this year. Our economy is moving in the right direction, but the recession has taught us that TANF must do a better job of responding during economic downturns.

Reauthorization is an opportunity to address TANF's potential to train American workers for professions currently experiencing a shortage of workers. I hear from business owners in Montana that professions like nursing, trucking, and data processing would benefit from the training of a skilled workforce.

We also have more work to do to improve our child welfare system. In particular, the Safe and Stable Families Program needs to be reauthorized this year. I look forward to working with Senator Hatch and the many child welfare champions on this Committee to build on the groundbreaking work we did when we last reauthorized this program.

As we revisit this vital program, let us remember the need to engage fathers more effectively in our strategies to prevent poverty.

Fathers have a role in the lives of their children that goes beyond their economic support. Engaging fathers has the potential to prevent poverty and stop more children from entering the overburdened child welfare system.

The human service programs we will work on this year present significant opportunities.

I look forward to reviewing the lessons we learned, I look forward to paying close attention to these programs, and I look forward to improving these programs with compassion and common sense.

Madam Secretary, thank you for being here today. We look forward to your testimony.

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**Statement of Senator Mike Enzi
Senate Finance Committee
February 15, 2011**

Madam Secretary, it's nice to see you again but I wish it was under better circumstances. Unfortunately we find ourselves surrounded by disappointment – partly at our economy's slow recovery but mostly at the President's missed opportunity. The President had a chance to lay down a budget that significantly altered the trajectory of our unsustainable fiscal flight path. Instead, the budget we see before us brings more of the same. More of the same spending, more of the same tax increases and more of the dreaded borrowing that is causing our debt payments to reach record levels.

The President's deficit commission, co-chaired by former Senator Alan Simpson, as well as the Congressional Budget Office have already advised that maintaining current spending levels – as the President's so-called “spending freeze” does - will quickly lead to another year with a deficit of more than a trillion dollars. Since 2008, the majority in Congress has increased federal agency budgets by more than 15 percent.

The President's budget contains yearly deficits of as much as \$1.6 trillion and spending as high as 25% of our nation's Gross Domestic Product. This is simply not sustainable. The projected deficit for this year alone would be the highest amount ever. The Administration's own projections show a deficit in 2015 of more than \$600 billion, nearly \$150 billion more than 2008.

Unfortunately these numbers are not just an academic exercise here in Washington; these represent extreme challenges for our economy and will touch every American. Our economy has shed more than 3 million jobs in the last two years and our unemployment rate is 9 percent. We need to get our economic engines going again and record deficits are not the way to do it.

Just last week Doug Elmendorf, Director of the Congressional Budget Office said the enactment of the new health reform law will further reduce the amount of jobs by 800,000. We are going in the wrong direction. The past two years of spending and borrowing has failed to turn our economy around and has plunged us deeper in to debt.

Now is the time to address spending and debt in a meaningful way. Businesses are holding back on hiring and expansion – the very things that will lead us out of our economic downturn. These businesses are mostly small and account for nearly two-thirds of all new jobs created. We need to empower these businesses and take away their fears of dramatic tax increases to cover the spending binges of the current Administration.

We must be responsible and take bold steps to drastically reduce our spending and overall debt. This cannot be done by freezing already bloated government spending. The President's budget falls short and Congress now has the opportunity to do the right thing for our economy and the American taxpayer by passing a budget that will actually move us out from under the shadow of debt, a budget that can grow the economy, not the government.

**STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER
U.S. SENATE COMMITTEE ON FINANCE HEARING OF FEBRUARY 15, 2011
PRESIDENT'S FISCAL YEAR 2012 BUDGET PROPOSAL**

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Committee on Finance, delivered opening remarks at a committee hearing examining the President's budget proposal for FY 2012. Health and Human Services Secretary Kathleen Sebelius testified before the Committee this afternoon.

A full copy of the remarks, as prepared for delivery, follows:

As you may have heard, the President released his Fiscal Year 2012 Budget yesterday. And as you may have also heard, it has not received the warmest of receptions. It is one thing to have Republicans criticizing you for failing to outline meaningful deficit reduction. But you know you have a problem when even mainstream media outlets voice skepticism about this budget's ability to right our fiscal ship.

Even before the President released his budget, members of this committee were eager to hear from you. This is your first appearance before this committee since the enactment of the Patient Protection and Affordable Care Act (PPACA) last March.

To be frank, that is a long time. I am sure, you will agree with me on that.

Congress is a coequal branch of government, endowed by the Constitution with the entirety of the legislative power. And this committee, in particular, has oversight of your department's operations and application of the laws that we pass.

Yet since you were last here, almost a year ago, your agency has been responsible for thousands of pages of regulations implementing the 2,700 page health care law, with next to no opportunity for public oversight by this committee.

We can all agree that the implementation process would have benefited from some careful oversight.

The process of implementing the health care bill has at times been chaotic, due in no small part to the decision to delegate so much rulemaking authority to a sprawling federal bureaucracy, and the fast-tracking of implementation timelines.

The result has been not only a rush to promulgate rules, but a need to issue subsequent subregulatory guidance in the form of Releases, Notices, Frequently Asked Questions, and Model Notice Language Samples that clarify and revise previously issued rules.

I know that many on this committee have questions about both the process and the substance of this implementation process.

This committee's questions for you have increased exponentially with the release of the President's budget. Last fall, it was clear that the people in my state of Utah — and I think every state in the union — voiced a desire for smaller government and less spending.

The citizens of this nation spoke.

But they were not given a voice in this budget.

The President sent us a budget that promises \$1.1 trillion in deficit reduction over ten years. That might sound like a lot of money, until you consider that this year's deficit alone is over \$1.6 trillion. Judging from the reaction of even the mainstream media this morning, I don't see that there is any way to spin these numbers into a good story. So I look forward to a forthright conversation with you today.

Here are just a few of the items that need to be addressed.

First, there is almost no effort in this budget to deal with the existing, and ever growing, crisis of Medicaid financing. While the budget acknowledges the \$111 billion collective shortfall that states are facing in 2011 alone, it fails to give flexibility to states in managing the nearly one-quarter of their budgets, which is spent on Medicaid. Specifically, it fails to respond to requests from governors for relief from the health law's onerous Medicaid maintenance of effort restrictions.

Second, this budget increases the size of the Department of Health and Human Services by more than 4,700 bureaucrats just in the next two years largely to implement this partisan \$2.6 trillion health care law. It is important to note that just last week the Congressional Budget Office (CBO) said that this new health law will be responsible for the loss of 800,000 jobs at a time when our unemployment rate continues to stagnate north of 9 percent. Americans have said over and over again – they want smaller government and more private sector jobs, not the other way around.

Third, there is some real smoke and mirrors in this budget. Just take a look at the physician payment fix or doc-fix. By your own estimates, the ten year cost of a doc fix, simply with a zero percent update, stands at an astonishing \$370 billion. Although the health care law cut more than \$529 billion out of an insolvent Medicare program to fund new entitlement spending, it did not even attempt to address this fundamental flaw in the program. At the end of this year alone, physicians will face a 28 percent cut in their payments, seriously threatening access for millions of seniors. The SGR should have been permanently fixed in so-called comprehensive health care reform. I suspect that the desire to spin that legislation as saving money had something to do with leaving out a fix that everyone knows will cost hundreds of billions of dollars.

Although this budget attempts to provide a two-year doc-fix, the largest single piece of savings outlined in the budget to pay for it is \$18 billion from a reduction in Medicaid provider taxes, placing a further strain on state budgets who are already struggling under the burdensome unfunded mandates of this new law. The budget also calls for nearly \$13 billion in savings by reducing the exclusivity periods for follow-on biologics and changes to so-called "pay-for-delay" arrangements. These proposals not only fly in the face of bipartisan agreements made in Congress, but more importantly will significantly harm incentives for innovation of life-saving medical treatments.

The problem with this budget is not just the failure to make meaningful cuts.

It is also that the failure to reduce government expenditures requires damaging revenue raisers. Investments in new medicines cost billions of dollars and years of effort. If businesses are going to invest in these life changing and lifesaving medicines, they need to have some expectation that they will recoup those investments. Yet, the proposal to reduce the period of data exclusivity unnecessarily undermines this crucial industry in order to generate revenue that will go toward financing wasteful government spending.

I will have more to say on this issue with your colleague, Secretary Geithner, tomorrow, but the assumption that the tax rates will expire in 2012 will have far reaching consequences for the small business owners who account for half of all small business flow-through income. Those small business owners would see their marginal rates hiked by 17 percent to 24 percent under this budget.

I find it hard to believe that this revenue raiser will not adversely impact the ability of small businesses to hire more workers and provide meaningful health benefits to their employees.

And I am curious what analysis has been done by the Office of Management and Budget (OMB) or the Department of Health and Human Services (HHS) about the impact of these tax hikes on the cost of the new entitlements in the health law. If we are making it harder for businesses to provide health benefits to their employees, more employees are going to get their health coverage from the federal government.

Finally, I would be remiss if I failed to address the growing red elephant in the room — that fact that our broken entitlements are pushing our country closer to bankruptcy with every passing day.

The President's Fiscal Commission recommended serious reforms to our entitlements. But to borrow from one liberal blogger's analysis of this budget, it is almost like the Fiscal Commission never happened. The President has the responsibility and the charge to lead on entitlement reform. There is no bypassing this responsibility. This budget, unfortunately, shows a real lack of leadership on this critical matter. Here is what Washington Post had to say — *Having been given the chance, the cover and the push by the fiscal commission he created to take bold steps to raise revenue and curb entitlement spending, President Obama, in his fiscal 2012 budget proposal, chose instead to duck. To duck, and to mask some of the ducking with the sort of budgetary gimmicks he once derided.*

Madame Secretary, thank you for coming here today. Under the best of circumstances, testifying before Congress can be like going into the lion's den. In this case, since it has been so long since you have testified, it is like you are going into a den where the lions have not been fed in a few weeks.

But I promise we will be kind.

We look forward to talking with you today and continuing this conversation on a more regular basis in the future.

**Senator Jay Rockefeller
Statement for the Record
Senate Finance Committee Hearing on
“The President’s FY2012 Budget Proposals”**

February 15, 2011

Madame Secretary, thank you for coming to the Finance Committee for this very important budget hearing. We are at a critical point in our history as we move forward to deliver true health reform for our nation and the people we serve.

I want to begin by stating that I believe that health reform is the right decision for our nation, and for my home state of West Virginia. There is an imperative need for health reform, around the country and in West Virginia. In 2009, West Virginia had more preventable hospitalizations, heart attacks, and diabetes than any other state. We suffered some of the highest rates of death from cancer and infant mortality. West Virginia was ranked among the three lowest states for both access to dental care and poor mental health. We have the most smokers and among the highest rates of obesity of any state.

Although our state has made progress covering kids, 15% of our citizens – 261,000 West Virginians – are uninsured. Our small businesses are less likely to offer coverage than their counterparts nationwide. And as a rural state, our citizens face additional, geographic challenges accessing care.

No state has more to gain from a reformed health care system than West Virginia. But, the converse is also true – no state has more to lose if the implementation of comprehensive health reform does not go forward. For once, we have an opportunity to ensure coverage while providing incentives for high quality affordable care for some of our most vulnerable populations. In West Virginia, an additional 184,000 West Virginians will have insurance coverage because of the new reform law. This indeed is a significant step forward.

While this historic legislation is comprehensive, it is also very complex. There are no easy solutions to successfully addressing rising health care costs, poor access and substandard quality of care. These problems will not go away on their own, which is why through health reform we created a comprehensive set of new tools and new initiatives to address these inter-related problems in a meaningful way.

Today, we will hear from those who do not want to move forward with implementing this law. However, if we do not move forward, health insurance premiums will continue to skyrocket and eat up more and more of family budgets. If we do not move forward, small businesses will continue to drop coverage for their employees, because they simply cannot afford the rising costs.

If we do not move forward, the number of uninsured will continue to rise to at least 55 million by 2019, and those who do have coverage will bear a higher burden as more costs are shifted to them.

Finally, any delay in moving forward will mean that rising health care costs will eat up a larger and larger share of state and federal budgets, crowding out other investments and requiring drastic cuts in future generations. This law takes the responsible first step for the future of our country, getting us to a health care system that works better and costs less.

Is the law perfect? No. But, the shortcomings in the law are few when compared to the clear opportunity to move our nation's health system forward.

So today, I am eager to hear how the President's FY2012 budget will help us to move forward with the transformational changes in the health reform law. I look forward to hearing how the Department of Health and Human Services plan to move forward with implementing the consumer protections in the new law – an end to annual and lifetime limits, stopping denials for people with pre-existing conditions, and giving consumers better information about their coverage so they can make more informed decisions.

I look forward to hearing how HHS is planning to continue to improve benefits for seniors and persons with disabilities. Already in West Virginia, more than 23,000 seniors last year received a \$250 check to help with their prescription drug costs, and more help is on the way in the form of a 50 percent discount for brand-name drugs in the Medicare prescription drug doughnut hole. Seniors will also be getting free annual wellness visits starting this year where they can learn how to prevent and manage chronic conditions like diabetes or high blood pressure. And, primary care doctors in the Medicare program are receiving a ten percent payment increase beginning this year.

I look forward to hearing how the Administration is moving forward with strengthening the Medicaid program, which as you know is an absolute cornerstone of health care coverage for children, working families, seniors and persons with disabilities. The Medicaid expansion in health reform – the vast majority of which is paid for by the federal government -- will help provide new coverage to some 16 million people. Medicaid is the absolute bedrock of our nation's health care system – it is the government's promise to our nation's most vulnerable citizens that they will have access to affordable health care when times get tough.

In West Virginia, nearly 400,000 people receive their health care through Medicaid every year. Medicaid is a huge economic engine in every state – it supports doctors, hospitals, nursing homes, and community health centers across the country. In West Virginia, the program is responsible for an estimated 19,800 jobs. We all recognize that Medicaid is facing serious challenges – skyrocketing health care costs, growing enrollment, and rising long-term care costs. But these challenges are not specific to

Medicaid; they affect our entire health care system. It is simply vital that we continue to protect this program.

And, the health reform law gives HHS unprecedented new tools to improve quality of care for everybody, especially the elderly and persons with disabilities who are eligible for both Medicare and Medicaid. In June 2009, in West Virginia, we had 69,065 dually eligible individuals enrolled in our state Medicaid program. I am happy to see the progress made in ensuring a seamless approach to delivering care to these most vulnerable individuals. The newly created Federal Coordinated Health Care Office will be very beneficial to these individuals as well as to the states. The improved coordination and reporting of care for this population would not be a reality without the Affordable Care Act. Madame Secretary, we all stand to gain from this renewed approach to care.

Improving quality in today's health care arena is one of the most essential components of the health care law. We cannot afford to continue to pay for substandard care and poor outcomes. The health care law includes numerous opportunities and incentives for improving the quality of care delivered to the American people. I am proud to have championed the inclusion in the health reform law of the National Health Care Quality Strategy and Plan, our road map for continued quality improvements in health care, and I look forward to hearing more about how HHS is implementing the quality provisions in the health reform law. We now have unprecedented potential for reducing errors, reducing health care cost, and improving the coordination of care across all health delivery settings. Health care consumers now are equipped with tools that will allow them to compare a variety of quality measures of care providers. It is time to finally provide all of our citizens – especially with the convenient, efficient, and high-quality care they deserve.

Health care is the economic engine for the 21st Century. During this recession, the health care sector has actually added jobs while virtually every other sector of our economy lost jobs. In West Virginia, a large number of counties have been designated health professional shortage areas. The health reform law provides new opportunities for training, and I am pleased to see that the President's budget includes funding to train 4,000 additional primary care providers in the next 5 years. We simply cannot be successful without a well-prepared workforce that can create the transformed health care delivery system we need. Provisions to expand the health care workforce – and especially our primary care workforce -- are well delineated in our new health care law. This is already making a difference in West Virginia – which is benefitting from an expanded National Health Service Corps program and new opportunities to train primary care providers through the recently-announced Teaching Health Center Graduate Medical Education program. This 5-year program will support an increased number of primary care medical and dental residents trained in community-based settings across the country, and I am proud that Community Health Systems in Beckley, West Virginia is one of the recipients that will be supported by this program.

Finally, the health care law is also making great strides by building on the health information technology provisions from the American Recovery and Reinvestment Act.

Harnessing the full capacity of our information systems is vital for improving health outcomes, enhancing communication among providers across settings and ensuring better coordination of care. For example, the West Virginia Regional Health Information Technology Extension Center (WVRHITEC), is already providing valuable technical assistance to doctors around the state as they work to implement and use certified health information technology and achieve health improvement outcomes through meaningful use.

The danger of de-funding health reform is very real and a bit frightening, if you ask me. Our Republican colleagues have vowed to do everything they can to ensure that health reform is inadequately funded. This will leave health reform in grave danger. I ask, what will this do to derail the success we have experienced to date because of this legislation? The potential to transform our health delivery system through payment reforms, expanded access, and enhanced quality measures will be greatly jeopardized if we do not stay on course. I intend to do all I can to ensure that de-funding does not happen.

We have only just begun. I am excited about this new era in healthcare. I look forward to experiencing a renewed system that provides affordable, cost efficient, high quality care to all. While I know the solutions will not happen overnight, we have new tools, new incentives, new opportunities, and yes, a renewed responsibility to ensure that health reform becomes a permanent reality in our American history. Thank you.



**STATEMENT OF
KATHLEEN SEBELIUS
SECRETARY
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

ON

THE PRESIDENT'S FISCAL YEAR 2012 BUDGET

**BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE**

FEBRUARY 15, 2011

**Testimony of
Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
before the
Senate Committee on Finance
February 15, 2011**

Chairman Baucus, Senator Hatch, and Members of the Committee, thank you for the invitation to discuss the President's FY 2012 Budget for the Department of Health and Human Services (HHS).

In President Obama's State of the Union address he outlined his vision for how the United States can win the future by out-educating, out-building and out-innovating the world so that we give every family and business the chance to thrive. His 2012 budget is the blueprint for putting that vision into action and making the investments that will grow our economy and create jobs.

At the Department of Health and Human Services this means giving families and business owners better access to health care and more freedom from rising health costs and insurance abuses. It means keeping America at the cutting edge of new cures, treatments and health information technology. It means helping our children get a healthy start in life and preparing them for academic success. It means promoting prevention and wellness to make it easier for families to make healthy choices. It means building a health care workforce that is ready for the 21st century health needs of our country. And it means attacking waste and fraud throughout our department to increase efficiency, transparency and accountability.

Our 2012 budget does all of this.

At the same time, we know that we can't build lasting prosperity on a mountain of debt. And we can't win the future if we pass on massive debts to our children and grandchildren. We have a responsibility to the American people to live within our means so we can invest in our future.

For every program we invest in, we know we need to cut somewhere else. So in developing this budget, we took a magnifying glass to every program in our department and made tough choices. When we found waste, we cut it. When we found duplication, we eliminated it. When programs weren't working well enough, we reorganized and streamlined them to put a new focus on results. When they weren't working at all, we ended them. In some cases, we cut programs we wouldn't in better fiscal times.

My discretionary budget is slightly below the 2010 level. Within that total we cover the increasing costs of ensuring the safety of our food supply, providing medical care to American Indians and Alaska Natives, managing our entitlement programs, investing in early childhood, and advancing scientific research. We contribute to deficit reduction and meet the President's freeze to non-security programs by offsetting these investments with over \$5 billion in targeted reductions. These reductions are to real programs and reflect tough choices. In some cases the reductions are to ineffective or outdated programs and in other areas they are cuts we would not have made absent the fiscal situation. The Budget proposes a number of reductions and terminations in HHS.

- The Budget cuts the Community Services Block Grant in half by \$350 million and injects competition into grant awards.
- The Budget cuts the Low Income Home Energy Assistance Program by \$2.5 billion bringing it back to the 2008 level appropriated prior to energy prices spikes.

- The Budget eliminates subsidies to Children's Hospitals Graduate Medical Education focusing instead on targeted investments to increase the primary care workforce.
- The Budget reduces the Senior Community Services Employment Program by \$375 million, proposes to transfer this program from the Department of Labor to HHS, and refocuses the program to train seniors to help other seniors.

The Budget also stretches existing resources through better targeting.

- The Budget redirects and increases funding in CDC to reduce chronic disease. Rather than splitting funding and making separate grants for heart disease, diabetes, and other chronic diseases, the Budget proposes one comprehensive grant that will allow States to address chronic disease more effectively.
- The Budget redirects prevention resources in SAMHSA to fund evidence-based interventions and better respond to evolving needs. States and local communities will benefit from the additional flexibility while funds will still be competed and directed toward proven interventions.

These are the two goals that run throughout this budget: making the smart investments for the future that will help build a stronger, healthier, more competitive, and more prosperous America, and making the tough choices to ensure we are building on a solid fiscal foundation.

The budget documents are available on our website. But for now, I want to share an outline of the budget, including the areas of most interest to this Committee, and how it will help our country invest in, and win, the future.

That starts with giving Americans more freedom in their health care choices, so they can get affordable, high-quality care when they need it.

TRANSFORM HEALTH CARE

Expanding Access to Coverage and Making Coverage More Secure: The Affordable Care Act expands access to affordable coverage to millions of Americans and strengthens consumer protections to ensure individuals have coverage when they need it most. These reforms create an important foundation of patients' rights in the private health insurance market and put Americans in charge of their own health care. As a result, we have already implemented historic private market reforms including eliminating pre-existing condition exclusions for children; prohibiting insurance companies from rescinding coverage and imposing lifetime dollar limits on coverage; and enabling many adult children to stay on their parent's insurance plan up to age 26. The Affordable Care Act also established new programs to lower premiums and support coverage options, such as the Pre-Existing Condition Insurance Plans Program and the Early Retiree Reinsurance Program. The Act provides Medicare beneficiaries and enrollees in most private plans access to free preventative services. Medicare beneficiaries also have increased access to prescription drugs under Medicare Part D by closing the coverage gap, known as the "donut hole," by 2020 so that seniors no longer have to fear being unable to afford their prescriptions. The Act also provides for an annual wellness visit to all Medicare beneficiaries free of charge.

Beginning in 2014, State-based health insurance Exchanges will create affordable, quality insurance options for many Americans who previously did not have health insurance coverage, had inadequate coverage, or were vulnerable to losing the coverage they had. Exchanges will make purchasing private

health coverage easier by providing eligible consumers and small businesses with “one-stop-shopping” where they can compare a range of plans. New premium tax credits and cost-sharing reductions will also increase the affordability of coverage and care. The Affordable Care Act will also extend Medicaid insurance to millions of low-income individuals who were previously not eligible for coverage, granting them access to affordable health care.

Ensuring Access to Quality, Culturally Competent Care for Vulnerable Populations: The Budget includes \$3.3 billion for the Health Centers Program, including \$1.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund, to expand the capacity of existing health center services and create new access points. The infusion of funding provided through the Affordable Care Act, combined with the discretionary request for FY 2012, will enable health centers to serve 900,000 new patients and increase access to medical, oral, and behavioral health services to a total of 24 million patients.

Improving Health Care Quality: The Affordable Care Act contains numerous provisions designed to ensure that patients receive safe, high quality care. Innovative payment and delivery reforms such as bundled payments for a single episode of care and the formation of Accountable Care Organizations will promote better coordinated and more efficient care. New value-based purchasing programs for hospitals, Medicare Advantage plans, and other health providers will reward those who deliver high quality care, rather than simply encouraging a high volume of services. The new Center for Medicare and Medicaid Innovation (“Innovation Center”) will design, test, and evaluate new models of payment and delivery that seek to promote higher quality and lower costs. Similarly, the new Centers for Medicare & Medicaid Services’ (CMS) Federal Coordinated Health Care Office will complement these efforts to provide higher quality and better integrated care for those who are eligible for both Medicare and Medicaid.

Reducing Health Care Costs: New innovative delivery and payment approaches will lead to both more efficient and higher quality care. For example, provisions in the Affordable Care Act designed to reduce health care acquired conditions and preventable readmissions will both improve patient outcomes and reduce unnecessary health spending. The Innovation Center, in coordination with private sector partners whenever possible, will pursue new approaches that not only improve quality of care, but also lead to cost savings for Medicare and Medicaid. Rate adjustments for Medicare providers and insurers participating in Medicare Advantage will promote greater efficiency in the delivery of care. Meanwhile, new rules for private insurers, such as medical loss ratio standards and enhanced review of premium increases, will lead to greater value and affordability for consumers.

Combating Healthcare Associated Infections:

HHS will use infection rates as a metric for hospital value-based purchasing, as called for in the Affordable Care Act. The FY 2012 Budget includes \$86 million – of which \$20 million is funded in the Prevention and Public Health Fund Prevention Trust Fund - to the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Office of the Secretary to reduce healthcare-associated infections. In FY 2012, HHS will continue research on health-care associated infections and tracking infections through the National Healthcare Safety Network. HHS will also identify and respond to new healthcare-associated infections by conducting outbreak and epidemiological investigations. In addition, HHS will implement, and ensure adherence to, evidence-based prevention practices to eliminate healthcare-associated infections. HHS activities, including those that the Innovation Center sponsors, will further the infection reduction goals of the Department’s Action Plan to Prevent Healthcare-Associated Infections.

Health Services for 9/11 World Trade Center Attacks: To implement the James Zadroga 9/11 Health and Compensation Act, the FY 2012 Budget includes \$313 million in mandatory funding to provide medical monitoring and treatment to responders of the September 11, 2001 World Trade Center attacks

and initial health evaluations, monitoring, and treatment to others directly affected by the attacks. In addition to supporting medical monitoring and treatment, HHS will use funds to establish an outreach program for potentially eligible individuals, collect health data on individuals receiving benefits, and establish a research program on health conditions resulting from the World Trade Center attacks.

Stabilizing Medicare Physician Payments: In December, the Administration worked with Congress to offset the cost of legislation preventing an imminent decrease in physician payments due to the Medicare Sustainable Growth Rate (SGR) formula. The Budget goes further and proposes to continue the current level of payment, and offset the increase above current law for the next two years with specific savings. Beyond the next two years, I am determined to work with you to put in place a long-term plan to reform physician payment rates in a fiscally responsible way, and to craft a reimbursement system that gives physicians incentives to improve quality and efficiency, while providing predictable payments for care furnished to Medicare beneficiaries.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

Accelerating Scientific Discovery to Improve Patient Care: The Budget includes \$32.0 billion for the National Institutes of Health (NIH), an increased investment of \$745 million over the FY 2010 enacted level, to support innovative basic and clinical research that promises to deliver better health and drive future economic growth. In FY 2012, NIH estimates it will support a total of 36,852 research project grants, including 9,158 new and competing awards.

Recent advances in the biomedical field, including genomics, high-throughput biotechnologies, and stem cell biology, are shortening the pathway from discovery to revolutionary treatments for a wide range of diseases, such as Alzheimer's, cancer, autism, diabetes, and obesity. The dramatic acceleration of our basic understanding of hundreds of diseases; the establishment of NIH-supported centers that can screen thousands of chemicals for potential drug candidates; and the emergence of public-private partnerships to aid the movement of drug candidates into the commercial development pipeline are fueling expectations that an era of personalized medicine is emerging where prevention, diagnosis, and treatment of disease can be tailored to the individual and targeted to be more effective. To help bridge the divide between basic science and therapeutic applications, NIH plans to establish in FY 2012 the National Center for Advancing Translational Sciences (NCATS), of which one component would be the new Cures Acceleration Network. With the creation of NCATS, the National Center for Research Resources will be abolished and its programs transferred to the new Center or other parts of NIH.

Advancing Patient-Centered Health Research: The Affordable Care Act created the Patient-Centered Outcomes Research Institute to fund research and get relevant, high quality information to patients, clinicians and policy-makers so that they can make informed health care decisions. The Patient-Centered Outcomes Research Trust Fund will fund this independent Institute, and related activities within HHS. In FY 2012, the Budget includes \$620 million in AHRQ, NIH and the Office of the Secretary, including \$30 million from the Trust Fund, to invest in core patient-centered health research activities and to disseminate research findings, train the next generation of patient-centered outcomes researchers, and improve data capacity.

Advancing Health Information Technology: The Budget includes \$78 million, an increase of \$17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate health information technology (health IT) adoption and promote electronic health records (EHRs) as tools to improve the health of individuals and transform the health care system. The increase will allow ONC to assist health care providers in becoming meaningful users of health IT.

ADVANCE THE HEALTH, SAFETY, AND WELL-BEING OF THE AMERICAN PEOPLE

Child Support and Fatherhood Initiative: The Budget includes \$305 million in FY 2012 and \$2.4 billion over 10 years for the Child Support and Fatherhood Initiative. This initiative is designed to promote strong family relationships by encouraging fathers to take responsibility for their children, changing policies so that more of fathers' support reaches their children, and continuing a commitment to vigorous enforcement. The Budget increases support for States to pass through child support payments to families, rather than retaining those payments, and requires States to establish access and visitation arrangements as a means of promoting father engagement in their children's lives. The Budget also provides a temporary increase in incentive payments to States based on performance, which continues an emphasis on program outcomes and will foster enforcement efforts when state budgets are stretched.

Reform and Reauthorize the Foster Care Financing System: The Budget includes an additional \$250 million in mandatory funds in FY 2012 and a total of \$2.9 billion over 10 years to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services from the child welfare system in order to prevent entry or re-entry into foster care. We look forward to working with the Committee to improve outcomes for vulnerable children in our child welfare system.

TANF Reauthorization: The President's Budget continues existing funding for the TANF program in FY 2012. The Budget also includes resources to fund the FY 2011 Supplemental Grants for Population Increases at the level provided in prior years. When TANF reauthorization is considered, the Administration would be interested in exploring with Congress a variety of strategies to strengthen the program's ability to improve outcomes for families and children, including helping more parents succeed as workers by building on the recent successes with subsidized employment, using performance indicators to drive program improvement; and preparing the program to respond more effectively in the event of a future economic downturn.

Enhancing the Quality of Early Care: The Budget provides \$6 billion in combined discretionary and mandatory funding for child care. These resources will enable 1.7 million children to receive child care services. The Administration also supports reforms to the child care program to serve more low-income children in safe, healthy, and nurturing child care settings that are highly effective in promoting early learning; supports parental employment and choice by providing information to parents on quality; promotes continuity of care; and strengthens program integrity and accountability. Additionally, the President's Budget includes \$8.1 billion for Head Start, which will allow us to continue to serve 968,000 children in 2012. The Administration is also working to implement key provisions of the Head Start Reauthorization, including requiring low-performing programs to compete for funding, that will improve program quality. These reforms and investments at HHS, in conjunction with the Administration's investments in the Early Learning Challenge Fund, are key elements of the broader education agenda designed to help every child reach his or her academic potential and improve our Nation's competitiveness.

Improving Health Outcomes of American Indians and Alaska Natives: The President is committed to improving health outcomes and providing health care for American Indian and Alaska Native communities. The Budget includes nearly \$5.7 billion, an increase of \$589 million, which will enable the Indian Health Service (IHS) to focus on reducing health disparities, ensuring that IHS services can be supplemented by care purchased outside the Indian health system where necessary, supporting Tribal efforts to deliver quality care, and funding health facility and medical equipment upgrades. These investments will ensure continued improvement to support the Administration's goal of significantly reducing health disparities for American Indians and Alaska Natives.

Transforming Food Safety: The Administration is committed to transforming our Nation's food safety system to one that is stronger and more reliable for American consumers. This Budget reflects the President's vision of a safer food safety system by including \$1.4 billion, an increase of \$333 million over FY 2010 for the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) food safety activities. Coupled with the enactment of the FDA Food Safety Modernization Act (the Act), which was signed into law on January 4, 2011, HHS will continue to modernize and implement an integrated National food safety system. HHS plans to work with Congress to enact additional food safety fees to support the full implementation of the Act. CDC will improve the speed and accuracy of food borne illness outbreak detection and investigation, while FDA will focus on establishing produce safety standards and working with manufacturers to implement preventative controls in an effort to avoid an outbreak of tainted food.

Preventing and Treating HIV/AIDS: The Budget supports the goals of the National HIV/AIDS Strategy to reduce HIV incidence, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related health disparities. The request focuses resources on high-risk populations and allocates funds to State and local health departments to align resources to the burden of the epidemic across the United States. The Budget includes \$2.4 billion, an increase of \$85 million, for HRSA's Ryan White program to expand access to care for persons living with HIV/AIDS who are otherwise unable to afford health care and related support services. The Budget also includes \$858 million for domestic HIV/AIDS Prevention in CDC, an increase of \$58 million, which will help CDC decrease the HIV transmission rate; decrease risk behaviors among persons at risk for acquiring HIV; increase the proportion of HIV infected people who know they are infected; and integrate services for populations most at risk of HIV, sexually transmitted diseases, and viral hepatitis. In addition, the Budget proposes that up to one percent of HHS discretionary funds appropriated for domestic HIV/AIDS activities, or approximately \$60 million, be provided to the Office of the Assistant Secretary for Health to foster collaborations across HHS agencies and finance high priority initiatives in support of the National HIV/AIDS Strategy. Such initiatives would focus on improving linkages between prevention and care, coordinating Federal resources within targeted high-risk populations, enhancing provider capacity to care for persons living with HIV/AIDS, and monitoring key Strategy targets.

Addressing the Leading Causes of Death and Disability: Chronic diseases and injuries represent the major causes of morbidity, disability, and premature death and contribute to the growth in health care costs. The Budget aims to improve the health of individuals by focusing on prevention of chronic diseases and injuries rather than focusing solely on treating conditions that could have been prevented. Specifically, the Budget includes \$705 million for a new competitive grant program in CDC that refocuses disease-specific grants into a comprehensive program that will enable health departments to implement the most effective strategies to address the leading causes of death. Because many chronic disease conditions share common risk factors, the new program will improve health outcomes by coordinating the interventions that can reduce the burden of chronic disease. In addition, the allocation of the \$1 billion available in the Prevention Fund will improve health and restrain the growth of health care costs through a balanced portfolio of investments. The FY 2012 allocation of the Fund builds on existing investments and will align with the vision and goals of the National Prevention and Health Promotion Strategy under development. For instance, the CDC Community Transformation Grants create and sustain communities that support prevention and wellness where people live, learn, work and play through the implementation, evaluation, and dissemination of evidence-based community preventive health activities.

Preventing Substance Abuse and Mental Illness: The Budget includes \$535 million within the Substance Abuse and Mental Health Services Administration (SAMHSA) for new, expanded, and refocused substance abuse prevention and mental health promotion grants to States and Tribes. To

maximize the effectiveness and efficiency of its resources, SAMHSA will deploy mental health and substance abuse prevention and treatment investments more thoughtfully and strategically. SAMHSA will use competitive grants to identify and test innovative prevention practices and will leverage State and Tribal investments to foster the widespread implementation of evidence-based prevention strategies through data driven planning and resource dissemination.

Ensuring Safety and Improving Access to Medical Products: FDA is the global leader for regulating medical products and the Administration is dedicated to ensuring that all drugs and medical devices that enter the market are safe and effective for the American consumer. The Budget provides \$1.4 billion for FDA to enhance the safety oversight of medical products and to establish a pathway for the approval of generic biologics thus allowing greater access to life saving biological products that are safe and effective.

Supporting Older Adults and their Caregivers: The Budget includes \$60 million, an increase of \$21 million over FY 2010, to help seniors live in their communities without fear of abuse, and includes an increase of \$96 million for caregiver services, like counseling, training, and respite care, to enable families to better care for their relatives in the community. The Budget also proposes to transfer a Department of Labor program that provides community service opportunities and job training to unemployed older adults to HHS. As part of this move, a new focus will be placed on developing professional skills that will enable participants to provide services that allow fellow seniors to live in their communities as long as possible.

Pandemic and Emergency Preparedness: While responding to the H1N1 influenza pandemic has been the focus of the most recent pandemic investments, the threat of a pandemic caused by H5N1 or other strains has not diminished. HHS is currently implementing pandemic preparedness activities in response to lessons learned from the H1N1 pandemic in order to strengthen the Nation's ability to respond to future health threats. Balances from the FY 2009 supplemental appropriations are being used to support recommendations from the HHS Medical Countermeasure Review and the President's Council of Advisors on Science and Technology. These multi-year activities include advanced development of influenza vaccines and the construction of a new cell-based vaccine facility in order to quickly produce vaccine in the U.S., as well as development of next generation antivirals, rapid diagnostics, and maintenance of the H5N1 vaccine stockpile.

The HHS Medical Countermeasure Review described a new strategy focused on forging partnerships, minimizing constraints, modernizing regulatory oversight, and supporting transformational technologies. The request includes \$665 million for the Biomedical Advanced Research and Development Authority, to improve existing and develop new next-generation medical countermeasures and \$100 million to establish a strategic investment corporation that would improve the chances of successful development of new medical countermeasure technologies and products by small and new companies. The Budget includes \$70 million for FDA to establish teams of public health experts to support the review of medical countermeasures and novel manufacturing approaches. Additionally, NIH will dedicate \$55 million to individually help shepherd investigators who have promising, early-stage, medical countermeasure products. Finally, the Budget includes \$655 million for the Strategic National Stockpile to replace expiring products, support BioShield acquisitions, and fill gaps in the stockpile inventory.

STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORKFORCE

Strengthening the Health Workforce: A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The Budget includes \$1.3 billion, including \$315 million in mandatory funding, within HRSA, to support a strategy which aims to promote a sufficient health workforce that is deployed effectively and efficiently and trained to meet the changing

needs of the American people. The Budget will initiate investments that will expand the capacity of institutions to train over 4,000 new primary care providers over five years.

Expanding Public Health Infrastructure: The FY 2012 Budget supports State and local capacity so that health departments are not left behind. Specifically, the Budget requests \$73 million, of which \$25 million is funded in the Prevention Fund, for the CDC public health workforce to increase the number of trained public health professionals in the field. CDC's experiential fellowships and training programs create an effective, prepared, and sustainable health workforce to meet emerging public health challenges. In addition, the Budget requests \$40 million in the Prevention Fund to support CDC's Public Health Infrastructure Program. This program will increase the capacity and ability of health departments to meet national public health standards in areas such as information technology and data systems, workforce training, and regulation and policy development.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILITY OF HHS PROGRAMS

Strengthening Program Integrity: Strengthening program integrity is a priority for both the President and myself. The Budget includes \$581 million in discretionary funding, a \$270 million increase over FY 2010, to expand prevention-focused, data-driven, and innovative initiatives to improve CMS program integrity. The Budget request also supports the expansion up to 20 Strike Force cities to target Medicare fraud in high risk areas and other efforts to achieve the President's goal of cutting the Medicare fee-for-service error rate in half by 2012. The proposed ten year discretionary investment yields \$10.3 billion in Medicare and Medicaid savings, a return of about \$1.5 for every dollar spent. In addition, the Budget includes a robust package of program integrity legislative proposals to expand HHS program integrity tools and produce \$32.3 billion in savings over ten years.

In addition, the Affordable Care Act provides unprecedented tools to CMS and law enforcement to enhance Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program integrity. The Act enhances provider screening to stop fraudsters from participating in these programs in the first place, gives the Secretary the authority to implement temporary enrollment moratoria for fraud hot spots, and increases law enforcement penalties. Additionally, the continued implementation of the Secretary's Program Integrity Initiative seeks to ensure that every program and office in HHS prioritizes the identification of systemic vulnerabilities and opportunities for waste and abuse, and implements heightened oversight.

Implementing the Recovery Act: The American Recovery and Reinvestment Act provides \$138 billion to HHS programs as part of a government-wide response to the economic downturn. HHS-funded projects around the country are working to achieve the goals of the Recovery Act by helping State Medicaid programs meet increasing demand for health services; supporting struggling families through expanded child care services and subsidized employment opportunities; and by making long-term investments in health information technology (IT), biomedical research and prevention and wellness efforts. HHS made available a total of \$118 billion to States and local communities through December 31, 2010; recipients of these funds have in turn spent \$100 billion by the same date. Most of the remaining funds will support a signature Recovery Act program to provide Medicare and Medicaid incentive payments to hospitals and eligible health care providers as they demonstrate the adoption and meaningful use of electronic health records. The first of these Medicaid incentive payments were made January 5, 2011. More than 23,000 grantees and contractors of HHS discretionary programs have to submit reports on the status of their projects each calendar quarter. These reports are available to the public on Recovery.gov. For the quarter ending December 31, 2010, 99.6 percent of the required recipient reports were filed timely. Recipients that do not comply with reporting requirements are subject to sanction.

CONCLUSION

This Budget is about investing our resources in a way that pays off again and again. By making smart investments and tough choices today, we can have a stronger, healthier, more competitive America tomorrow.

This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans.

Under this Budget, we will continue to work to make sure every American child, family, and senior has the opportunity to thrive.

And we will take responsibility for our deficits by cutting programs that were outdated, ineffective, or that we simply could not afford.

But, we need to make sure we're cutting waste and excess, not making across the board, deep cuts in programs that are helping our economy grow and making a difference for families and businesses. We need to move forward responsibly, by investing in what helps us grow and cutting what doesn't.

My department can't accomplish any of these goals alone. It will require all of us to work together.

I look forward to working with you to advance the health, safety, and well-being of the American people. Thank you for this opportunity to speak with you today. I look forward to our conversation.

**Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011**

The Honorable Max Baucus

1. The TANF Emergency Contingency Fund (Fund), created in the 2009 stimulus bill, has enabled states to create subsidized jobs for TANF recipients and other low income unemployed individuals. The Fund has also provided basic cash assistance and non-recurring short term assistance to families further bolstering local economies. The Fund expired on September 30, 2010. During its existence 39 states used the Fund to create jobs through subsidized employment program where they reimbursed employers or paid wages directly. The total number of job placements was 124,470 for adults and 138,050 for youth for a total of 262,520 job placements.

Montana received \$10.2 million in Fund dollars and used 50 percent of the funding for subsidized jobs. This is a program that should continue with an increased focus on job subsidies and work supports.

I'm particularly interested in growing the number of trained workers for jobs in fields that are currently experiencing worker shortages. I think the TANF Emergency Contingency Fund proved successful on this front.

How should we be using TANF to prepare workers to meet this demand and boost the US economy?

Answer: As the President has said, we must "win the future" and to do so we need all Americans to be able to contribute. To that end, we need TANF to do all it can to bring people into the labor market and to help them succeed there. When state TANF programs do so, it helps all of us.

When Congress and the Administration discuss TANF reauthorization legislation, we should consider ways to use performance indicators to drive program improvement, including improvements in preparing parents to enter the workforce and placing them in jobs. This kind of approach would respect the flexibility states have in TANF while focusing on achieving better outcomes for participants.

One area we are particularly interested in exploring is subsidized employment. The Recovery Act provided states with funding that could be used for subsidized employment programs. States took this opportunity and ran with it – and many had significant success working with employers, creating subsidized jobs where parents contributed to the business, and placing some subsidized job participants in unsubsidized jobs.

We have held discussions with our state partners about the best next steps to take on TANF and we have repeatedly heard that states want federal rules to focus more on the outcomes we want

to see for families and less on the details of work activity rules and on the documentation related to work participation that are now in place. For example, a number of states have expressed concern that current provisions limit their ability to engage some parents in education and training in situations where it would provide the surest path to gaining and retaining employment. HHS also talked with participating employers who said their businesses were strengthened by the subsidized employment program and that the employees were a real asset to their businesses. We should consider whether there are ways to make subsidized employment a more important part of TANF.

2. What have we learned in the last year about creating jobs through subsidies to employers?

Answer: The TANF Emergency Fund, authorized by the Recovery Act, provided states with funding for their efforts to create or expand subsidized employment programs. States took this opportunity and ran with it. Thirty-nine States and the District of Columbia looked at the economic situation and decided that finding ways to put parents and disadvantaged young people to work would be the most beneficial use of resources. States had significant success working with employers, creating subsidized jobs where workers contributed to the business, and placing some subsidized job participants in unsubsidized jobs. Parents were able to earn income to pay for their expenses, and had the dignity that comes with working.

Last June I met Christy Webber, who owns a landscape business in Illinois. She was one of the many employers in Illinois who was able to hire parents who needed a job and, in turn, expand her business during the recession. HHS also talked with participating employers who said their businesses were strengthened by the subsidized employment program and that the employees were a real asset to their businesses.

As we look to the future, we should work together with states to find ways to make subsidized employment a more important part of TANF. When times are good, subsidized jobs programs can focus more on those who lack fundamental job skills and work with businesses struggling to find qualified workers. When times are bad, subsidized jobs programs can provide a paycheck to a struggling family and help a struggling business stay afloat or even grow.

3. Nine million people are dually eligible for Medicaid and Medicare and account for over \$300 billion in annual healthcare costs. This group represents only 21% of the Medicare and 15% of the Medicaid population, yet it accounts for 36% and 39% of costs for those programs, respectively. Through increased access to high-quality medical care, the Affordable Care Act improves the care of high-cost complex populations, including the dual eligibles. Most notably, the law creates an office within CMS to solely focus on the dual-eligible population.

In addition, the President's budget extends the Qualified Individuals program, which helps low-income seniors pay Medicare Part B premiums, and creates a new Comprehensive Chronic Disease Prevention Program, which provides flexibility to States to improve care coordination for the top five leading causes of death.

In order to tackle our budget problems, for both federal and state governments, we need to do a better job caring for dual-eligibles. The Affordable Care Act creates, for the first time, an office with direct responsibility for coordinating the care of these high-cost individuals: the Federal Coordinated Health Care Office. Secretary Sebelius, what is the status of this office, and what steps is it taking to improve the quality of care and control the costs for this population?

Answer: The Affordable Care Act established a Federal Coordinated Health Care Office to improve coordination of the care provided to beneficiaries eligible for both Medicare and Medicaid. We're very excited about this provision, which we believe can improve the quality of care for these individuals while reducing costs.

Medicare-Medicaid enrollees are among the most vulnerable and chronically ill beneficiaries, who represent 15 percent of enrollees and 39 percent of Medicaid expenditures, and 16 percent of enrollees and 27 percent of Medicare expenditures. These individuals need to navigate two separate systems: Medicare for coverage of basic health care services, and Medicaid for coverage of long-term care supports and services, and help with Medicare premiums and cost-sharing.

The Medicare-Medicaid Coordination Office has already launched a variety of initiatives to meet its Congressional charge to improve access, coordination and cost of care for Medicare-Medicaid enrollees. Our work falls into the following broad areas:

- Program Alignment
- Data and Analytics
- Models and Demonstrations

The Alignment Initiative is an effort to advance beneficiaries' understanding of, interaction with, and access to seamless, high quality care that is as effective and efficient as possible. Better alignment of the two programs can reduce costs by improving health outcomes and more effectively and efficiently coordinating care and can make the programs easier to understand and navigate for beneficiaries.

On May 11, 2011, the Medicare-Medicaid Coordination Office also announced a new process to provide States access to Medicare data to support care coordination for individuals enrolled in both Medicare and Medicaid.¹ Access to Medicare data is an essential tool for States seeking to coordinate care, improve quality, and control costs for their highest cost beneficiaries.

The Medicare-Medicaid Coordination Office recently announced several opportunities through demonstrations of delivery and payment models to improve the quality of care Medicare-Medicaid enrollees receive by expanding access to seamless, integrated programs, and better care management. One new demonstration is designed to test models to align financing between Medicare and Medicaid to support improvements in the quality and cost of care for individuals eligible for Medicare and Medicaid. CMS has issued guidance to States so that they can apply to test either a fee-for-service model or a capitated payment model to better align the financing of these two programs and integrate primary, acute, behavioral health and long term services and

¹ http://www.cms.gov/medicare-medicaid-coordination/06_MedicareDataforStates.asp#TopOfPage

supports for their Medicare-Medicaid enrollees. The CMS Center for Medicare and Medicaid Innovation will test these models to determine whether they save money while also preserving or enhancing the quality of care for Medicare-Medicaid enrollees. All States that meet specified standards and conditions will have the option to pursue either or both of these models.

Additionally, the Medicare-Medicaid Coordination Office has launched a new demonstration program to help States improve the quality of care for people in nursing homes by providing these individuals with the treatment they need without having to unnecessarily go to a hospital. Hospitalizations are often expensive, disruptive, disorienting, and dangerous for frail elders and people with disabilities, and cost Medicare billions of dollars each year. Starting this fall, CMS will competitively select independent organizations to partner with and implement evidence-based interventions at interested nursing facilities. This demonstration supports the Administration's Partnership for Patients goal of reducing hospital readmission rates by 20-percent by the end of 2013.

4. In this recession, TANF has not responded as other safety net programs have. TANF has not automatically expanded, as Food Stamps and Medicaid did, but the system was not built for a recession like the one that started in 2008. At the end of last year, fewer than 2 million families received cash assistance through TANF. That's 3 million less than received Aid to Families with Dependent Children in 1994. A welfare reform system focused on jobs can work when there are plenty of jobs but that kind of system poses harsh realities when a recession sets in. The time-limited cash assistance and flexible TANF program has enabled many to transition into jobs and self-sufficiency. But there's also evidence that efforts to encourage state welfare-to-work innovations have not succeeded across the board.

During the recession, TANF has been responsive in some states, but not in others.

What would you suggest to help make TANF responsive in all states?

Answer: The TANF Emergency Fund was a big success with virtually every state able to access the fund, despite a structure in which TANF funds only reimbursed 80 percent of additional costs. The Fund allowed reimbursement for increased costs to provide short-term help for families, create or expand subsidized jobs programs, and contend with rising assistance costs. We should look to our experience with the Emergency Fund for lessons of how to make TANF respond more effectively in the event of a future economic downturn. In particular, we should establish a funding structure to respond more effectively in the event of a future economic downturn.

5. How can TANF help states to continue to focus on employment, even in periods of high unemployment?

Answer: The recent experience with subsidized employment funded in large part through the Emergency Fund suggests that this program should be an important part of a strategy to help parents find and keep jobs. In addition, we should consider ways of using performance indicators to keep the program's focus on employment even during periods of high unemployment.

6. An important goal of health reform is to measure and improve the quality of health care provided to Americans. However, for the majority of Medicaid enrollees, there exist no federal requirements for comparable quality monitoring or improvement. In addition, there is no structured oversight for Medicaid enrollees when they move between FFS and managed care plans.

In order to address the need for quality improvement of Medicaid, CMS and States have been developing, in collaboration with national organizations, a National Medicaid Quality Framework, with an underlying theme of “the right care for every person, every time.” The National Medicaid Quality Framework does not develop technical quality standards, but it provides some key strategies across many aspects of Medicaid, including: preventive care, acute care, chronic medical care, long-term care and end-of-life care. These key strategies focus on areas within our health care delivery system that would benefit from improvement.

A goal of health reform is to assess and improve the quality of health. For health reform to be successful, it is imperative to monitor and improve the quality of care provided to Americans, making people healthier. For beneficiaries, this means providing the right care for every person, every time.

Please tell us what you’ve done thus far in order to expand quality measurement efforts in Medicaid. Also, how the development of the National Medicaid Quality Framework will help improve the quality of our health care delivery system?

Answer: CMS continues to work cooperatively with States to encourage quality measurement and the use of that information to drive quality improvements in Medicaid and CHIP. Medicaid and CHIP currently use the HHS National Quality Strategy, <http://www.ahrq.gov/workingforquality/nqs/>, issued in March 2011, as the roadmap for improving quality of care for program enrollees. The Strategy identifies principles to guide the development of an infrastructure to achieve the interrelated aims of better health, better care, and lower costs through improvements in quality. The principles address areas important to the program enrollees such as: person centeredness and family engagement; eliminating disparities in care; making primary care a bigger focus; enhancing coordination of care; and the integration of care delivery.

Measuring Quality of Care in Medicaid: Children

CMS is currently working with States through its CHIPRA quality demonstration grantees and its Technical Advisory Groups (which are state workgroups that focus on policy areas such as quality, oral health, mental health, managed care, and coverage) to strengthen systems for measuring and collecting data on access and quality. In addition, efforts are now underway to develop a larger strategy to meet the data and information exchange needs of CMS and the States. These efforts include improving the Medicaid Statistical Information System (MSIS) and encouraging providers to adopt and use electronic health records (EHRs). Leveraging EHRs where possible today, and working toward a future in which data are electronically collected and shared is an investment that CMS perceives will have a great value over time in not only

improving the quality of care, but also in improving CMS's capacity to monitor services provided to program enrollees.

CMS also is collaborating with States to establish an infrastructure that can uniformly and reliably measure and report on an initial core set of children's quality measures for Medicaid and CHIP. As required by CHIPRA, CMS released an initial core set of 24 children's quality measures for voluntary reporting by States. These measures represented a monumental step toward CMS developing an evidence-informed, nationwide system for measuring and reporting on children's quality of care in Medicaid/CHIP. In February 2011, CMS released guidance to States describing the components of the quality measurement system and the reporting procedures (see <http://www.cms.gov/smdl/downloads/SHO11001.pdf>).

Working in partnership with the Agency for Healthcare Research and Quality (AHRQ), CMS awarded grants to seven CHIPRA Centers of Excellence in Pediatric Quality Measures in 2011. These Centers comprise the Pediatric Quality Measures Program (PQMP) and will test and refine the initial core set of measures to make them more broadly applicable to Medicaid, CHIP, and other programs and develop additional quality measures that address dimensions of care where standardized measures do not currently exist.

Measuring Quality of Care: Adults

Section 2701 of the Affordable Care Act requires the development of a recommended core set of adult health quality measures for Medicaid eligible adults. CMS, in partnership with AHRQ, is using the development of these adult health quality measures to identify ways to align State reporting requirements with other HHS quality reporting initiatives and to coordinate measurement efforts with payment reform strategies, health information technology, and electronic health record initiatives. CMS and AHRQ are also using this as an opportunity to identify priority areas for the development of new measures to improve health, provide better care, and lower costs through improvement. In December of 2010, CMS published a Federal Register notice (75 FR 82397) soliciting comments on the initial core set of adult health quality measures for Medicaid-eligible adults; the public comment period for this notice ended in March 2011. To date, the Adult Quality Measures Subcommittee to the National Advisory Council has convened twice and is reviewing comments in the move towards finalizing the adult measures by January 1, 2012. This final set of recommended core adult quality measures will complement the set of children's health care quality measures.

Managed Care Federal Quality Standards and CMS' Organizational Activities

CMS also has a number of tools for monitoring access and quality of care in managed care arrangements. States that use managed care organizations (MCOs) or prepaid inpatient health plans (PIHPs) for providing Medicaid services must comply with quality measurement guidelines and regulations found at 42 CFR 438 Subparts D and E. Specifically, each State contracting with an MCO or PIHP to develop and update a written "Quality Strategy." The purpose of the Quality Strategy is to map out methods and processes to assess and improve the quality of managed care services delivered in the State. States also are required to have an external quality review (EQR) of each contracted MCO or PIHP. After developing the Quality

Strategy, States then submit the strategy to CMS for approval. CMS provides various levels of oversight and technical assistance for each State's Quality Strategy, both at the regional and central office level, to ensure that the State is proceeding on target with its specifications and HHS priorities.

Other Activities Undertaken to Improve Quality Measurement & Monitoring

- In September 2010, CMS released the first annual report on the Quality of Care for Children in Medicaid and CHIP, required by section 1139A(c)(2) of the Social Security Act. The report provided information on current State reporting of quality measures. It included a review of EQR reports for States, analyzed data on four child quality measures reported to CMS in 2008, and summarized findings from an NCQA report that assessed quality performance measures in 34 State Medicaid programs.
- Provided technical assistance to States in developing their Medicaid quality strategies for managed care as well as quality improvement projects for home, community-based, and institutional services;
- Provided feedback to States on their external quality review technical reports and conducting a State training on the reporting of quality measures using the CMS reporting tool, CHIP Annual Reporting Template System (CARTS);
- Hosted two State-Federal workshops on oral health, one in partnership with National Association for State Health Policy in New Orleans and the other with National Association of State Medicaid Directors in D.C., to discuss CMS goals and strategy to improve oral health;
- Sponsored several webinars for State Medicaid/CHIP programs and their clinical partners (topics included improving maternal and birth outcomes; inpatient safety in the neonatal intensive care unit); and,
- In August of 2011, CMS held a Medicaid/CHIP Quality Conference to provide States with the opportunity to share experiences and receive direct technical assistance on collecting the CHIPRA and eventually the ACA quality measures to drive quality improvement. States also had an opportunity to share experiences and get first-hand technical assistance on collecting data on the quality measures. More information can be found at www.cms.gov/MedicaidCHIPQualPrac/02_Spotlight.asp.

7. CMS implemented the Durable Medical Equipment (DME) Competitive Bidding Program in 9 geographic areas on January 1, 2011 after it was delayed by Congress in 2008 due to a number of issues. The Affordable Care Act expands this program to additional geographic areas in future years. CMS also implemented the End Stage Renal Disease (ESRD) bundled payment system on January 1, 2011. This new system was required by the July 2008 doc fix bill, and it pays dialysis clinics a single bundled payment rate for all of the items and services they furnish to ESRD beneficiaries.

Several new Medicare programs were implemented beginning on January 1st this year and I want to get a status update on how these programs are doing.

Specifically, I would like an update on the DME Competitive Bidding Program. Are beneficiaries able to find a DME contract supplier and get the necessary medical equipment?

Answer: The Administration believes that the competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is an essential tool to help Medicare pay appropriately for these items and to lower Medicare beneficiaries' out-of-pocket costs for them. As you note, the Centers for Medicare & Medicaid Services (CMS) launched the first phase of this program in nine different areas of the country on January 1, 2011. Through the use of supplier competition, the program set new, lower payment rates for certain medical equipment, such as oxygen equipment and certain power wheelchairs. As a result, more than four million Medicare beneficiaries living in the nine competitive bidding areas will save money, while continuing to have access to quality medical equipment from accredited suppliers they can trust. To date, the first phase of competitive bidding has yielded: savings of 35% compared to the fee schedule, 51% of contracts awarded to small businesses, and no changes in beneficiary health status. It is estimated by the CMS Office of the Actuary that the competitive bidding program will save more than \$17 billion in taxpayer fund and more than \$11 billion in beneficiary out of pocket costs in the first ten years of the program. CMS is currently preparing for implementation of Round 2 of the competitive bidding program and has recently announced the new DME items and geographic areas that will be included in this round. Bidding for Round 2 will begin early 2012.

I am pleased to report that implementation of the program is going very smoothly. CMS continues to deploy a wide array of resources across all of the competitive bidding areas to address any concerns that may arise. These resources include local State Health Insurance and Assistance Program (SHIP) offices, specially trained customer service representatives at 1-800-MEDICARE, and caseworkers in Medicare's regional offices who all stand ready to assist beneficiaries who may have questions about the program. In addition, there is a complaint and inquiry process for beneficiaries, caregivers, doctors, referral agents and suppliers to use for reporting concerns about a contract supplier or other competitive bidding implementation issues. This process is designed to ensure that all complaints are correctly routed, investigated, resolved, tracked and reported. Further, there is a Competitive Acquisition Ombudsman who will respond to complaints and inquiries from suppliers and others about the application of the program and issue an annual Report to Congress.

Since the beginning of the program, CMS has only received a handful of beneficiary complaints and has acted quickly to resolve each one. While 1-800 MEDICARE has received a number of inquiries about the program, the majority of such inquiries are on routine matters, such as selecting a supplier. In addition, CMS continues to monitor the implementation of the program very carefully and will take action when necessary. This monitoring includes the use of beneficiary surveys, active claims surveillance and analysis, contract supplier reporting, and tracking and analysis of complaints and inquiries. In the first 3 months of the program, a very

small number of inquiries—about 45 of the 89,254, less than one-tenth of one percent—have been classified as complaints.

8. I would also like an update on the ESRD bundled payment system. Are ESRD beneficiaries receiving quality dialysis care under this new payment system?

Answer: Yes, I have every confidence that beneficiaries are receiving quality dialysis services under the new ESRD prospective payment system (PPS). Together, the ESRD PPS and the ESRD Quality Incentive Program (QIP) are important tools the Centers for Medicare & Medicaid Services (CMS) is using to drive quality and efficiency improvements in ESRD facilities, while preserving access to care for beneficiaries.

The ESRD QIP establishes performance standards for dialysis facilities and provides payment adjustments to individual ESRD facilities based on how well they meet these standards. This legislatively mandated program was implemented with an initial performance measurement period of January 1, 2010-December 31, 2010 with payment consequences applied to calendar year 2012. Thus, efforts are well underway to promote high-quality dialysis services at Medicare facilities by linking CMS payments directly to facility performance on quality measures.

In addition to the QIP, CMS is in the midst of monitoring efforts to track the quality of care for this vulnerable population. Such activities include analysis of both qualitative data with direct input from patients, monitoring of complaints and grievances, and tracking the number of involuntary discharges. Additionally, since the implementation of the ESRD PPS on January 1, CMS has been carefully monitoring real-time access and clinical outcomes using active surveillance to ensure that Medicare beneficiaries are receiving quality dialysis services under the ESRD PPS. This analysis allows the agency to better understand the impact that the PPS is having on patients in the ESRD community and to take action when needed to ensure that Medicare beneficiaries continue to receive high quality renal dialysis services.

9. There are very vulnerable seniors in these programs. How is CMS ensuring that these seniors maintain access to high quality services? And how is CMS handling any issues that arise?

Answer: The Administration shares your commitment to ensuring that patients with End-Stage Renal Disease (ESRD) receive quality care under the Medicare program. Through various initiatives, including the new ESRD prospective payment system (PPS), quality incentive program (QIP), and collection of data on infection control, the Centers for Medicare & Medicaid Services (CMS) has actively worked to implement reforms that support quality of care in this critical area of the Medicare program.

CMS is in the midst of monitoring efforts to track the quality of care for this vulnerable population. Such activities include analysis of qualitative data with direct input from patients, monitoring of complaints and grievances, and keeping a careful eye on the number of involuntary discharges. Additionally, CMS has devised a surveillance plan to carefully monitor real-time access and clinical outcomes to ensure that Medicare beneficiaries are receiving quality dialysis services under the ESRD PPS. This analysis allows the agency to better understand the

impact that the PPS is having on patients in the ESRD community and to take action when needed to ensure that Medicare beneficiaries continue to receive high quality renal dialysis services.

10. The stimulus bill invested \$30 billion in health IT and required HHS to develop and publish standards for system functionality and interoperability by January 1, 2010. Beginning in 2011, the stimulus law provides Medicare and Medicaid bonus payments to hospitals and doctors that are “meaningful users” of qualified health IT systems. Starting in 2014, hospitals and doctors who are not meaningful users will face Medicare payment penalties.

There has long been bipartisan support for federal investments in health information technology. Recently, some in Congress have expressed a desire to eliminate federal incentives for health IT. But many providers have made significant investments in health IT based on the government’s financial commitment to modernizing the health system. In fact, many providers are taking out loans and hiring additional staff to bring their facilities and practices fully into the electronic age. It is reported that over 21,000 providers have signed up for the health IT incentive program since January. And Medicaid payments for health IT are flowing, and the first Medicare payments are expected in May.

Can you explain the Administration's view on health IT and what it would mean for the health care system in terms of cost and quality of care if the government breaks its promise to providers and eliminates this incentive program?

Answer: As directed by the Health Information Technology for Economic and Clinical Health Act (HITECH Act), the federal government is committed to stimulating the adoption and meaningful use of certified electronic health record (EHR) technology across the spectrum of health care. Accelerating health IT adoption will both improve the performance of our current health care system and serve as the foundation for broader improvements in quality, cost, and patient involvement in their care. Meaningful use of robust health IT will make it easier for providers to coordinate care by sharing important clinical information, promote patient safety by providing drug interaction alerts and other decision support tools, and enable patients to become more involved in treatment decisions.

In the places where it has already been deployed, we see strong evidence supporting the benefits of using EHRs and similar technologies. A paper recently published by Health Affairs examined 154 peer-reviewed studies published between July 2007 to February 2010 that focused on the effects of health IT on various aspects of care delivery, including effectiveness of care, patient safety, and efficiency of care. Among those studies, 92 percent found that use of health IT had overall positive effects. Equally important, there is increasing evidence that health IT has benefits for all health care providers, and benefits are not limited to the more technologically sophisticated organizations that have provided most of the data used to evaluate health IT in the past.

Providers throughout the country are increasingly arriving at the conclusion that adoption and meaningful use of health IT is in the best interest of them and their patients. The most recent

survey on EHR adoption among office-based physicians found that nearly 30 percent (29.6) of primary care physicians have an electronic health record system meeting “basic” functionality in their practice. This is nearly a 50 percent increase of those reporting the same capacity in 2009 (20.0). This survey, the National Ambulatory Medical Center EHR Supplement, is conducted annually by Office of the National Coordinator for Health IT (ONC) and the National Center for Health Statistics. Surveys indicate that 81 percent of hospitals and 41 percent of office-based physicians are already planning to participate in the EHR Meaningful Use incentive program. In addition, the Regional Extension Center (REC) program is one of several initiatives developed by the ONC designed to help providers who wish to achieve meaningful use of electronic health records.

Widespread support for the adoption and meaningful use of health IT is also evidenced by the number of vendors certifying health IT products for eligible professionals and hospitals to use in qualifying for incentive payments. Certification provides assurance to purchasers and other users that an EHR product offers the necessary technological capability, functionality, and security to help them meet the meaningful use criteria established for a given phase. Confidence in health IT systems is an important part of advancing health IT system adoption and realizing the associated benefits of improved patient care.

ONC established a temporary certification program in June 2010 for the purpose of testing and certifying EHR products, which could be used by eligible professionals and hospitals seeking to qualify for incentive payments under the Medicare and Medicaid programs. There are currently six ONC-Authorized Testing and Certification Bodies (ATCBs). To date, these ATCBs collectively have certified over 978 complete EHRs or EHR modules, many of which were developed by small companies.

The federal investment in health IT represents a critical step forward for our nation’s health care system. It is an indispensable building block in efforts underway at every level of our health care system – both public and private – to improve individual health, promote population health, and reduce the growth in health care costs.

The following examples demonstrate that eliminating the Medicare and Medicaid EHR Incentive Program would have a potentially devastating effect on efforts to achieve these goals.

- Banner Health, one of the largest non-profit healthcare systems in the US with approximately 27,000 employees and \$3.3 billion in annual revenue, saved \$2.6 million annually at its Estrella Medical Center after implementing an electronic health record system through improvements in nurse retention, decreased incidence of adverse drug events, reduced length of stay and other decreased expenses. *Hensing J, Dahlen D, Warden M, Van Norman J, Wilson BC, Kisiel S. Measuring the benefits of IT-enabled care transformation. Healthc Financ Manage. 2008 Feb;62(2):74-80.*
- A study of 41 urban hospitals in Texas found that hospitals with more advanced health IT had fewer complications, lower mortality, and lower costs than hospitals with less advanced health IT. *Amarasingham R, Plantinga L, Diener-West M, Gaskin DJ, Powe*

NR. Clinical information technologies and inpatient outcomes: a multiple hospital study. Arch Intern Med. United States 2009. p. 108-14.

- A recent study at the Mayo clinic in Rochester, MN found that the addition of a clinical decision support tool reduced unnecessary transfusions but did not have a negative effect on length of stay or mortality. Three intensive care units save tens of thousands of dollars on transfusion costs in the first year of the implementation. *Fernandez Perez ER, Winters JL, Gajic O. The addition of decision support into computerized physician order entry reduces red blood cell transfusion resource utilization in the intensive care unit. Am J Hematol. 2007 Jul;82(7):631-3.*
- After implementing an electronic health record system, three New York City dialysis centers found that patient mortality and staffing levels decreased by as much as 48 percent and 25 percent respectively in a 9 year period following the EHR implementation. *Pollak VE, Lorch JA. Effect of electronic patient record use on mortality in End Stage Renal Disease, a model chronic disease: retrospective analysis of 9 years of prospectively collected data. BMC Med Inform Decis Mak. England 2007. p. 38.*

11. Under current law, the marriage promotion and fatherhood programs are funded at a combined total of \$150 million per year. Last year, legislation passed that split the \$150 million per year equally between fatherhood and marriage. Prior to that legislation the split had been \$100 million for marriage and \$50 million for fatherhood. This year, the Administration has proposed policies that require more child support to reach children while continuing a commitment to enforcement. The Budget increases support for States to pass through child support payments to families, rather than retaining those payments, and encourages States to provide access and visitation services that can improve a father's relationship with his family. The Budget targets additional State incentives based on performance, which continues an emphasis on program outcomes and efficiency.

Secretary Sebelius, the President's budget contains a new approach to fatherhood programs and child support enforcement. Could you elaborate and explain the goals of these initiatives?

Answer: It is well established that children benefit from having the emotional and financial support of both parents. Evidence suggests that when fathers provide financial support to and are engaged with their children, their children are less likely to be poor and more likely to do better in school, avoid drugs and alcohol, and postpone pregnancy until marriage. In addition, child support is a critical source of income for many families. For poor, custodial parents who receive it, child support comprises 40% of their total family income. Therefore, we are working to improve the ability of non-custodial parents to provide that support and maintain connections with their children by putting forth proposals that encourage non-custodial parents to work, support their children, and play an active role in their children's lives.

The child support enforcement program clearly demonstrates a high return on investment. Currently, for every dollar invested in the program, \$4.78 in child support is collected. When

poor families receive child support payments they can be less reliant on other public assistance programs, producing savings in programs like SNAP and SSI.

However, reliable payment of child support depends upon steady jobs and parental cooperation. Since the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, the child support program has become highly automated, with 70 percent of child support collections being withheld from the paychecks of non-custodial parents. Utilizing highly automated processes is an effective strategy for collecting support from three-fourths of non-custodial parents (mostly fathers) who have stable employment. However, they do not work as well for the remaining quarter of fathers who do not have regular jobs and who face many of the same barriers as the mothers. Most child support debt is owed by fathers whose reported income is less than \$15,000 per year. Some evidence suggests that low-income men may be discouraged from legitimate employment when faced with child support obligations that are not well aligned with their circumstances. Low-income fathers are more likely to stay in jobs and pay child support when their child support obligations are set at realistic levels. A number of states have implemented "rapid review" procedures to determine if obligations continue to be realistic and state debt forgiveness opportunities to encourage fathers to obtain and maintain employment and make regular child support payments. The President's budget would require states to use best practices to review and adjust child support debt owed to the state and to discourage accumulation of unpaid child support debt during incarceration.

Research also indicates that fathers are more likely to remain employed and pay child support when they know that the money benefits their children. While 94 percent of collected support is paid to families, for those families that receive TANF, the government keeps most of the child support collected to reimburse welfare costs. However, research has shown that when child support is passed through to children, fathers pay more support, are more likely to hold jobs and less likely to participate in the underground economy. Some research indicates, additionally, that the likelihood of conflict between the parents may be reduced and reports of maltreatment decreased. As a result, we are proposing changes that encourage the pass through of all current monthly child support collections to TANF families.

Finally, research finds that child support payments, parent-child relationships, and cooperation between the parents improve when parenting arrangements are addressed through provision of services such as mediation and development of joint parenting plans. Although divorce decrees currently address both child support and access and visitation responsibilities, there is no regular mechanism to establish legal parenting responsibilities in cases where the parents never married. Thus, many fathers who pay child support do not have a legal right to see their children. To facilitate the relationship between non-custodial parents and their children, we propose updating the statutory purposes of the Child Support Enforcement program to recognize its evolving mission and activities to help parents cooperate and support their children and to require states to establish access and visitation responsibilities in all initial child support orders. Implementing domestic violence safeguards will be a critical component of this new state responsibility.

We also continue to support the responsible fatherhood and healthy marriage grants you reference, at the funding levels approved by Congress last fall. These funds support demonstrations of other efforts to build stronger families. We know there's a close connection

between having a job and being able to provide for a self-sufficient, functional family, and these programs will connect dads to jobs, training programs, and financial advice. They will also strengthen the bonds between couples with kids, reducing domestic violence and providing role models for adulthood. This work supports families without dads, too, affirming the central role that mothers have in the lives of their children.

12. As part of health reform, Medicare Advantage plans will be paid, partially, on their performance in CMS's 5-star quality rating system. This rating system measures a variety of performance factors of these private insurance plans. These factors range from the frequency of cancer screening to vaccination rates to how fast a plan's call center answers the phone. One of our overall goals in health reform is to better reward quality health care.

How quickly can HHS move the 5-star rating system to be more focused on quality measures and health care outcome measures?

Answer: The Star Rating System measures the overall quality of care and performance provided by MA organizations. The Star Rating system looks at many aspects necessary to determine plan quality including: outcomes, patient experience, access and process. While some measures do evaluate more administrative functions, new clinical measures aimed at evaluating outcomes are added regularly. Before each measure is adopted, it undergoes an exhaustive peer review process to ensure the accuracy and validity of the measure. For the 2012 ratings, new measures will be implemented, for example, measures regarding hospital readmissions and calculation of body mass index. The 2012 ratings also weight outcome measures more than process measures.

13. A number of important Medicare provisions expire each year. Congress has consistently extended these protections for seniors, but it is not a good way to run the program. I am particularly concerned about the Medicare therapy caps. Since 2006, Congress has authorized CMS to allow medically-necessary exceptions to the therapy caps. This costs about \$1 billion per year.

A better approach needs to be developed than to continuously extend the therapy exceptions process.

Has HHS looked into alternatives to the therapy cap and exceptions structure?

Answer: While the Centers for Medicare & Medicaid Services (CMS) has not proposed specific alternatives to the therapy cap and exceptions structure, there are a number of activities underway to examine and develop recommendations in this area. In the proposed rule to update the Physician Fee Schedule for CY 2011, CMS noted that there are two studies in progress to develop recommendations for alternatives and the agency solicited comments on potential short- and long-term alternatives to the therapy caps.

More specifically, the proposed rule described the Short Term Alternatives for Therapy Services (STATS) project, which was a 2-year project that ended on September 30, 2010, and identified a number of options. The first option would modify the current therapy caps exceptions process to capture additional clinical information regarding therapy patient severity and complexity in order

to facilitate medical review. The second option would involve introducing additional claims edits regarding medical necessity to reduce potential overutilization. The third option would adopt a per-session bundled payment that would vary based on patient characteristics and the complexity of evaluation and treatment services furnished in the session.

With regard to long-term alternatives, CMS expects that the Development of Outpatient Therapy Payment Alternatives (DOTPA) project will present long-term alternative recommendations to the therapy caps in CY 2013. The DOTPA project is a 5-year study (due for completion on January 28, 2013) to gather information about the condition of beneficiaries who use therapy services and to develop long term alternatives to therapy caps.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Orrin Hatch

1. I find it puzzling that the Administration has stated that the health overhaul law will increase Medicare Part A trust fund solvency by 12 years to 2029.

As you may already know, I sent a letter to the Medicare Trustees on June 24, 2010 along with Senator Gregg on the issue of double-counting Medicare savings in the new law.

The health care law contains more than \$500 billion in cuts to the Medicare program which were claimed by the Administration not only to improve Medicare solvency but also fund new entitlement spending at the same time.

Furthermore, the non-partisan Congressional Budget Office said on December 23, 2009, "The key point is that savings to the Hospital Insurance trust fund under PPACA would be received by the government only once, so they cannot be set aside to pay for future Medicare spending and, at the same time, pay for current spending on other parts of the legislation or on other programs."

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

Do you agree with you're the CMS Actuary's view that you cannot use the same dollar to extend the solvency of the Medicare Part A trust fund while also using it to pay for new federal spending?

Answer: The outlooks and projections for the Hospital Insurance (HI) Trust Fund and the budget are two separate calculations. Changes to Medicare are incorporated in estimates for both the budget and the HI Trust Fund. As a result of the changes and efficiencies in the Affordable Care Act, the Federal Deficit has been reduced, and the Medicare Trust Funds are more sustainable.

The President committed to fully pay for health care reform that would reduce the deficit over ten years. This was accomplished with the Affordable Care Act.

2. Last December, the President's "National Commission on Fiscal Responsibility and Reform" released a series of recommendations for reigning in federal spending. Many of those recommendations received support from members on both sides of the aisle and in both chambers of Congress. In addition, the Medicare Payment Advisory Committee

(MedPAC) has issued similar recommendations and yet this budget does not incorporate any of the recommendations provided to the Administration and Congress.

Why were these recommendations not included in this budget?

Answer: The President charged the bipartisan National Commission on Fiscal Responsibility and Reform with identifying policies to improve the fiscal situation in the medium term and to achieve long-term fiscal sustainability. The Commission began the important process of building a bi-partisan consensus on fiscal responsibility and expanded the debate to a broader range of options. The President's Budget does reflect many of the Commission's ideas even though it does not include all of its recommendations. For example, the Terminations, Reductions, and Savings volume of the Budget includes proposals for reduction or termination that were also recommended by the Commission. We look forward to continued dialogue with Congress on the budget in the spirit of the Commission's work.

3. The Administration's budget includes new spending for foster care. The "Budget in Brief," document describes "incentives to improve child outcomes in key areas by reducing the length of stay in foster care; increasing permanency through reunification, adoption and guardianship; decreasing rates of maltreatment and reducing rates of re-entry into foster care."

Can you elaborate on this proposal? What entities would be eligible for funding? How would these outcomes be measured?

Answer: This proposal will align financial incentives with improved outcomes for children in foster care, and those who are receiving in-home services or post-permanency services from the child welfare system to prevent entry or re-entry into foster care. States and Tribes that are running their own Title IV-E program would be eligible to earn these funds. We look forward to working with Congress to establish the mechanisms for setting targets and measuring performance, and allocating funding to States and Tribes that meet those targets.

4. The proposal to improve foster care further states that it would reduce "costly and unnecessary administrative requirements." Can you specify which of the administrative requirements would be reduced?

Answer: The President proposes to explore ways in which the Federal government can reduce the administrative burden on States and instead provide them with more flexibility to produce better outcomes for children. Reducing the administrative burden on States provides them with the flexibility to allocate more resources to serving children and families. We look forward to working with Congress in moving forward with ways to address administrative efficiencies.

5. In the Budget document released to Congress, the Administration did not include a detailed legislative proposal for TANF reauthorization, even though the program is set to expire at the end of this fiscal year.

Does the Administration once again, support another 1 year extension of TANF? Is the Administration concerned that continuing to fail to propose detailed legislation for TANF reauthorization will imperil this effort?

Answer: We look forward to working with Congress to develop a bipartisan TANF reauthorization proposal. When a long-term reauthorization is considered, the Administration would be interested in exploring with Congress a variety of strategies to strength the program's ability to improve outcomes for families and children, including helping more parents succeed as workers by building on the recent successes with subsidized employment; using performance indicators to drive program improvement; and establishing a funding structure to respond more effectively in the event of a future economic downturn.

6. Secretary Sebelius, one of the challenges in determining an appropriate level of child care spending has been the difficulty in quantifying what an increase in child care funding means in terms of increasing actual child care slots.

Yet, the Administration's budget includes \$500 million in increased mandatory funding and \$800 million in increased discretionary funding for child care and makes the claim that increasing those child care funds would enable 220,000 more children to receive child care.

Please provide the analysis that supports this claim.

Answer: The estimate of 220,000 additional children is a projection derived by comparing the number of children who would be served in FY 2012 assuming funding at FY 2010 levels, to the number of children that could be served with an additional \$1.3 billion in funding. When the FY 2012 was developed we did not yet have a discretionary appropriation for FY 2011.

In FY 2011, discretionary funding was increased by \$100 million. Therefore, if we revisit this estimate and assume the actual FY 2011 funding level carries over into FY 2012, we estimate that States could serve an additional 210,000 children that could otherwise be served in the absence of the proposed \$1.2 billion increase.

These estimates take into account a number of factors including spending rates, State matching requirements, the percentage of funds spent on direct services to families, and increases in the cost of child care based on historical trends.

7. In the President's budget for the FDA, it shows an increase of 2,055 additional FTEs from 2010 to 2012.

Please provide a breakdown of the FTEs per program area and those being hired with funding from user fees versus those hired using appropriated funds under the agency's budget authority.

Answer: In FY 2012, the additional FTEs are needed to continue implementation of the Food Safety Modernization Act, strengthen the Agency's ability to support the development of

medical countermeasures, conduct research on tobacco products, and further efforts to modernize and improve safety throughout the foreign and domestic supply chain of medical products.

Food and Drug Administration			
FY 2012 President's Budget Request FTEs			
Program	FY 2010	FY 2012 President's Budget Request	
	Actuals	Total	+/- FY2010
	FTE	FTE	FTE
Salaries and Expenses:			
Foods.....	3,387	4,173	786
<i>Budget Authority</i>	<i>3,387</i>	<i>3,824</i>	<i>437</i>
<i>User Fee.....</i>	<i>0</i>	<i>349</i>	<i>349</i>
Human Drug	3,835	4,503	668
<i>Budget Authority</i>	<i>1,937</i>	<i>2,193</i>	<i>256</i>
<i>User Fee.....</i>	<i>1,898</i>	<i>2,310</i>	<i>412</i>
Biologics.....	1,250	1,370	120
<i>Budget Authority</i>	<i>874</i>	<i>926</i>	<i>52</i>
<i>User Fee.....</i>	<i>376</i>	<i>444</i>	<i>68</i>
Animal Drugs and Feeds	767	794	27
<i>Budget Authority</i>	<i>677</i>	<i>682</i>	<i>5</i>
<i>User Fee.....</i>	<i>90</i>	<i>112</i>	<i>22</i>
Devices and Radiological Health	1,801	1,884	83
<i>Budget Authority</i>	<i>1,525</i>	<i>1,553</i>	<i>28</i>
<i>User Fee.....</i>	<i>276</i>	<i>331</i>	<i>55</i>
National Center for Toxicological Research	246	215	(31)
<i>Budget Authority</i>	<i>246</i>	<i>215</i>	<i>(31)</i>
<i>User Fee.....</i>	<i>0</i>	<i>0</i>	<i>0</i>
Tobacco Act Program.....	90	392	302
<i>Budget Authority</i>	<i>0</i>	<i>0</i>	<i>0</i>
<i>User Fee.....</i>	<i>90</i>	<i>392</i>	<i>302</i>
Headquarters and Office of the Commissioner.....	947	1,047	100
<i>Budget Authority</i>	<i>722</i>	<i>742</i>	<i>20</i>
<i>User Fee.....</i>	<i>225</i>	<i>305</i>	<i>80</i>
FDA White Oak Consolidation.....	0	0	0
Other Rent and Rent Related Activities	0	0	0
GSA Rent.....	0	0	0
<i>Subtotal, Budget Authority.....</i>	<i>9,368</i>	<i>10,135</i>	<i>767</i>
<i>Subtotal, User Fee.....</i>	<i>2,955</i>	<i>4,243</i>	<i>1,288</i>
TOTAL Salaries & Expenses	12,323	14,378	2,055
Export Certification User Fee	20	18	(2)
Color Certification Fund User Fee.....	38	40	2
Buildings and Facilities.....	0	0	0
TOTAL PROGRAM LEVEL	12,381	14,436	2,055

8. On February 10th, Congressional Budget Office (CBO) Director Elmendorf testified before the House Budget Committee where he elaborated on CBO's earlier estimation that the new health law would have the effect of reducing jobs by approximately 800,000 individuals. At a time when Americans are urging Congress to create jobs, this law clearly is having the opposite effect.

According to the proposed budget, HHS will add more than 4,700 new positions in the next two years. This year alone, CMS will add 1000 new positions, which is an increase of 21% over 2010 levels. However, in my opinion, this is not the type of job growth Americans are requesting.

Can you please tell us exactly how many new staff will be hired to work on the implementation of the new health law and how many taxpayer dollars will be spent on this endeavor?

Answer: CBO estimated in an August 2010 Report that "the legislation (the Affordable Care Act), on net, will reduce the amount of labor used in the economy by a small amount—roughly half a percent—primarily by reducing the amount of labor that workers choose to supply."¹ It is therefore entirely misleading to imply that CBO estimates that jobs will decline because employers would reduce the number of positions available. Instead, CBO clearly states that the number of people who are working primarily for the purposes of getting health insurance (including seniors and those working multiple jobs) would voluntarily scale back their labor force participation.

The Affordable Care Act made a number of changes to current programs that are under the purview of HHS. It is difficult to separate the full time equivalents (FTE) working on health reform specific activities from those working on activities that are the normal course of business for these programs. However, the Act did establish funding sources which could be used to pay for new staff. As of December 31, 2010, HHS has hired 672 people from the \$1 billion appropriation provided in the Act for implementation. In addition, over 350 staff across the Department are supported by other appropriations in the Act. Based on HHS averages for these types of employees, the full cost (including salaries/benefits, rent, and other expenses) of these employees would be in the range of \$187 million per year.

9. I note that the President's budget includes a \$270 million increase in Health Care Fraud and Abuse Control (HCFAC) fund money for FY 2012 of which CMS will get \$389.9 million. This seems curious given that Administrator Berwick and you have both stated publicly that the Centers for Medicare & Medicaid Services (CMS) has "all the tools and resources it needs to fight waste, fraud and abuse" and that CMS received a significant

¹ *The Budget and Economic Outlook: An Update*. Congressional Budget Office, Aug. 2010. Web. <<http://www.cbo.gov/ftpdocs/117xx/doc11705/08-18-Update.pdf>>.

budget increase for program integrity efforts through the new health law and other recent legislation such as the Small Business Act.

Can you provide a detailed breakdown of how the \$389.9 million will be spent? Does this include money for full time employees or is this money specifically for programmatic initiatives?

Answer: As CMS implements the new authorities in the Affordable Care Act, we have a significant opportunity to enhance our existing efforts to combat fraud, waste, and abuse in Federal health care programs. These new authorities offer more front-end protections to keep those who are intent on committing fraud out of the programs and new tools for deterring wasteful and fiscally abusive practices, identifying and addressing fraudulent payment issues promptly, and ensuring the integrity of Medicare, Medicaid, and CHIP. A breakdown of how CMS plans to spend the \$389.9 million in allocated HCFAC funds is below.

Total Program Integrity Funding FY 2012	
<i>Dollars in Thousands</i>	
Project or Activity	FY 12 Request
I. Strengthening Program Integrity Activities in Medicare Advantage and Medicare Part D	
Medicare Drug Integrity Contractors (MEDICs)	\$20,900
Part C & D Contract/Plan Oversight	\$29,648
Monitoring, Performance Assessment, and Surveillance	\$52,318
Program Audit	\$38,200
Compliance/Enforcement	\$24,900
Sub Total	\$165,966
II. Establishing Additional Regional Call Centers and Focused Beneficiary Outreach	
Fraud & Abuse Customer Service Initiative	\$7,300
Field Offices/Rapid Response Staffing/Oversight (3 field offices and additional rapid response team)	\$5,000
Sub Total	\$12,300
III. Increasing Funding for Program Integrity Demonstrations/Special Initiatives	
DME Initiative	\$7,800
High Risk Demonstration	\$0
Predictive Modeling Prepayment	\$5,500
Predictive Modeling / Provider Enrollment Screening	\$5,500
1-800 next generation desktop	\$2,450
Case Management System	\$5,000
MSN Improvements	\$1,100
Sub Total	\$27,350
IV. Prevent Excessive Payments	
Automated Fraud Edits	\$3,400
Edit Validation Module (National)	\$10,110
Executive Order Do Not Pay List	\$3,950
Medical Review and Provider Enrollment Consolidation	\$14,445
Sub Total	\$31,905
V. Enhanced Provider Oversight Efforts	
Revalidation of Providers/Suppliers/Site Visits	\$8,900
Overpayment/Payment Suspension Screening	\$5,000
DMEPOS Validation Contractor	\$1,500
Compromised Numbers Database	\$6,000

CMS: Prevention / Detection - One PI Data Analysis and Staffing	\$21,000
Sub Total	\$42,400
VI. Error Rate Measurement	
Payment Error Rate Measurement (PERM) Medicaid	\$33,000
Executive Order 50 % reduction in error rate +	\$26,286
Sub Total	\$59,286
X. New Activities Integral to HEAT Goals	
CMS:HEAT Support / Strike Force Team	\$23,788
CMS: Enhanced Medicaid Audits	\$11,644
HEAT maps	\$300
ALJ Expansion Participation	\$4,000
Appeals/Provider Inquires	\$2,000
Parts B, D, & Medi-Medi Integrated Data Repository	\$9,000
Sub Total	\$50,732
CMS Program Integrity Funding Budget Total	
	\$389,939

10. For the programmatic initiatives, the HHS Budget in Brief details a number of efforts dealing with data analytics and pre-payment edits, can you explain how this differs from efforts mandated in those areas under the new health law and the Small Business Act where funding was already allocated?

Answer: The predictive modeling provisions in P.L. 111-240 require CMS to deploy predictive modeling in certain programs at specific times. Allowing the flexibility we are seeking in the FY 2012 legislative proposal does not mean that CMS will not continue to aggressively develop predictive analytics; however, it would allow CMS to expand predictive analytics in a way that spends and targets our resources as efficiently as possible. Greater flexibility sought in the legislative proposal would allow CMS to target technology in areas with the greatest return on investment, and enable us to adjust the implementation timeline, scope of services subject to predictive analytics, and the time period under which models need to be evaluated as necessary. The proposal would also recognize that some States may require extra time to implement and perfect their predictive models. The legislative proposal is estimated to result in \$100 million in savings over 10 years, due to increased efficiency.

The proposal also recognizes that implementing predictive analytics in Medicaid and CHIP could be a heavy lift for some States and may require extra time for adoption and perfection of their models. Predictive modeling is only a part of an ongoing CMS effort to reduce the Medicare fee-for-service error rate. Additional discretionary investments would allow CMS to increase the number of claims subject to pre-payment review, enhance medical review for high risk providers, and improve provider education on proper billing for common errors. Increased funding would also allow CMS to deploy national pre-payment edits to prevent improper payments before they occur and to further expand the Integrated Data Repository.

11. The General Departmental Management Budget for the Department of Health and Human Services shows a \$377 million dollar increase, part of which is to be used at Departmental discretion to strengthen program integrity by reducing fraud, waste and abuse and by holding programs accountable.

Can you please provide more detail regarding the specific types of activities related to reducing fraud, waste and abuse which will be undertaken with this funding and how this differs from the activities being undertaken at the various HHS operational divisions for which specific funding was requested?

Answer: In addition to the HHS operating divisions' efforts to reduce fraud, waste, and abuse, in May of 2010, the Secretary announced her Program Integrity Initiative. The core principle of the initiative is to increase efforts to integrate program integrity into its program operations and business processes to reduce waste, fraud, and abuse. The initiative is intended to cover every program within HHS over time – from Medicare and Medicaid, to Head Start and LIHEAP, to medical research and the public health grants.

12. President Obama stated in June 2010 that the Administration would cut the Medicare fee-for-service improper payment rate in half by 2012 to eliminate billions of dollars in improper payments. One of the primary means by which the Administration appears to be trying to achieve that goal is through the use of Recovery Audit Contractors (RACs).

However, if the goal of reducing improper payments and the RAC recoveries is to return more money to the Medicare trust fund, can you please explain to me why CMS is now proposing to retain a portion of the RAC recoveries to help prevent fraud and abuse? What types of initiatives is CMS proposing to implement in order to achieve the \$230 million in savings from the use of the RAC recoveries that is projected in the budget?

Answer: CMS believes it is very important for the majority of collections made by Recovery Auditors to be returned to the Medicare Trust Funds. The President's FY 2012 Budget proposes that CMS retain a maximum of 25 percent of collections, which would ensure protection of the Trust Funds. In addition, as additional corrective actions are instituted, the administrative cost of the program should decline as fewer improper payments are identified. These additional dollars will allow CMS to institute widespread corrective actions, such as new processing edits and provider education and training to prevent future improper payments.

13. The Administration has a tendency to promise savings or "pay-fors" through newly-identified *efficiencies* and *fraud and abuse* programs with little recourse if the programs fail to meet stated goals.

Isn't it true that of the \$62.2 billion cost of a two year freeze, over 20 percent, or \$14.3 billion, of the offset is attributed to fraud and abuse programs the administration should already be successfully implementing?

Answer: The Administration supports permanent, fiscally responsible reform to the SGR so that seniors and their doctors can depend on stable, predictable physician payments. If enacted by Congress, the legislative proposals in the President's Budget Request to enhance and strengthen program integrity activities would provide CMS with additional authorities, beyond those that are in current law, to protect the integrity of our programs. These proposals would build on the program integrity enhancements included in the Affordable Care Act, which CMS is already implementing. Beyond the important program integrity authorities already given to CMS in the Affordable Care Act, the new tools proposed in the President's FY 2012 Budget program integrity legislative package are estimated to save \$32.3 billion over 10 years.

14. This SGR proposal by the Administration seems much like the double counting in the new health law, where the administration utilizes the full budget window for offsets but only part of it for the outlays. In this case, the Administration has listed a payment freeze in the 10 year budget window, but fails to provide any offsets beyond 2013.

Is it true that the pay-fors provided by the Administration to address a temporary two year payment fix to the SGR are paid out over the full ten years in the budget?

Answer: The Administration has and continues to support permanent reform to the SGR in a *fiscally responsible* way so that seniors and their doctors can depend on stable, predictable physician payments. To that end, the budget includes offsets that would more than cover two years of an extension to prevent dramatic cuts in physician payments. Finding a long-term solution is critical to ensure Medicare is viewed as a dependable business partner, and to form a solid foundation for health care in our country.

We're committed to working with Congress to address this matter in the coming year.

15. The budget addresses the newly-created Center for Medicare and Medicaid Innovation (CMI). The new health law granted CMS extensive authorities to test payment and delivery models for Medicare beneficiaries through this center and dedicated \$10 billion of funding over the next 10 years, and for each subsequent 10-year period, to these efforts with very few limitations on the scope of authority permitted in this initiative.

Is it true there is no judicial review of the CMI programs? How will beneficiary access and quality not be impacted by CMS experimentation?

Answer: The Innovation Center is a new component of CMS, dedicated to improving the quality of care afforded to Medicare, Medicaid, and CHIP beneficiaries. The ACA requires the Center work "to reduce program expenditures...while preserving or enhancing the quality of care furnished to individuals." From this mandate, the Center developed a mission "to help transform the Medicare, Medicaid and CHIP programs to deliver better healthcare, better health and reduced costs through improvement for CMS beneficiaries." The Center has developed criteria for the portfolio of projects it will initiate and maintain, which is available on the website at www.innovations.cms.gov.

While certain aspects of the work of the Innovation Center are not subject to judicial review, per statute, the Center's mission makes clear that improving patient outcomes and experiences is the focal point of its work.

16. The Administration has touted the success of the High Risk Pools Program and the Early Retiree Reinsurance Program established under the health overhaul law.

However, the President's budget highlights flaws in the sustainability of these programs due to dramatically decreasing levels of funding. For example, according to the President's budget the Early Retiree Reinsurance Program received \$3.5 billion in FY11, is scheduled to receive \$1.3 billion in FY12, but is scheduled to receive only \$24 million in 2013. Therefore available funds for the program in FY13 will drop by 99.4% from FY11 funding levels.

The total funding for the program for FY2011 through FY2013 was \$5 billion, which provided the Administration with the ability to budget the total cost of the program over three years. However, this is yet another example of uncertainty fueled by the health overhaul law for businesses at a time when certainty is critical to growing our economy. What impact will this have on businesses participating in the program? Will the current participation levels be sustainable with such the dramatic decreases in funding in the last two years?

Answer: The President's Budget projects that the \$5 billion will be exhausted in FY 2012. HHS is closely monitoring the program, and as further data become available on implementation, we look forward to working with Congress to address emerging issues. HHS will publish updated ERRP data periodically to keep the plan sponsor community apprised of current program status. Reimbursement requests are processed in the order in which they are received. ERRP will process reimbursement requests and issue reimbursements as funds are available.

17. The President's own Bipartisan Fiscal Commission noted that the Community Living Assistance Services and Supports (CLASS) Act was viewed as "financially unsound" by many experts, and the Commission recommended significantly reforming or repealing the CLASS program.

I am concerned that the Budget did not propose changes to the CLASS Act. Do you agree with your CMS chief actuary that the program is at a "significant risk of failure," and with the Fiscal Commission's recommendations to reform or repeal CLASS?

Answer: Please see the Department's report on the CLASS Act, which was released on October 14, 2011. It can be accessed at <http://aspe.hhs.gov/daltcp/Reports/2011/class/index.shtml>.

18. I am concerned that the FY 2012 Budget fails to propose the major recommendations of the Bipartisan Fiscal Commission.

Why does the Budget not address more effective ways to provide care for dual eligible beneficiaries, a policy the Fiscal Commission estimated would save \$12 billion? Or propose to reduce funding for unnecessary administrative costs- a policy the Fiscal Commission estimated would save \$2 billion?

Answer: The President charged the bipartisan National Commission on Fiscal Responsibility and Reform with identifying policies to improve the fiscal situation in the medium term and to achieve long-term fiscal sustainability. The Commission began the important process of building a bi-partisan consensus on fiscal responsibility and expanded the debate to a broader range of options. The President's Budget does reflect many of the Commission's ideas even though it does not include all of its recommendations. We look forward to continued dialogue with Congress on the budget in the spirit of the Commission's work. While Medicare and Medicaid generally cover different populations, there are a significant number of individuals eligible for both programs. Medicare-Medicaid enrollees represent among the most chronically ill and costly segments of both the Medicare and Medicaid populations, with many having multiple severe chronic conditions and/or long-term care needs. Dual eligible beneficiaries represent 15 percent of Medicaid enrollees and account for 39 percent of total Medicaid costs. Since these beneficiaries must navigate the two programs separately, care provided to this population may be less than optimally efficient and effective. The Fiscal commission proposed to place these individuals in Medicaid managed care to address this issue.

However, created by the Affordable Care Act, the Federal Coordinated Health Care Office, also known as the Medicare-Medicaid Coordination Office has already launched a variety of initiatives to meet its Congressional charge to improve access, coordination and cost of care for Medicare-Medicaid enrollees. Our work falls into the following broad areas:

- Program Alignment
- Data and Analytics
- Models and Demonstrations

The Alignment Initiative is an effort to advance beneficiaries' understanding of, interaction with, and access to seamless, high quality care that is as effective and efficient as possible. Better alignment of the two programs can reduce costs by improving health outcomes and more effectively and efficiently coordinating care while increasing beneficiaries' awareness and satisfaction with the programs to ease their care journey.

On May 11, 2011, the Medicare-Medicaid Coordination Office also announced a new process to provide States access to Medicare data to support care coordination for individuals enrolled in both Medicare and Medicaid.² Access to Medicare data is an essential tool for States seeking to coordinate care, improve quality, and control costs for their highest cost beneficiaries.

On July 08, 2011, the Medicare-Medicaid Coordination Office announced several initiatives through demonstrations of delivery and payment models to improve the quality of care Medicare-Medicaid enrollees receive by expanding access to seamless, integrated programs, and

² http://www.cms.gov/medicare-medicaid-coordination/06_MedicareDataforStates.asp#TopOfPage

better care management. The first demonstrations³ provide further opportunities to partner with States focusing on new financing models to catalyze State investments in coordination of care for Medicare-Medicaid enrollees. Aligning incentives for improving care and lowering costs between the programs is a key component of a fully integrated system. As a result, these new payment and service delivery models reduce program expenditures under Medicare and Medicaid, while preserving or enhancing the quality of care furnished to Medicare-Medicaid enrollees.

The second demonstration⁴ focuses on reducing preventable inpatient hospitalizations among residents of nursing facilities. Hospitalizations are often expensive, disruptive, disorienting, and dangerous for frail elders and people with disabilities, and cost Medicare billions of dollars each year. CMS-funded research on Medicare-Medicaid eligible nursing facility residents in 2005 found that almost 40-percent of hospital admissions were preventable, accounting for 314,000 potentially avoidable hospitalizations and \$2.6 billion in Medicare expenditures.⁵ As part of the demonstration, this fall CMS will initiate a competitive process to select independent organizations to partner with and implement evidence-based interventions at interested nursing facilities.

The Fiscal Commission recommended reducing funding for Medicaid administrative costs that are duplicative of funding originally included in the Temporary Assistance for Needy Families (TANF) block grants. While the FY 2012 President's Budget does not include this specific proposal, the Budget includes a package of program integrity proposals yielding ten-year savings of nearly \$24 billion to reduce fraud, waste, and abuse in the Medicaid program and provides CMS with tools to promote integrity in Federal-State financing. We believe the proposals in the President's Budget are a more targeted approach to efficiently managing these programs without decreasing Federal support to States.

19. The President's Budget proposal estimates \$6.1 billion in savings from the risk adjustment data validation (RADV) for Medicare Advantage contracts. While we all want to see taxpayers dollars appropriately spent, I have heard many complaints about the lack of transparency and lack of consistency with which CMS has performed these audits on Medicare Advantage plans.

I have heard concerns that CMS is not applying consistent audit standards from plan to plan within Medicare Advantage and also that CMS is not applying consistent audit standards between fee-for-service and Medicare Advantage.

³ http://www.cms.gov/medicare-medicaid-coordination/08_FinancialModelstoSupportStatesEffortsinCareCoordination.asp#TopOfPage

⁴ http://www.cms.gov/medicare-medicaid-coordination/09_ReducingPreventableHospitalizationsAmongNursingFacilityResidents.asp#TopOfPage

⁵ Walsh, E., Freiman, M., Haber, S., Bragg, A., Ouslander, J., & Wiener, J. (2010). Cost drivers for dually eligible beneficiaries: Potentially avoidable hospitalizations from nursing facility, skilled nursing facility, and home and community-based services waiver programs. CMS Contract No. HHSM-500-2005-00291. Available at: <https://www.cms.gov/reports/downloads/costdriverstask2.pdf>

It is difficult for Medicare Advantage plans to be accountable when there is a black box methodology being used to evaluate them. I appreciate the fact that CMS has finally proposed draft methodology for the RADV audits, but there are audits ongoing now.

When can we expect to see clear, transparent, and consistent standards be released by CMS for these RADV audits?

Answer: I share your concern with balancing the need to ensure that tax payer funds are spent appropriately with the industry's need for consistent and transparent oversight. As you know, CMS is closely reviewing the methodology by which we sample and calculate Part C risk adjustment payment errors.

By way of background, in mid-2008, CMS began to test a different method for auditing Part C plans (currently called risk adjustment data validation (RADV) audits). Under this approach, auditors select a sample of enrollees from an MA organization and, based on medical record review, a contract-specific risk adjustment payment error rate is calculated. Thirty-seven RADV audits are currently underway and to date no overpayments have been collected as a result of these audits.

On December 22, 2010, CMS released its proposed methodology for sampling MA enrollees, computing under or overpayments, and calculating recovery amounts. Comments were due on January 21, 2011 and CMS received numerous comments and concerns from industry on the proposed methodology. CMS is carefully reviewing and considering those comments while working to finalize a consistent and fair methodology that CMS would clearly communicate through regulation and through written memoranda to the industry.

20. While we have disagreed about the repeal of the entire health overhaul law, the Administration has recently decided it strongly agreed with Republican members in Congress that 1099 should be repealed.

However, the budget includes language that would only repeal the requirement for goods but not for services. This contradicts the President's strong support for its repeal.

Can you please clarify the position of the Administration, and provide any other caveats related to 1099 that we will need to know as we continue with our efforts to repeal the onerous and costly mandate on businesses across the country?

Answer: A bill repealing this provision was signed into law on April 14, 2011.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable John Rockefeller

1. Medicaid is a huge economic engine – it supports doctors, hospitals, nursing homes, and community health centers in every state. Nearly 400,000 West Virginians receive their health care through Medicaid. Medicaid pays almost 20 percent of the total cost of West Virginia’s health care system and is responsible for an estimated 19,800 jobs. Congress provided states with \$87 billion in extra Medicaid funds through the Recovery Act, and an extra \$16 billion through June. The people covered by Medicaid matter. They are 68 million people, including 27 million children, working adults, seniors and persons with disabilities covered at the discretion of states.

Madame Secretary, if Medicaid were not available to these people, where else would they go for care? How does Medicaid act as an important building block for health reform?

Answer: As Secretary, I am committed to ensuring access to care for Medicaid beneficiaries. Medicaid has a proven track record of delivering high quality care to vulnerable, low-income populations who do not have another source of care. The Affordable Care Act builds on the Medicaid program, providing substantial support to our State partners to help finance the majority of their costs for covering newly eligible individuals up to 133 percent of FPL. Further, for low-income people that do not qualify for the expansion of coverage in Medicaid, the Affordable Care Act will provide health insurance premium tax credits and supports to help them access coverage through State-Based Affordable Insurance Exchanges in 2014.

2. Everybody wants consumers to be clear on what they are buying. Thanks to the health reform law, if something is not covered in a particular health insurance policy, insurers will now have to make that crystal clear, instead of hiding behind pages of legalese. Health insurers will also have to provide a “Coverage Facts Label” like the nutrition label on a box of cereal that allows consumers to compare benefits and costs more easily across plans.

Secretary Sebelius, can you provide an update on how the health reform law will empower consumers to help them understand what their health insurance really covers and how much it really costs? What has HHS done so far to implement these provisions? How will this change the way consumers buy health insurance?

Answer: On August 22, 2011, the Departments of Health and Human Services (HHS), Labor, and the Treasury proposed new rules (CMS-9982-P) under the Affordable Care Act that require health insurers and group health plans to provide Americans with private insurance with clear, consistent and comparable information about their health plan benefits and coverage. Specifically, the proposed regulations provide rules implementing Affordable Care Act provisions that would ensure consumers have access to two forms that will help them understand and evaluate their health insurance choices. These forms include:

- An easy to understand Summary of Benefits and Coverage; and
- A uniform glossary of terms commonly used in health insurance coverage such as “deductible” and “co-pay”.

Under the rules proposed in the guidance, insurance companies and group health plans will provide consumers with a concise document detailing, in plain language, simple and consistent information about health plan benefits and coverage. The proposed regulations contain standards that are intended to ensure that this summary document, the Summary of Benefits and Coverage, will help consumers better understand the coverage they have and, for the first time, allow them to easily compare different coverage options. It will summarize the key features of the plan or coverage, such as the covered benefits, cost-sharing provisions, and coverage limitations and exceptions. People will receive the summary when shopping for coverage, enrolling in coverage, at each new plan year, and within seven days of requesting a copy from their health insurance issuer or group health plan. More information on the proposed rules is available at <http://www.healthcare.gov/news/factsheets/labels08172011a.html>.

3. Under the health reform law, health insurance companies will no longer be allowed to deny coverage to people with pre-existing conditions, nor will they be allowed to charge so much that people cannot afford coverage. Without a mandate, because healthy people will be less likely to enroll, premiums for individuals buying health insurance will be 15-20% higher, and there will be 16 million more uninsured people by 2019, according to the Congressional Budget Office. The health reform law already provides significant subsidies, and it provides exemptions for people who still cannot afford it.

Madame Secretary, what will happen to the 129 million people who currently have a preexisting condition without the individual responsibility requirement in health reform?

Answer: The individual responsibility provision in the Affordable Care Act says that as participants in the health-care market, Americans should pay for insurance if they can afford it. That's important because when people who don't have insurance show up at emergency rooms, we don't deny them care. The costs of this uncompensated care - \$43 billion in 2008 - are then passed on to State, local, and Federal governments, providers, small businesses and Americans who have insurance. We all want health care to be affordable and available when people need it. To make that a reality, we have to stop imposing extra costs on people who carry insurance, and that means everyone who can afford coverage shall carry minimum health coverage starting in 2014.

If we want to prevent insurers from denying coverage to people with preexisting conditions, it's essential that everyone have coverage. Imagine what would happen if everyone waited to buy car insurance until after they got in an accident. Premiums would skyrocket, coverage would be unaffordable, and responsible drivers would be priced out of the market. The same is true for health insurance. Without an individual responsibility provision, controlling costs and ending discrimination against people with preexisting conditions doesn't work.

Under the Affordable Care Act, most individuals who can afford it will be required to obtain basic health insurance coverage or pay a tax penalty. However, the Affordable Care Act

specifies a number of circumstances in which individuals would be eligible for an exemption from the individual responsibility requirement or payment. These include: individuals who cannot afford coverage, individuals whose income is below the tax filing threshold, individuals who claim a hardship exemption, individuals who request a religious conscience exemption or membership in a health care sharing ministry, and individuals who are members of an Indian tribe, among others.

4. Health care is the economic engine for the 21st Century. During this recession, the health care sector has actually added jobs while virtually every other sector of our economy lost jobs. Health reform provides \$1.5 billion in funding for the National Health Service Corps, expanded other loan repayment programs, and a 10% increase in Medicare reimbursement for primary care providers. We also know we will need an additional 50,000 health information technology workers in the coming years.

Madame Secretary, can you describe the important link between investments in the health care workforce and economic growth – particularly in rural and underserved areas? How is HHS working to expand the number of primary care providers? How would de-funding health reform undermine efforts to close the health workforce gap?

Answer: There is a strong link between health care workforce and economic development and the Bureau of Labor Statistics projects that employment in the health care and social assistance industry is projected to increase by approximately 25 percent by 2018. The link between health care jobs and economic development is particularly strong in rural communities where health care is often the number one or number two employer. Studies from the National Center for Rural Health Works indicate that the revenues to the hospital from physician activity will also support employment and generate payroll. An additional 12.6 jobs and \$434,627 in income will be created at the hospital from patient visits. Total hospital revenues are \$751,949. The same study indicates that the economic impact of a doctor on a local rural community is 23 jobs and \$1,533,000 income.

HHS has been focusing on expanding the primary care workforce for several years through investments in programs such as the National Health Service Corps as well as through training programs such as Title VII and VIII and the Department of Labor has awarded 38 Recovery Act High Growth and Emerging Industry initiative grants that help train health care workers to meet the growing demand from this industry. There are shortages of primary care providers across the country but particularly in rural communities. Currently, approximately 50 percent of NHSC placements practice in rural communities. The National Health Service Corps (NHSC) addresses the nationwide shortage of health care providers in both rural and urban health professional shortage areas by providing scholarship and loan repayment programs to health professionals committed to a career in primary care and service in underserved communities. The increase in funding for the NHSC provided by the health reform law will help bolster the supply of clinicians serving at NHSC sites including rural health clinics, community health centers, and other primary care sites with a shortage of health professionals. By the end of FY 2011, the NHSC is projected to have 9,325 clinicians serving in health professional shortage areas, supported by annual appropriations, the American Recovery and Reinvestment Act (ARRA), and the Affordable Care Act (ACA).

Still, the challenges remain. While rural America is home to roughly 20 percent of the population, only about 10 percent of the country's physicians practice in rural communities. Close to two-thirds (77 percent) of rural counties are primary care health professional shortage areas (HPSAs). In 2005 there were 55 primary care physicians per 100,000 persons in rural areas compared with 72 in urban areas.

The Administration has made investing in the primary care workforce a priority. In Fiscal Year 2010, the Administration allocated \$250 million from the Prevention and Public Health Fund to health professions training. These investments will fully train 1,700 new primary care providers, including primary care physicians, nurse practitioners and physician assistants, by 2015. The ACA also created the Teaching Health Center Graduate Medical Education program with \$230 million in mandatory appropriations to train new primary care providers in community-based settings. In addition, the President's Fiscal Year 2012 budget includes a proposed initiative to expand the primary care workforce by 4,000 providers over five years. The Fiscal Year 2012 budget also proposes to invest in health workforce data collection and analysis and state health workforce planning efforts to better match resources with health workforce needs. The Administration is committed to continuing to invest in building the health care workforce for the future while partnering with states and others to ensure that investments are well-targeted and meeting local needs. The ACA provides new tools for addressing the health workforce challenge such as greater incentives for community-based training and strengthening primary care. Without these tools, we will be hampered in our efforts to address the needs of an aging population and the growing burden of chronic disease.

5. The FY2012 budget includes a provision to end patent settlements, or “pay for delay” provisions in health reform. I have been very clear that I oppose this provision in the absence of a full fix to the problem of authorized generics. Authorized generics are brand-name drugs in disguise – they take away the 180-day exclusivity period that is the reward for independent generics for entering the marketplace. If pay-for-delay agreements were banned, that would be a double whammy because sometimes, as part of a patent settlement agreement, brand-name drugs agree not to launch an authorized generic. If we do not ban authorized generic drugs, as I have proposed to do, independent generics have a much lower incentive to challenge a brand-name patent and enter the marketplace.

Secretary Sebelius, why was a ban on authorized generics left out of the President's FY2012 budget proposal?

Answer: The President's budget proposal would prohibit “pay-for-delay” agreements so that generic competition will be brought to market sooner, saving the Federal government and consumers money. Currently brand-name pharmaceutical companies can delay introduction of their generic counterparts into the market by agreeing to pay the generic company to hold off on introducing the competing generic product for a certain period of time. As a result, according to the Federal Trade Commission (FTC), brand-name drug manufacturers can maintain monopoly pricing for an average of nearly 17 months, on the basis of patents that do not represent true innovation. These agreements reward drug manufacturers for collusion that inhibits competition, not for patents on innovative therapies. Therefore, we do not believe prohibiting pay-for-delay

agreements would hamper innovation, but rather will redirect energies and resources toward the development of new treatments.

Under the current law consumers have to pay brand name prices that are sometimes 90 percent higher than what they would pay for the competing generic. Significant Federal dollars are also lost with these agreements in place in the form of higher Medicare and Medicaid payments for the brand name drugs. The FTC estimates that pay-for-delay agreements cost American consumers \$3.5 billion per year, or \$35 billion over the next ten years. OACT estimates that this change could save Medicare and Medicaid \$3.4 billion over five years and \$8.8 billion over ten years.

The FTC is the lead agency on authorized generics and they delivered a final report on their investigation of this issue on August 31, 2011. The report can be accessed here: <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>.

6. Medicare currently covers 47 million people: 39 million age 65 and older, and 8 million nonelderly with a permanent disability. Enrollment in Medicare will double to 80 million by 2030. The provisions in health care reform will reduce millions in Medicare spending as well as generate billions in Medicare related revenue between 2010 and 2019. Caring for our seniors should remain a high priority for this nation. Yet some people have put forward proposals that would increase cost sharing for beneficiaries, or reduce their benefits—even turning Medicare into a voucher system.

Secretary Sebelius, this new law directly affects millions of our seniors. Why is it important to preserve their benefits and not increase cost sharing? Can you explain how the Administration's approach to improving Medicare differs from other proposals that would dramatically increase cost sharing for beneficiaries and generally not provide them the care they need?

Answer: I appreciate your comments. The Affordable Care Act makes Medicare stronger and more sustainable. The Affordable Care Act improves Medicare benefits, and Medicare's long-term sustainability is stronger as a result of efficiencies, new tools, resources to reduce waste and fraud, and slower growth in Medicare costs. These important changes will produce savings for the taxpayers and help to prolong the life of the Trust Funds. The Act will also benefit people with Medicare by keeping their premiums and cost sharing low. Thanks to the Affordable Care Act, Medicare beneficiaries will enjoy better quality care, better access to care, and a more innovative care delivery system that will improve outcomes and reduce cost.

While we welcome all ideas on making Medicare work now and into the future, I have serious concerns about replacing Medicare with voucher. While a voucher would limit the government's liability, it is not clear that private plans can provide the same services for less. As such, the savings would most likely come from shifting those costs on to beneficiaries. Congressional Budget Office analysis indicates this will add about \$6400 to the out-of-pocket health care costs for a typical 65-year-old who becomes eligible for Medicare in 2022. A key benefit of the Affordable Care Act is protecting Americans from bankruptcy due to medical debt. A voucher goes in the wrong direction.

In addition, if we were to repeal the Affordable Care Act and replace it with a voucher, we would lose all the important delivery system innovations in the Affordable Care Act that will help reduce costs and move our delivery system toward one that pays for quality of care and not quantity and improve care. That is one change our health system cannot afford. For example, the Affordable Care Act contains provisions designed to help avoid preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes. It also requires CMS and providers to focus on the prevention of infections, conditions, and other complications that patients acquire from the care that is supposed to help them. The Affordable Care Act also established an Innovation Center, which will test and study the most promising innovative payment and service delivery models. CMS is moving forward with the implementation of Accountable Care Organizations and bundled payments, which will incentivize high quality care. Replacing Medicare with a voucher undermine all these promising efforts to improve the health care delivery system.

7. We need effective integration of benefits and better coordination between the federal government and states in the delivery of benefits and care for the 9 million seniors and persons with disabilities who are dually eligible for Medicare and Medicaid. I was proud to author Section 2602 of the Affordable Care Act, creating the Federal Coordinated Health Care Office, and am glad to see the progress HHS has made in implementing this provision. However, I am concerned by recommendations such as those made by the President's Fiscal Commission that would seek to place all dually eligible beneficiaries into managed care until we have fully explored all the options.

Madame Secretary, the health reform law specifically addresses the needs of dual eligibles in several ways. How can we integrate and streamline care that will ensure quality and improve health outcomes for this population? How can we both improve care for dually eligible beneficiaries, and save money for both the states and federal government? What info

Answer: The Affordable Care Act established a Federal Coordinated Health Care Office, also known as the Medicare-Medicaid Coordination Office, to improve coordination of the care provided to beneficiaries eligible for both Medicare and Medicaid. We're very excited about this provision, which we believe can improve the quality of care for these individuals while reducing costs.

Medicare-Medicaid enrollees are among the most vulnerable and chronically ill beneficiaries, who represent 15 percent of enrollees and 39 percent of Medicaid expenditures and 16 percent of enrollees and 27 percent of Medicare expenditures. Dual eligibles need to navigate two separate systems: Medicare for coverage of basic health care services, and Medicaid for coverage of long-term care supports and services, and help with Medicare premiums and cost-sharing.

The Medicare-Medicaid Coordination Office will work to better streamline care for Medicare-Medicaid enrollees, while ensuring they receive full access to the items and services that will result in better health care outcomes. Partnering with the Center for Medicare and Medicaid

Innovation (Innovation Center), the Federal Coordinated Health Care Office has awarded contracts of up to \$1 million each to fifteen states to design new approaches to better coordinate care for dual eligible individuals. These design contracts will support the development of new models that integrate the full range of acute, behavioral health, and long-term supports and services for dual eligible individuals.

On May 11, 2011, the Medicare-Medicaid Coordination Office also announced a new process to provide States access to Medicare data to support care coordination for individuals enrolled in both Medicare and Medicaid.¹ Access to Medicare data is an essential tool for States seeking to coordinate care, improve quality, and control costs for their highest cost beneficiaries.

The Medicare-Medicaid Coordination Office recently announced several opportunities through demonstrations of delivery and payment models designed to increase efficiency and improve the quality of care Medicare-Medicaid enrollees receive by expanding access to seamless, integrated programs, and better care management. One new demonstration is designed to test models to align financing between Medicare and Medicaid to support improvements in the quality and cost of care for individuals eligible for Medicare and Medicaid. CMS has issued guidance to States so that they can apply to test either a fee-for-service model or a capitated payment model to better align the financing of these two programs and integrate primary, acute, behavioral health and long term services and supports for their Medicare-Medicaid enrollees. The CMS Center for Medicare and Medicaid Innovation will test these models to determine whether they save money while also preserving or enhancing the quality of care for Medicare-Medicaid enrollees. All States that meet specified standards and conditions will have the option to pursue either or both of these models.

Additionally, the Medicare-Medicaid Coordination Office has launched a new demonstration program to help States improve the quality of care for people in nursing homes by providing these individuals with the treatment they need without having to unnecessarily go to a hospital. Hospitalizations are often expensive, disruptive, disorienting, and dangerous for frail elders and people with disabilities, and cost Medicare billions of dollars each year. Starting this fall, CMS will competitively select independent organizations to partner with and implement evidence-based interventions at interested nursing facilities. This demonstration supports the Administration's Partnership for Patients goal of reducing hospital readmission rates by 20-percent by the end of 2013.

8. For the past forty years, hundreds of thousands of disabled people have had their health care paid for by Medicaid; however, their health care was actually the responsibility of Medicare. States have been held financially responsible for individuals whose care should have been paid for entirely by the federal government. Both CMS and SSA acknowledge Medicare's responsibility for these beneficiaries. However, CMS has not acted to establish a means of satisfying Medicare's liability to the states. You have been pushing for a legislative fix.

¹ http://www.cms.gov/medicare-medicare-coordination/06_MedicareDataforStates.asp#TopOfPage

Madame Secretary, one issue that is not addressed in the President's budget, which I believe should be, is the issue of Medicare's liability to the states. Some people refer to this issue as the "special disability workload."

When it is determined that a state owes the federal government money for Medicaid expenses, states have only 60 days to pay this debt. Yet, now that the situation is reversed, the federal government has not even established a timeline with which to pay its debt to the states.

I believe we should provide \$4 billion in federal funding to settle this debt to the states. We were able to successfully include language to address this problem in the Senate-passed Recovery Act, but it was dropped in conference. We should correct it now – once and for all.

Madame Secretary, what are your thoughts on how we can resolve this problem? Wouldn't we be providing another form of economic stimulus for the states by addressing the special disability workload issue now?

Answer: At issue here is whether the Federal government can reimburse States for Medicaid overpayments on behalf of people who should have been instead enrolled in Medicare (at the Federal government's expense). We recognize that members of the Special Disability Workload might not have been correctly identified as Medicare-eligible at the time they incurred health care expenditures.

We understand that this issue has imposed a financial burden on States. We recognize that some States have proposed an administrative solution, and, while we are seriously reviewing that proposal, at this point in time we cannot say with any certainty that we will be able to effectuate that solution. As you note, a legislative change would be most effective in leading to resolution of this burden on the States.

9. I am extremely concerned with the proposed elimination of the State Health Access Program (SHAP) grant program in the FY2012 budget. SHAP was created in 2009 and supports grants to States to implement a program design that will expand access to affordable health care coverage for uninsured people.

West Virginia received a \$6.3 million grant under the federal State Health Access Planning (SHAP) grant program through the Health Resources and Services Administration (HRSA) for FY2010, and anticipates receiving \$34 million through 2014, pursuant to availability of funds. WV is using these funds to expand health insurance coverage and access to care for working uninsured West Virginians through an initiative called "WV CONNECT", which links families and small business to health coverage options through a health information exchange and uses premium assistance stipends to assure basic primary and preventive care and some extended care through community-based medical homes. This initiative is expected to deliver primary and preventive care to 10,000 West Virginians by 2014. The 2010 enacted funding level for SHAP was \$74 million with West Virginia

receiving a \$6.3 million grant. West Virginia anticipated receiving \$34 million through 2014.

West Virginia is using its State Health Access Planning Grant as a vital bridge to the full implementation of health reform in 2014, particularly in its effort to deliver primary and preventive care to 10,000 West Virginians prior to 2014. The Budget states that other implementation funds are now available to help states like West Virginia prepare for health reform. What are the specific programs available to states like West Virginia, will they provide the same amount of financial support to states, and will states be able to use those funds for innovative programs such as WV CONNECT, which is not only serving as a prototype for the health insurance exchange in WV but will also deliver primary care to an estimated 10,000 people when fully funded?

Answer: The Affordable Care Act provides several new programs to help support States in the development and implementation of health insurance Exchanges and other insurance coverage requirements. West Virginia has benefitted from these programs already:

- The West Virginia Offices of the Insurance Commissioner (DOI) received \$1 million to conduct rate review. The Department will use the funding to hire consulting actuaries to review current rate filing requirements and recommend additional data elements needed to strengthen review process. The DOI will make modifications to its IT systems to be able to make public consumer-friendly descriptions of rate filings.
- West Virginia received \$1 million in funding to begin planning for an Affordable Insurance Exchange. The state will examine its health insurance consumer and business markets using previous demographic surveys, develop an economic assessment of West Virginia health insurance market and determine who will participate in Exchange, develop education and outreach strategy for Exchange project, which will result in education and outreach plan. They will also assess efficiency and effectiveness of technical capacity of current West Virginia systems to perform technical tasks for the Exchange.
- The State has an opportunity to apply for further funding through the Exchange Establishment grants.

The West Virginia DOI was also awarded more than \$205,000 through Consumer Assistance Grants which will be used to expand consumer advocacy through trained staff and development of partnerships with non-profit community and consumer organizations and other agencies, and conduct consumer outreach and education through statewide community forums, meetings, fairs and festivals and media spots.

10. The President's FY2012 budget includes a proposal to boost Medicaid monitoring of high-prescribing doctors and high-using patients. Because prescription drug abuse is a major public health concern in West Virginia, the WV Medicaid program and the Public Employee Insurance Agency (PEIA) currently monitor claims for controlled substances. For example, PEIA's pharmacy benefit manager sets parameters on the amount of

controlled substances a member receives, the number of doctors who prescribes it, and the number of pharmacies the member visits for these prescriptions within a designated time. When a member meets these parameters, their doctors get a letter alerting them.

Madame Secretary, how will the proposal in the President's budget help states in their efforts to monitor and curb prescription drug abuse? Are there provisions that will aid states in evaluating their efforts over time?

Answer: The Administration is committed to eliminating fraud, waste and abuse in federal health care programs. We want to help States employ the wide variety of available tools to ensure Medicaid does not subsidize addiction to or diversion of controlled substances.

The President's FY 2012 Budget proposes requiring States to monitor high-risk billing activity to identify and remedy patterns of utilization that may indicate prescription drug fraud or abuse in their Medicaid program. We expect that this proposal would improve the integrity of State Medicaid programs and strengthen beneficiary quality of care.

We are focused on improving how we measure States' performance and results, drawing national attention to program vulnerabilities, deploying tools, and building capability to prevent and attack fraud.

CMS issued an advisory to States to help them in using the Drug Enforcement Administration (DEA) Controlled Substance Registration file that is available weekly at no cost to any law enforcement or regulatory agency. CMS strongly encourages State Medicaid agencies to use this file to enhance their ability to more effectively control drug utilization and make including the DEA number a mandatory requirement for provider participation in State Medicaid programs. Finally, as a result of the Affordable Care Act, States are updating their provider enrollment applications which provide a timely opportunity to implement this recommendation.

11. I am delighted to see that the Administration is recognizing the importance and effectiveness of our child support enforcement program. In tough budget times, it makes good sense to invest in programs with a proven record of accomplishment. Child support leverage \$4.78 dollars to children for every \$1 we invest. Along with Senators Cornyn, Snowe and Kohl, I have introduced the Child Support Protection Act, a bipartisan bill to maintain the successful incentive program.

Secretary Sebelius, I want to work with you on child support, but can you provide more details about the various child support proposals, ranging from passing through more funding to families and partial funding on incentive grants?

Answer: It is well established that children benefit from having the emotional and financial support of both parents. Evidence suggests that when fathers provide financial support to and are engaged with their children, their children are less likely to be poor and more likely to do better in school, avoid drugs and alcohol, and postpone pregnancy until marriage. In addition, child support is a critical source of income for many families. For poor, custodial parents who receive it, child support comprises 40% of their total family income. Therefore, we are working to

improve the ability of non-custodial parents to provide that support and maintain connections with their children by putting forth proposals that encourage non-custodial parents to work, support their children, and play an active role in their children's lives.

The child support enforcement program clearly demonstrates a high return on investment. Currently, for every dollar invested in the program, \$4.78 in child support is collected. When poor families receive child support payments they can be less reliant on other public assistance programs, producing savings in programs like SNAP and SSI.

However, reliable payment of child support depends upon steady jobs and parental cooperation. Since the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, the child support program has become highly automated, with 70 percent of child support collections being withheld from the paychecks of non-custodial parents. Utilizing highly automated processes is an effective strategy for collecting support from three-fourths of non-custodial parents (mostly fathers) who have stable employment. However, they do not work as well for the remaining quarter of fathers who do not have regular jobs and who face many of the same barriers as the mothers. Most child support debt is owed by fathers whose reported income is less than \$15,000 per year. Some evidence suggests that low-income men may be discouraged from legitimate employment when faced with child support obligations that are not well aligned with their circumstances. Low-income fathers are more likely to stay in jobs and pay child support when their child support obligations are set at realistic levels. A number of states have implemented "rapid review" procedures to determine if obligations continue to be realistic and state debt forgiveness opportunities to encourage fathers to obtain and maintain employment and make regular child support payments. The President's budget would require states to use best practices to review and adjust child support debt owed to the state and to discourage accumulation of unpaid child support debt during incarceration.

Research also indicates that fathers are more likely to remain employed and pay child support when they know that the money benefits their children. While 94 percent of collected support is paid to families, for those families that receive TANF, the government keeps most of the child support collected to reimburse welfare costs. However, research has shown that when child support is passed through to children, fathers pay more support, are more likely to hold jobs and less likely to participate in the underground economy. Some research indicates, additionally, that the likelihood of conflict between the parents may be reduced and reports of maltreatment decreased. As a result, we are proposing changes that encourage the pass through of all current monthly child support collections to TANF families.

Finally, research finds that child support payments, parent-child relationships, and cooperation between the parents improve when parenting arrangements are addressed through provision of services such as mediation and development of joint parenting plans. Although divorce decrees currently address both child support and access and visitation responsibilities, there is no regular mechanism to establish legal parenting responsibilities in cases where the parents never married. Thus, many fathers who pay child support do not have a legal right to see their children. To facilitate the relationship between non-custodial parents and their children, we propose updating the statutory purposes of the Child Support Enforcement program to recognize its evolving mission and activities to help parents cooperate and support their children and to require states to

establish access and visitation responsibilities in all initial child support orders. Implementing domestic violence safeguards will be a critical component of this new state responsibility.

Finally, the Budget includes \$600 million for a temporary increase in incentive payments to states in FY 2012 and FY 2013, based on state performance. This continues an ongoing emphasis on program outcomes and efficiency while also helping states overcome short term fiscal stresses.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable John Kerry and The Honorable Robert Menendez

1. We have been strong supporters of the Children's Hospital Graduate Medical Education (CHGME) payment program for many years. The program has been a major success and has enjoyed broad bipartisan support. That is why we are concerned that the budget proposes to eliminate the CHGME program. The small class of hospitals that receive CHGME train thousands of pediatric primary care physicians, and also serve as the sites for pediatric rotations for internal medicine and family medicine doctors and other primary care providers. Children's hospitals that receive this funding train over 40% of general pediatricians, 43% of all pediatric specialists and the majority of pediatric researchers. Eliminating this program would not only have a major negative impact on access to primary care but it would have devastating impact on access to specialty care for children. As you know, there are serious national shortages in many pediatric subspecialties, shortages which the CHGME program has been crucial in helping to address. Eliminating the program would exacerbate these shortages and create additional barriers to access to specialty care for children.

We recognize that we are in a tough economy with difficult choices to be made but are concerned about who will treat the next generation—our grandchildren—if we do not invest in these doctors today. The Fiscal Year 2012 Budget justification states that CHGME resources will be directed to competitive and targeted activities that will support more primary care providers and that Medicaid GME will fund graduate medical education in children's hospitals. As you know, many states have already cut Medicaid GME payments and we expect more to follow as states look for increasing flexibility in Medicaid programs in the midst of difficult budget circumstances.

How exactly can Medicaid GME dollars fill in the huge void left by the proposed termination of the CHGME program?

Answer: Medicaid graduate medical education (GME) is one source of support for training medical residents, including pediatric residents. Other sources include the primary care residency programs and other health professions education programs funded by the Department of Health and Human Services through annual appropriations. In addition, non-governmental grants and endowments support graduate medical education. The President's FY 2012 Budget proposal focuses on competitive discretionary programs to expand the primary care workforce, including general pediatricians. In addition, the Affordable Care Act created a new mandatory funding stream to support primary care residency training in ambulatory settings. The new Teaching Health Center GME program, through which pediatric residents can be supported, received \$230 million in mandatory appropriations for a five-year period.

2. What specific competitive grant programs will be used to train pediatric primary care physicians and specialists?

Answer: The Administration is committed to strengthening and growing the primary care workforce, which includes general pediatric medicine. In Fiscal Year 2010, the Administration allocated \$250 million from the Prevention and Public Health Fund to health professions training. Of these resources, \$167 million was made available for a new primary care residency expansion program. Through this competitive program, 15 pediatric medicine residency programs received funding to support the training of an estimated 175 pediatric residents over a five-year period. The ACA also created the Teaching Health Center Graduate Medical Education program with \$230 million in mandatory appropriations. This competitive initiative, through which Teaching Health Centers can support pediatric residents, will grow the number of primary care medical residents trained in community-based ambulatory care settings. Grant programs also support the advancement of pediatric training through curriculum development, faculty development and continuing education. In addition, the President's Fiscal Year 2012 budget includes a proposed initiative to expand the primary care workforce by 4,000 providers over five years.

3. Please also explain how this proposed redirection of federal resources will adequately ensure resources are available to train the pediatric workforce of tomorrow.

Answer: The Administration believes that a well-trained health care workforce is critical to reforming the nation's health care system. We are committed to working with states, academic institutions, professional organizations and other key stakeholders to address our shared responsibility to prepare the health workforce of the 21st century. From the federal perspective, our investments in the primary care workforce, which includes general pediatrics, include not only the National Health Service Corps, the Primary Care Residency Expansion initiative, the Primary Care Training and Enhancement Program, and the Teaching Health Center Graduate Medical Education Program, but also our initiatives to develop a diverse health care workforce, to expand continuing medical education opportunities and to recruit and support students entering the health professions.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Ron Wyden

1. Secretary Sebelius, thanks to Section 3140, Hospice providers will now be able to provide curative care to their patients. I have a concern however, that as written in statute, reimbursement for such curative services must come from a patient's hospice payment. I have heard from some of my Hospice providers back home that if the demonstration is implemented this way, they will not be able to participate as operating budgets with the current hospice reimbursement rate are already tight. This means of payment was never the intent of the demonstration.

What can be done to ensure that these providers can participate?

Answer: There may be benefits from a patient concurrently receiving palliative as well as curative care. Consequently, the Affordable Care Act authorizes a demonstration that allows curative care to be paid for from the amounts otherwise paid to hospices for their programs.

The Affordable Care Act also directs that the demonstration test whether the concurrent provision of palliative and curative care in the hospice setting is budget neutral – that is, whether it increases expenditures. As we develop the demonstration, we will consider your concerns about participation.

2. As you know, providers that receive Medicare or Medicaid reimbursement must meet “Conditions of Participation” set forth by the Centers for Medicare and Medicaid Services (CMS). The “Exercise of rights” subsection states that “[t]he patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these advance directives.” The same section specifies that “the patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.” An Executive Order issued by President Obama in April 2010 requires HHS to “ensure that all hospitals participating in Medicare or Medicaid are in full compliance with [these regulations].

What is the regulatory framework under HHS to ensure that Medicare and Medicaid participating institutional providers or organizations deliver care consistent with an individual’s advance directive and contemporaneous wishes?

Answer: The Medicare regulations governing advance directives in general are found at 42 CFR Part 489 Subpart I (please see Appendix A at the end of this document). Under these regulations (which apply to a wide variety of health care facilities, including hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, hospices and religious nonmedical healthcare institutions), an advance directive is defined as “a written

instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.” Under Medicare’s health and safety standards for hospitals, or Conditions of Participation, a patient of a hospital has the right to formulate an advance directive, and to have hospital/CAH staff implement and comply with his/her advance directive. The regulations specify the rights of a patient for the patient’s representative (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual’s option, advance directives. In addition, the Medicare/Medicaid skilled nursing facility (SNF) and nursing facility (NF) health and safety requirements direct these facilities to meet the advance directives standards found at 42 C.F.R. §489.102 of the Medicare regulations. There are also specific provisions in the Conditions of Participation for home health agencies and Conditions for Coverage for hospices, including informing patients of their policies on advance directives and providing the applicable State law. Home health agencies additionally must inform and distribute information to the patients on advance directives prior to the initiation of care.

With regard to the Medicaid program, any hospital participating in Medicaid must comply with the Medicare Conditions of Participation for hospitals, with the exception of requirements for the supervision of nurse-midwife services. Separately, Section 1902(w) of the Social Security Act (the Act) applies the same advance directive provisions on hospitals and other types of providers as are found in Section 1866(f) of the Act for the Medicare program.

3. Does HHS currently collect information regarding Medicare and Medicaid participating institutional providers/organizations’ compliance (or lack thereof) with an individual’s advance directives and/or contemporaneous wishes?

Answer: CMS is able to track how often institutions are cited by surveying for non-compliance with advance directive requirements, either as a result of standard review of Conditions of Participation/Requirements/Conditions for Coverage, as applicable, or in response to complaint surveys. In particular, we would be able to track how often a hospital was cited by a State Survey Agency for deficiencies related to the hospital Condition of Participation standards. However, it is important to note that over 80 percent of Medicare-participating hospitals are certified for compliance with Medicare’s Conditions of Participation on the basis of accreditation under a Medicare-approved hospital accreditation program. As a result, these hospitals are not routinely evaluated by State Survey Agencies for compliance with all of the requirements. Instead, States conduct focused surveys of accredited hospitals when investigating complaints that suggest substantial noncompliance with one or more of the requirements. If a complaint does not raise issues related to advance directives, then the accredited hospital’s compliance with advance directive requirements will not be assessed. On a more limited basis States also conduct “standard” surveys of accredited hospitals, evaluating compliance with all of Medicare’s hospital Conditions of Participation. As a result, the citation data below cannot be used to establish advance directive compliance rates, since this State Survey data does not represent surveys of all Medicare participating hospitals.

The table below provides information on the total number of hospital standard and complaint surveys conducted by State Survey Agencies in FY 2005 – FY 2010, and the number of times that hospitals were cited for advance directives deficiencies. Since not all complaint surveys involved assessment of compliance with advance directives, no rates of compliance are provided for those surveys.

Fiscal Year	# Standard Surveys	# Standard Surveys with advance directive citation	% Standard Surveys with advance directive citation	# Complaint Surveys	# Complaint Surveys with advance directive citation
2005	521	19	3.6%	4,876	15
2006	664	22	3.3%	4,645	14
2007	678	15	2.2%	4,859	18
2008	587	31	5.3%	6,037	18
2009	656	24	3.7%	5,770	5
2010	571	24	4.2%	4,907	20
Total	3,677	135	3.7%	31,094	90

Since October 1, 2009, CMS has required accreditation organizations with Medicare-approved accreditation programs to enter their survey deficiency findings that correlate to a Medicare Condition of Participation provision into a new database used for CMS oversight of approved accreditation organization programs. We have queried this database for the period October 2, 2009 to December 31, 2010 (the most recent date for which we have data from the accreditation organizations). The data indicates that 1,559 full hospital accreditation surveys were conducted during this period, and 123 surveys included a citation related to the advance directive standard at 42 CFR §482.13(b)(3), a citation rate of 7.9 percent.

During FY 2010, there were 5,515 home health surveys performed nationwide (combined standard and complaint surveys) and there were 93 citations written for non-compliance with the advance directive requirement, a citation rate of 1.7 percent. Also during FY 2010, there were 1,155 hospice surveys conducted nationwide (combined standard and complaint surveys) and there were 12 citations written for non-compliance with the advance directive requirement, a citation rate of 1.0 percent.

With regard to skilled nursing facilities and nursing facilities, CMS is also able to track deficiencies related to the nursing home regulations at 42 CFR §§483.10(b)(4) and (b)(8), which contain the advance directive requirement. However, it is important to note that these sections contain several provisions regarding resident's rights, and not all the citations may be related to advance directives. The table below reflects the number of nursing homes cited (on a complaint or standard survey) for these sections of the regulations. There are about 15,800 nursing homes, so these numbers represent roughly 7.5-8 percent of nursing homes.

FY08	FY09	FY10
1,231	1,363	1,311

4. Can HHS provide me with an update on Medicare and Medicaid participating institutional providers/organizations' compliance with advance directives through the Patient Self-Determination Act of 1990 (PSDA)?

Answer: The regulations at 42 CFR Part 489 Subpart I described above contains the same requirements as are found in the PSDA, and thus the compliance information provided above is applicable.

5. One new initiative proposed in the FY2012 Budget is an effort to encourage a more effective and efficient medical malpractice system. The President calls for "a more aggressive effort to reform our medical malpractice system to reduce defensive medicine, promote patient safety, and improve patient outcomes." The Budget proposes \$250M (over 4 years), to the Department of Justice, to incentivize states to develop malpractice reform initiatives.

How does HHS plan to work with the Department of Justice to assure the development of an effective medical malpractice program?

Answer: If the proposal is enacted, HHS plans to work in close consultation with the Department of Justice's Bureau of Justice Assistance (BJA), which would award and administer these grants. The goal of any reform would be to fairly compensate patients who are harmed by negligence, reduce providers' insurance premiums, weed out frivolous lawsuits, improve the quality of health care, and reduce medical costs associated with "defensive medicine."

This initiative complements and builds on HHS's Patient Safety and Medical Liability initiative, which awarded grants to states and health systems to develop, implement, and evaluate patient safety approaches and medical liability reforms in June 2010. The Patient Safety and Medical Liability initiative is the most ambitious effort to date by HHS and the largest government investment connecting medical liability to quality and avoiding harm rather than just negligence and punishment. HHS's experience running this initiative will help inform the development and implementation of the state medical liability grant program proposed in the President's FY 2012 Budget.

6. To what extent will this effort be integrated into CMS' current programs and initiatives?

Answer: The Patient Safety and Medical Liability grants awarded by HHS in June 2010, and the independent evaluation of the demonstrations that AHRQ commissioned, will provide valuable information on the connection between improving patient safety and reducing the costs and administrative burdens of our medical liability system. The evaluation is designed to develop a consolidated evidence base that will inform long-term solutions to improve patient safety and address medical liability issues. While the grants and the evaluation are not targeted specifically to Medicare and Medicaid enrollees, it is expected that lessons from these projects could help inform CMS's current programs and initiatives.

7. How will HHS evaluate the impact of these reforms on the Medicare and Medicaid system?

Answer: As noted, the evaluation of the Patient Safety and Medical Liability initiative is designed to develop a consolidated evidence base that will inform long-term solutions to improve patient safety and address medical liability issues. Findings from this program can help inform solutions to the patient safety, quality, and medical liability challenges that Medicare and Medicaid enrollees and providers face.

8. What means of transparency in demonstration outcomes can be expected?

Answer: The Administration is committed to supporting transparency in all of its operations, including demonstration outcomes. HHS's Agency for Healthcare Research and Quality (AHRQ) awarded a contract to JBA/RAND for an independent program evaluation across all twenty patient safety and medical liability demonstration and planning grants. The evaluation is designed to develop a consolidated evidence base that will inform long-term solutions to improve patient safety and address medical liability issues. The evaluation results will be posted on AHRQ's web site and available to the public, policymakers, and researchers.

9. In your view, will DOJ have the authority to expand on grant programs that work?

Answer: DOJ is in the best position to determine whether it has the authority to expand on the HHS's Patient Safety and Medical Liability Initiative. The DOJ program does have the same goals (fair compensation to patients, reduce providers' insurance premiums, weed out frivolous lawsuits, improve the quality of health care, and reduce the medical costs associated with "defensive medicine") as that of the HHS Patient Safety and Medical Liability Initiative. The DOJ program is intended to complement and build on HHS's Patient Safety and Medical Liability Initiative and the grants awarded under such initiative. Furthermore, like other Administration proposals, this one would build on the lessons learned from programs that work.

10. As you know, we have tried to enhance our system of caring for the severely ill in non-institutionalized settings through initiatives such as the Independence at Home demonstration project. These approaches are preferred by seniors and their family caregivers. They can also save our system money when coordinated care is properly delivered by trained caregivers. One challenge that we have, and will have in the future, is finding properly trained caregivers, at various skill levels, to minister to the health needs of our aging baby boomers.

How does the funding dedicated to healthcare workforce development attempt to rectify this situation?

Answer: The Affordable Care Act and the President's FY 2012 budget request both support the implementation of programs that are focused on direct caregivers, such as home aides. These programs are needed to ensure that the entire range of health care workers that provide care for

the chronically ill and the nation's aging population are well-trained. Programs that support training of health professionals, including direct care workers, include:

- Comprehensive Geriatric Education Program (CGEP)
 - Among other activities, the Comprehensive Geriatric Education Program supports geriatric education and training for home health aides, nurse assistants/patient care associates and lay people. The FY 2012 budget request for the Geriatric Education Program is \$5 million.
- Personal and Home Care Aide State Training (PHCAST) program
 - The Affordable Care Act made \$5 million available for each of fiscal years 2010 through 2012 to support state efforts to develop, evaluate, and demonstrate a competency based-uniform curriculum to train qualified personal and home care aides.
- Nursing Assistant and Home Health Aide (NAHHA) program

The NAHAA program is part of HRSA's Nursing Education, Practice, Quality, and Retention Program. NAHHA supports colleges and community-based training programs focused on preparing individuals to become nursing assistants and home health aides. A portion of the FY 2012 \$59.8 million budget request for the Nursing Education, Practice, Quality, and Retention Program would support the NAHHA program.

11. It appears to me that we could better utilize some of our underutilized older workers by retraining them to provide the homecare that many of our seniors desperately need and desire. With cutbacks in programs such as the Senior Community Services Employment Program (SCSEP), what are your thoughts on this approach?

Answer: Older workers at all income levels are underutilized for a number of reasons, including, but not limited to: shortage of training programs directed towards their specific needs; work requirements may not be flexible enough to meet a retiree's needs, and ageism may prevent some employers from seeking and hiring older workers.

For low income older people, the SCSEP program has been a venue for giving back to the community—sometimes helping other seniors and sometimes working with children or others in the community. When SCSEP trainees have worked with seniors, they have provided congregate and home delivered meals programs, provided chore assistance in congregate housing settings, served in adult day centers, provided telephone reassurance to the frail and homebound, provided transportation services and served in other capacities. We believe that the provision of home and community based services is one way a SCSEP trainee can provide service to their community, but there are others as well. For example, some seniors enjoy spending time with children and serve as tutors to school age children or classroom assistants in preschools. Others may be interested in being trained to provide various homecare types of assistance.

12. Health Insurance reform should highlight the new availability of choices in the market place. In my view, Americans should be able to access the same benefits that a member of Congress can choose from and free choice vouchers are a way to give more workers choices

like members of Congress. After working with you and committee, I was happy to see that the Free Choice Voucher made its way into the final legislation.

Who will be responsible for determining eligibility for those receiving a free choice voucher? The premise of the voucher was to provide further choice to an employee regarding their health insurance options. This process should therefore be as straightforward as possible so as not to disincentivize an employer from compliance with current statute (which states that an employer must provide information on Exchange options). How will the Administration ensure that the process is straightforward for both employers and employees?

Answer: In Section 1858 of the FY 2011 Continuing Resolution, Congress repealed the Free Choice Voucher program. As a result, the program will not be implemented.

13. Once eligibility is determined, how will these employees be notified? How will the employee receive this contribution?

Answer: In Section 1858 of the FY 2011 Continuing Resolution, Congress repealed the Free Choice Voucher program. As a result, the program will not be implemented.

14. In the event that an employee decides to take their employer contribution to the Exchange, how can we ensure that the employee will continue to receive the exclusion?

Answer: In Section 1858 of the FY 2011 Continuing Resolution, Congress repealed the Free Choice Voucher program. As a result, the program will not be implemented.

15. The Medical Loss Ratio regulation allows for costs associated with “activities that improve health care quality” to be counted toward the MLR requirement. A number of important tools that have been proven to improve quality and enhance patient care, however, have been overlooked.

Given the broad recognition by policymakers and other experts of the importance of fraud detection and prevention activities, why are these activities not included in the definition? Are you considering further guidance regarding the role of the broker and their commission as part of this ratio?

Answer: Quality Improvement (QI) expenses, for the purpose of the MLR, include plan activities that are designed to improve health care quality and increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements. The expenses must be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees.

The Affordable Care Act required the National Association of Insurance Commissioners (NAIC) to develop uniform definitions of MLR activities, including activities that improve health care quality. The NAIC, in its model MLR regulation, determined that fraud prevention activities do not qualify as a quality improving activity. However, the NAIC also determined that, when

factoring the MLR, an adjustment may be made to incurred claims to account for the amount of claims payments recovered through fraud reduction efforts not to exceed the amount of the fraud reduction expense. The MLR interim final regulation adopted and certified those recommendations in the model regulation of the NAIC.

HHS understands the important role brokers play in the insurance market and we are looking carefully at the issue of broker commissions as they relate to the medical loss ratio.

16. Can you please provide further details on the proposal in the President's budget to reform child welfare financing rules?

Answer: The \$250 million in additional resources will be used to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services or post-permanency services from the child welfare system, in order to prevent entry or re-entry into foster care. We envision States that receive performance-based funding to be able to support activities that can improve outcomes for children who have been abused or neglected or at risk of maltreatment. We look forward to working with Congress on developing specific details as we approach reform of the child welfare system, guided by the principles outlined in our FY 2012 budget:

- Creating financial incentives to improve child outcomes in key areas, by reducing the length of stay in foster care, increasing permanency through reunification, adoption, and guardianship, decreasing rates of maltreatment recurrence and any maltreatment while in foster care, and reducing rates of re-entry into foster care;
- Improving the well-being of children and youth in the foster care system, transitioning to permanent homes, or transitioning to adulthood;
- Reducing costly and unnecessary administrative requirements, while retaining the focus on children in need;
- Using the best research currently available on child welfare policies and interventions to help the states achieve further declines in the numbers of children who need to enter or remain in foster care, to better reach families with more complex needs, and to improve outcomes for children who are abused, neglected, or at risk of abuse or neglect; and
- Expanding our knowledge base by allowing States to test innovative strategies that improve outcomes for children and reward States for efficient use of Federal and State resources.

17. Does the Obama Administration support de-linking Title IV-E funds from the Aid to Families with Dependent Children eligibility requirements?

Answer: We recognize the concerns related to the continued link between IV-E eligibility and the former AFDC program and the fiscal issues that arise with various approaches to de-linking. We welcome the opportunity to further discuss de-linking and associated reforms with Congress within the broader framework of child welfare systems improvement as outlined in our principles (above).

18. How will the proposed changes affect the number of children who are eligible for federal foster care assistance under Title IV-E of the Social Security Act in Oregon and around the country?

Answer: The President's proposal does not reduce the number of children served by child welfare services nor does it reduce Federal resources for States. In fact, the proposal increases the total resources available to States and provides flexibility designed to help States improve child outcomes. As noted above, we would welcome the opportunity to further discuss Title IV-E eligibility and de-linking with Congress.

19. How does this compare to inaction on this important issue?

Answer: We believe our proposal will keep the focus on moving child welfare in the right direction, particularly during these difficult budget times in States. The current Title IV-E structure can discourage investment and innovation that would serve children's best interest. The Federal investment in child welfare is also imbalanced such that States have insufficient resources to support children at risk of abuse and neglect. The proposal incentivizes all States to improve outcomes by allowing them to earn additional funds that can be invested in activities that can drive further progress for the children and families served. Under current law, the number of children eligible to for Title IV-E is projected to decline each year, leaving fewer resources for States to serve this vulnerable population.

20. Does the Administration propose doing this in a budget neutral manner?

Answer: The President's Budget proposes an additional \$250 million in FY 2012 above the current child welfare funding budget baseline projection and an additional \$2.5 billion over the next ten years. These costs are offset in the context of the President's overall budget.

21. Over time, will this proposal free up more resources to use on the prevention of child abuse and neglect and to strengthen vulnerable families?

Answer: The overall goal of the President's proposal is to improve outcomes for children and families – specifically reducing the length of stay in foster care, increasing permanency, reducing repeat maltreatment and reducing re-entry into foster care. If a state succeeds at improving performance in these areas, its foster care costs will decline the State may use the savings to invest in other areas, such as prevention services. In addition, our proposal provides incentive funds that could be used for prevention and family support activities.

22. How will the proposed changes affect the reimbursements Oregon receives for the cost of child welfare services?

Answer: The President's proposal increases the overall resources available for Title IV-E. The \$250 million incentive proposal would not impact the manner in which Oregon currently receives reimbursements. The proposal would provide an opportunity for Oregon to earn additional funds as improvements are achieved.

Appendix A**Sen. Wyden, Question 2****Subpart I—Advance Directives**

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

§ 489.100 Definition.

For purposes of this part, advance directive means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), hospices, and religious nonmedical health care institutions must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care, or patient care in the case of a patient in a religious nonmedical health care institution, by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in § 417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995; 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 68 FR 66720, Nov. 28, 2003]

§ 489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Debbie Stabenow

1. I am pleased to see the President's commitment to strengthening our primary care workforce. Not only is this important for our nation's health but it also helps prepare people for good paying jobs.

One area we need to focus on is the nursing shortage. As part of the Affordable Care Act, I authored Section 5509, which creates a Medicare Graduate Nursing Education demonstration program and provides mandatory funds to carry out this important initiative. The intent is to demonstrate that Medicare can effectively and efficiently incentivize the production of more advanced practice registered nurses (APRNs) by paying for the clinical training costs of these students. More APRNs will be needed to carry out the delivery system reforms at the heart of health care reform: more primary and preventive care, better chronic care management, care coordination, reduction of preventable hospital readmissions. These are all of crucial to improving care and restraining growth in costs for Medicare.

I want to make sure this initiative is cost effective and implemented to reach the broadest number of potential students.

Will you use authority to test a full geographically representative mix of small and large, rural and urban APRN educational programs utilizing different mixes of hospital and non-hospital community-based clinical training sites which maximize the total number of additional APRNs trained with support from the demonstration?

Answer: The Medicare Graduate Nursing Education Demonstration Program offers an important opportunity to assess and identify effective ways for Medicare to support high quality primary care by investing in the clinical training of advanced practice registered nurses (APRNs). We share your concern about the need to engage a range of hospitals and non-hospital community-based clinical training sites in order to encourage broad participation in the demonstration. In developing the demonstration, we are exploring a number of options to help achieve this goal, including offering incentives to encourage geographically diverse consortia of schools of nursing to serve as hospital partners. In addition, we are considering ways to ensure that hospitals have established relationships with a diverse array of community-based clinical training sites to assure that quality clinical experiences in community-focused primary care are available. The Department of Labor's investments through ETA's High Growth and Emerging Industries' grants in the healthcare sector complement this work and provide career ladders (i.e., Nursing aid leading to Licensed Nurse Practitioner and to Registered Nurse) for entry-level nurses by extending training through the workforce investment system, Registered Apprenticeship sponsors, and partnerships with the public K-12 and postsecondary education system.

2. And will you assure that reasonable costs for the demonstration take into account all types of clinical training regularly employed in and appropriate to the training of APRNs and are not arbitrarily reduced by a factor related to the proportion of hospital inpatient days that are Medicare inpatient days?

Answer: We recognize that quality clinical training of advanced practice registered nurses (APRNs) through the Medicare Graduate Nurse Education Demonstration Program will require a broad and diverse array of clinical training experiences that need to be considered when determining reasonable costs. In designing the demonstration, we intend to focus on ensuring that the costs associated with all appropriate clinical training experiences, including those in community-based training sites, are taken into account in determining full payment.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Maria Cantwell

1. Secretary Sebelius, I am concerned that the President's budget would completely eliminate subsidies to Children's Hospitals Graduate Medical Education. I understand that the Department of Health and Human Services (HHS) wants to focus on increasing the primary care workforce, which is a laudable goal. In my state, the University of Washington is the top producer of primary care doctors in the nation. However, Seattle Children's Hospital helps to train hundreds of residents, medical students, and fellows in pediatric medicine, not only for Washington State, but the entire 5-state Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) region and Oregon. Specifically, Seattle Children's provides pediatric care for 25 percent of the U.S. land mass.

Seattle Children's receives \$10 million annually through Children's Graduate Medical Education funds. Intermountain Health Services-Primary Children's Medical Center, which serves Utah and southeastern Idaho, has received \$6 million annually under the program (since 2006). Phoenix Children's Hospital in Arizona received \$3 million under the program last year.

In 2006, Congress passed and the President signed, a 5-year Children's Graduate Medical Education reauthorization for a total of \$330 million annually. In fiscal year 2010, the program was appropriated \$317.5million in funding. It marked the 3rd reauthorization since its creation by Congress in 1999. In 2009, the program supported the training of 5,631 resident physicians. This strong, bipartisan support reflects Children's Graduate Medical Education's great success.

Elimination of this funding will have detrimental effects for the 5-state WWAMI region and other rural or outlying communities in great need of pediatric care. Further, although a relatively small program, Children's Graduate Medical Education is one of our most important investments to strengthen children's health in America, a stated Administration priority. Free-standing children's hospitals are critical to the nation's pediatric workforce. They train 35 percent of the nation's pediatricians and more than 50 percent of the pediatric workforce. My question is two-fold:

Children's hospitals are training more and more pediatricians – far more than what they receive funding for under the Children's Hospital Graduate Medical Education Program (total cost for training at Seattle Children's is about \$18 million, while HHS pays \$10 million for training). What is the justification for eliminating this funding when the nation is facing a health care workforce shortage?

Answer: While the Fiscal Year 2012 proposed budget required difficult choices, it includes a strong focus on responding the health care workforce shortage by investing in the training and

development of primary care providers. A challenging budget environment required proposing spending reductions that we may not have under different circumstances. Within the constrained budget environment, the Fiscal Year 2012 proposed budget prioritizes competitive and targeted activities that will support the training of primary care providers, including general pediatricians. Strengthening and growing the primary care workforce is a critical component of reforming the nation's health care system. Increasing access to primary care providers can help prevent disease and illness and help ensure that all Americans – regardless of where they live – have access to high quality care.

2. What options do children's hospitals have to train the pediatricians of the future without this funding?

Answer: Eligible children's hospitals would continue to be able to compete for funding through the competitive medical education and training grant programs for which they are eligible. For example, six children's hospitals received over \$16 million in funding from the primary care residency expansion program funded by the Affordable Care Act. Pediatric residencies are also supported through the Primary Care Training and Enhancement program, which supports faculty development, residency training, and predoctoral training in primary care. The new Teaching Health Center Graduate Medical Education (GME) program, which supports primary care medical residents (including pediatric residents) in community-based ambulatory care settings, is a new opportunity for training pediatric residents outside of the hospital environment. This new GME program was created by the Affordable Care Act and received \$230 million in funding over five years. In addition, the President's Fiscal Year 2012 budget includes a proposed initiative to expand the primary care workforce by 4,000 providers over five years.

3. You have stated that the Administration is supporting graduate medical education for the training of primary care doctors. As I mentioned, the University of Washington is the top producer of primary care doctors in the country and I support the focus on primary care. I applaud the Administration's investment of \$700 million in the National Health Service Corps to expand the capacity of institutions to train over 4,000 new primary care providers over 5 years.

Section 5503 of the Affordable Care Act allows for redistribution to certain hospitals of the estimated number of Full-Time Equivalent (FTE) resident reductions to other hospitals that have reached their residency caps. Seventy percent of those slots are to be distributed to hospitals located in states with resident-to-population ratios in the lowest quartile, with the remaining 30 percent to states among the top 10 in terms of Health Professional Shortage Area (HPSA) population to total population or hospitals in rural areas.

Given the Administration's investment in primary care, what is the Administration's position about states like Washington that have areas of high urban concentration (like Seattle), which may skew the overall resident-to-population ratio, while other regions of the state are considerably underserved?

Answer: While I applaud the efforts of Washington State to produce primary care physicians and share your support of primary care, the statutory provision in this case does not allow for

discretion in looking at regions or smaller areas within a state when making a determination regarding the resident-to-population ratio criterion. I look forward to working with you on ways to improve Medicare's graduate medical education program to better support primary care.

4. What would the Administration do to support placement of additional primary care residents in these underserved regions within states?

Answer: The Administration also supports the placement of additional primary care providers in underserved regions through the National Health Service Corps (NHSC) Loan Repayment and Scholarship Programs. The NHSC Loan Repayment Program (LRP) provides primary care clinicians loan repayment assistance in exchange for working in underserved rural and urban communities throughout the United States known as Health Professional Shortage Areas (HPSAs). The NHSC Scholarship Program (SP) supports students training in primary care through the provision of scholarships for their clinical training in exchange for working in HPSAs, upon graduation and licensure. As of the end of fiscal year 2010, 227 clinicians were in service in the State of Washington through the LRP and SP. An additional 35 clinicians were supported through the State Loan Repayment Program, which is a grant program supported by the NHSC that provides matching funds to States who support loan repayment programs for primary care providers. While the NHSC does not dictate where scholars complete a residency and the LRP is geared towards fully-trained providers, the NHSC is reviewing opportunities to strengthen outreach to those finishing medical school and while in a residency program to encourage them to pursue a primary care career in underserved communities.

In addition, the Affordable Care Act created a new mandatory funding stream to support primary care residency training in ambulatory settings. The new Teaching Health Centers GME Program received \$230 million in mandatory appropriations for a five-year period.

5. Secretary, I was pleased to see the Administration's investment of \$60 million, an increase of \$21 million over fiscal year 2010, to enable seniors to live in their communities without fear of abuse or neglect (through programs like the Long Term Care Ombudsman Program), and an increase of over \$86 million for caregiver services, such as counseling, training, and respite care, to help family members care for relatives in their homes. With the aging Baby Boomer population, we face a population of older adults that will double over the next 20 years. A recent AARP study shows that almost 90 percent of Americans age 50 or older desire to remain in their own homes as long as possible.

Further, we know that long term care accounts for 32 percent of total Medicaid expenditures (or \$360.9 billion in 2009). We also know that home care saves nearly 70 percent over nursing home care. Washington saved an estimated \$243 million from 1995 to 2008 by shifting to more home-based services. So I am really pleased to see an investment in home-and community-based services.

This is also why I worked with Senator Kohl of the Aging Committee to ensure that states could be rewarded for shifting their Medicaid spending from institutional care to home and community-based care under the Balancing Incentives Payment Program in section 10202 of the Affordable Care Act. This program is designed to help states build strong delivery

systems that can support a variety of cost-effective home- and community-based services. And it will do that by providing a combination of financial incentives and parameters for the basic elements of a well-designed system.

Secretary, can you speak in more detail about the President's investment of an additional \$48 million (over fiscal year 2010 levels) for Home-and Community-Based Supportive Services (under the Administration on Aging) and the potential long-term cost savings of such an investment?

Answer: The Home and Community-Based Supportive Services (HCBS) program, like other AoA programs, strives to serve seniors holistically. While each service is valuable in and of itself, it is often the combination of supports, when tailored to the needs of the individual, which ensures clients remain in their own homes and communities instead of entering nursing homes. The services provided to seniors through the HCBS program include transportation; case management; information and referral; in-home services such as personal care, chore, and homemaker assistance; and community services such as adult day care. These services also aid caregivers, who might otherwise have to be even more intensively involved with the care of their loved ones, taking time away from work and other family responsibilities. Since States have discretion to tailor service provision to their needs it is difficult to say what the exact mix of additional service provision would be, but we estimate that the requested +\$48 million increase would provide at least an additional 950,000 rides; 300,000 units of personal care, home maker, and/or chore services; and 140,000 units of adult day care.

HCBS are critical services that enable frail seniors to remain in their homes and out of nursing home care. Research has shown that at-risk seniors who have greater access to these services have significantly lower risk of nursing home admissions, which could potentially lower costs.

The Affordable Care Act provides important new tools for States to make home and community-based services (HCBS) more readily available. These tools include continuation of the Money Follows the Person (MFP) demonstration and enhanced State Plan Options that will enable States to improve their ability to provide HCBS. In addition, the Administration is committed to inviting all qualifying States to apply for the Balancing Incentive Payment Program and working with States closely to best maximize Balancing Incentive Payment Program and other Medicaid home and community-based authorities to further balance their long-term care systems. As you know, the Balancing Incentive Payment Program is effective October 1, 2011. The Centers for Medicare & Medicaid Services (CMS) issued a State Medicaid Director (SMD) letter to implement this program. In addition to the SMD letter, CMS also issued an application for funding that will provide more guidance on Balancing Incentive Payment Program.

6. Will the Administration commit to inviting all states to apply for the Balancing Incentive Program funds and then work closely with states to ensure that these enhanced FMAP funds are used to their greatest extent to put together new and expanded programs that can provide home-and community-based services to the thousands of beneficiaries who are now on waiting lists?

Answer: Yes, the Administration is committed to inviting all qualifying States to apply for the Balancing Incentive Payment Program and working with States closely to best maximize Balancing Incentive Payment Program and other Medicaid home and community-based authorities to further balance their long-term care systems. As you know, the Balancing Incentive Payment Program is effective October 1, 2011. The Centers for Medicare & Medicaid Services issued a State Medicaid Director (SMD) letter to implement this program. In addition to the SMD letter, CMS also issued an application for funding that will provide more guidance on Balancing Incentive Payment Program. All qualifying States are welcome to apply for this program. States with less than 50 percent of Medicaid expenditures attributable to non-institutional long-term services and supports are eligible to receive an increase in the Medicaid Federal Medical Assistance Program (FMAP) of five percentage points and States with greater than 25 percent but less than 50 percent of Medicaid expenditures attributable to non-institutional long-term services and support are eligible to receive an increase in FMAP of two percentage points. The FMAP applies to non-institutionally based services and supports furnished between October 1, 2011 and September 30, 2015.

7. Finally, I want to applaud the Administration for its increase of \$866 million in funding for the Head Start program, and for recognizing the importance of early childhood education and its role in creating a solid foundation for future academic success. Studies consistently find that Head Start increases the vocabulary, pre-reading, and math skills of participants, reduces the need for costly special education services when children enter school, and reduces the number of children who have to repeat a grade. The House will soon vote on a Continuing Resolution for Fiscal Year 2011 that would cut over \$1 billion dollars and 200,000 children from Head Start Programs across the country by October 1, 2011. According to the National Head Start Association, that would drop more than 2,700 children in Washington State from the program. In Washington State, more than 26,000 children are eligible for Head Start and the Early Childhood Education and Assistance Program (ECEAP)-my state's Pre-Kindergarten Program, but are unable to participate due to lack of funding.

What is the Administration doing to make the case about the importance of maintaining Head Start and the long-term savings and benefits for eventual job readiness that the program provides?

Answer: President Obama is committed to a robust education reform agenda to ensure we have a workforce that can succeed in the 21st century. High-quality early learning programs for young children from birth through third grade are a key component of this broader agenda because research tells us that what happens in the early years can mean the difference between a child who is successful in elementary school, and one who struggles. High-quality early learning programs are an integral component to establishing an educational system that is internationally competitive, spurs innovation, and ensures every child reaches his or her full potential.

The Administration's commitment to Head Start is evident in the President's 2011 and 2012 Budgets which request more than \$8 billion for Head Start to allow programs across the country to serve 968,000 infants, toddlers and preschoolers. As we make these investments, the Administration is committed to raising the bar on quality and making significant investments in

early learning to help all children succeed, especially children with high needs, such as many of those served in Head Start and Early Head Start. The President expressed his concern about the proposed Head Start cuts for FY 2011 under HR 1 which would eliminate 200,000 Head Start slots and result in the layoffs of 55,000 teachers.

The quality improvements under this administration have included:

- **Proposing regulations to implement a Designation Renewal System** to infuse competition into the Head Start grant process in all communities where the current grantee is not delivering high-quality services;
- **Introducing the Classroom Assessment Scoring System (CLASS) instrument**, a research-based, valid and reliable observation instrument to assess classroom quality and multiple dimensions of teacher child interaction into monitoring and training and technical assistance to focus on the key element of quality – the interactions between teachers and children;
- **Redesigning the Training and Technical Assistance system** in order to better support program staff in their delivery of high-quality services to children and families by communicating “best practices” and providing research-based, usable, practical resources and information to improve program effectiveness;
- **Revising the Child Outcomes Framework**, completed in 2010, to reflect the latest evidence in child development and learning; and
- **Improving teacher qualifications** in 2010, 85% of teachers had an Associates Degree or higher (up from 64% in 2003) and 53% of teachers had a Baccalaureate Degree (BA) or higher (up from 35% in 2003). (The 2007 Head Start reauthorization legislation required steady improvement in this area and we are making strides to meet the law’s goals.)

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Bill Nelson

1. I applaud the Administration's focus on identifying opportunities to improve care while cutting costs.

CDC guidelines for the prevention of catheter infections recommend that patients living with catheters must maintain their hygiene, and when doing so, must use a waterproof dressing to prevent harmful skin bacteria from entering their catheters and blood stream.

Given the ability of these types of dressings to significantly reduce catheter infections, what steps is HHS taking to ensure that catheter patients receive these types of dressings?

Answer: Infection control guidelines are developed by CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory committee made up of 14 external infection control experts. Guidelines are based on targeted systematic reviews of the best available evidence. CDC and HICPAC will be publishing an updated Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infections in April 2011. CDC does not have an evidence-based recommendation to use waterproof dressings. Currently the evidence suggests that the types of catheter dressings do not affect the risk of catheter related bloodstream infections. In fact for certain types of catheters (e.g., well-healed exit sites of long-term cuffed and tunneled central venous catheters) may not need dressing at all. CDC has long recommended, and is the current standard of care, the use of either sterile gauze or sterile, transparent, semi-permeable dressing to cover the catheter site. The choice of dressing can be clinically guided. For example, if blood is oozing from the catheter insertion site, gauze dressing is preferred. Guidelines are reassessed periodically, and general or targeted revisions to guidelines will be dictated by new research and technological advancements in the particular area of interest.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Tom Carper

1. Obesity places an enormous burden on our health care system, costing our country more than \$147 billion dollars each year. In Delaware alone, 4 out of every 10 children are overweight or obese. Unless we find effective ways to reduce the population of overweight and obese individuals in our country, the cost of treating preventable chronic conditions such as diabetes, heart disease, high blood pressure, and other conditions will continue to overwhelm Medicare, Medicaid, and our private health system.

How can we ensure that our public investments in obesity reduction programs are coordinated and effective?

Answer: Regular physical activity and good nutrition are both vital to good health and are essential for the healthy growth and development of children and adolescents. Not only can physical activity—from childhood to older age—increase one’s chances of living longer, it also can help control weight and reduce risks for cardiovascular disease, type 2 diabetes, and some cancers. Good nutrition also helps lower risk for many chronic diseases, and increased consumption of fruits and vegetables helps reduce the risk for heart disease and certain cancers, as well. Physical activity and good nutrition can help people with diabetes control blood glucose levels. Cancer survivors have a better quality of life and improved ability to do basic daily activities if they are physically active.

We know that: where we live affects how we live; that major health problems will not be solved by individual actions and choices alone, and; by moving upstream to address causes of disease and by improving the environments where we live, work, learn, play and receive health care, we can prevent many people from becoming obese or chronically ill in the first place and better manage those chronic illnesses when they do occur.

At the Federal level, the National Prevention Council is charged with providing coordination and leadership among all executive departments and agencies with respect to prevention, wellness and health promotion practices. With input from the public and interested stakeholders, the Council - consisting of representatives from 17 federal departments and agencies - has recently developed a draft National Prevention and Health Promotion Strategy that includes strategic directions for healthy eating and physical activity. The draft Strategy builds on current Federal activities to prevent disease and promote health, and represents an unprecedented opportunity to further promote collaboration across Federal agencies.

In addition to its work with the Council, CDC is working at the federal, state and local level to ensure coordination and maximize the impact of evidence based strategies and policies that will promote physical activity and improve dietary behaviors.

At the Federal level, CDC is collaborating with other agencies working to improve nutrition and physical activity. For example:

- CDC actively participates in an FTC-led Interagency Work Group examining foods marketed to children. The workgroup is developing nutrition principles to guide industry self-regulatory efforts that will be released later this year.
- CDC collaborates with USDA to provide technical assistance and support for the implementation of certain provisions of the Healthy, Hunger-Free Kids Act of 2010, including competitive food standards, local wellness policies, and SNAP-ED.
- Through the National Collaborative on Childhood Obesity Research, CDC, NIH, USDA and RWJF are working together to improving the efficiency, effectiveness and application of childhood obesity research. NCCOR accelerates progress to reduce childhood obesity in the United States by: maximizing outcomes from research; building the capacity for research and surveillance; creating and supporting the mechanisms and infrastructure needed for research translation and dissemination, and; supporting evaluations.
- CDC, FDA, USDA, and NIH are working collaboratively to enhance the ability to track current and future sodium reduction efforts. A particular emphasis is being placed on monitoring changes in the food supply as well as the amount of sodium Americans consume.
- CDC is working with HHS and the First Lady's *Let's Move* childhood obesity prevention initiative to ensure that nutrition and physical activity messages are complementary.
- CDC recently collaborated with GSA and HHS to develop healthy food service guidelines for federal concessions and vending machines. CDC also developed a toolkit for state and local agencies seeking to create their own healthy procurement policies.

At the cornerstone of CDC's efforts to promote healthy environments is our work with states. To promote coordination, CDC requires that state recipients of funding for nutrition, physical activity and obesity develop and sustain a leadership role for a coordinated statewide nutrition, physical activity, and obesity strategy. Funded states, in collaboration with partners, are required to develop and implement state plans for nutrition, physical activity, and obesity. States are also required to evaluate progress toward meeting their state plan and the state partnerships.

Given the correlation between inadequate physical activity and poor nutrition and chronic illnesses, The FY 2012 President's Budget further ensures that CDC's investments in chronic disease prevention at the state level are coordinated and effective by creating a Coordinated Chronic Disease Prevention and Health Promotion Grant Program. The new comprehensive program will enable CDC to: strengthen state-based coordination of chronic disease prevention activities, improve program efficiencies, provide leadership and support for cross-cutting activities, and enhance the effectiveness of chronic disease prevention and risk factor reduction efforts.

2. How can we better align the obesity prevention efforts at the Centers for Medicare and Medicaid Services and the public health service agencies?

Answer: Impacting our nation's obesity epidemic requires a multi-sectoral approach that spans both clinical and community settings. The most effective and sustainable prevention efforts to promote physical activity and healthy eating are policy, systems and environmental changes that increase individuals' ability to make the healthy choices that maintain life-long good health. Yet, research in the field, largely based on commercial insurance program experience, has shown that financial incentives can be effective in the short run for simple preventive care and distinct behavioral goals.

CMS has taken some specific steps to address obesity prevention, building off of recommendations of the U.S. Preventive Services Task Force. More specifically, on August 31, CMS issued a proposed National Coverage Determination (NCD) on "Intensive Behavioral Therapy for Obesity" in primary care settings. The NCD was initiated under CMS' authority to add new Medicare preventive benefits that are recommended with a grade of "A" or "B" by the U.S. Preventive Services Task Force. As part of this decision, CMS is proposing to cover intensive behavioral therapy for obesity for the prevention or early detection of illness or disability for Medicare beneficiaries. Such therapy consists of screening for obesity in adults using measurement of BMI (body mass index); a dietary (nutritional) assessment; and intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise. The proposed decision is described in detail on the CMS website at <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=253&fromdb=true>. Public comments are invited through September 30 and a final coverage decision is expected by late November. In addition, for 2012 CMS has implemented a BMI measure for its Medicare Advantage plan quality rating system.

CMS programs provide medical care for nearly one in three Americans. CMS recently announced availability of \$100 million in demonstration grant funding, authorized under Section 4108 of the Affordable Care Act, allowing states to offer incentives to Medicaid beneficiaries who adopt healthy behaviors including losing weight. CDC and other federal agencies were actively involved in providing input into the design and evaluation of the demonstration program. Under this program, CMS will encourage States to adopt strategies to reward Medicaid beneficiaries who meet goals such as weight loss. This demonstration is designed to identify effective strategies for individual long-term changes in unhealthy habits.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111-3, authorized childhood obesity demonstration grants aimed at developing an effective model for reducing obesity in children. CDC is implementing this program. With \$25 million from the Affordable Care Act, CDC released a Funding Opportunity Announcement for the demonstration grants on January 19, 2011. In line with the legislation, this FOA supports the development of multi-level and multi-sectoral interventions that link primary care with public health approaches and promote behavioral change in conjunction with policy and environmental changes. The impacts and lessons from these investments will inform future funding decisions.

3. How is this integration reflected in the budget?

Answer: Impacting our nation's obesity epidemic requires a multi-sectoral approach that spans both clinical and community settings. The most effective and sustainable prevention efforts to

promote physical activity and healthy eating are policy, systems and environmental changes that increase individuals' ability to make the healthy choices that maintain life-long good health. Yet, research in the field, largely based on commercial insurance program experience, has shown that financial incentives can be effective in the short run for simple preventive care and distinct behavioral goals.

As mentioned above, CMS recently announced the availability of \$100 million in demonstration grant funding made available through section 4108 of the Affordable Care Act for projects that offer incentives to Medicaid enrollees for their participation in proven programs that help individuals lower or control cholesterol and/or blood pressure, lose weight, control diabetes, or stop smoking. As mentioned above, CDC also provided funding for CHIPRA obesity demonstration grants, with \$25 million from the Affordable Care Act. Our interagency work will continue to inform new strategies that HHS can support to better integrate the work of CMS and CDC.

4. I was very happy to see that the President's budget includes \$250 million dollars for a grant program to encourage medical malpractice reform in the states. This is a significant increase from the initial \$25 million investment, which has already promoted medical liability reforms and patient safety programs in 16 states. By strengthening this state-led program to reform the medical malpractice system, we can reduce the practice and high cost of defensive medicine, while also improving the quality and safety of our health care system.

Can you describe some of the state programs for medical malpractice reform that are being implemented as a result of the \$25 million program administered by the Agency for Health Care Research and Quality (AHRQ)?

Answer: New York State's Unified Court System is running a project using judge-directed settlement negotiations to get earlier resolution to error-related disputes, saving both the court and litigants' time and money. Unlike many other medical malpractice suits, the same judge presides over this case from beginning to end, and the judge ensures that only parties who have the authority to settle are in negotiations. Although in the early stages, more than 60 judges from around the state have already participated in a 3-day "Medicine for Judges" training program, which used prominent medical and legal practitioners as faculty, and hundreds of cases are currently in process under this system.

The Office of Oregon Health Policy and Research (OHPR) is using its planning grant to 1) develop a method for setting priorities to create evidence-based practice guidelines; 2) craft a broadly supported safe harbor legislative proposal that will define an evidence-based legal standard of care; and 3) develop a plan to evaluate the effectiveness of the legislative proposal, if enacted. OHPR did a preliminary analysis of data to identify clinical issues that, if addressed, have potential to save money in the medical liability system and improve patient safety. OHPR has also coordinated with other state guideline-related efforts and is pilot testing a tool for closed claim file analysis.

Information on all 20 demonstration and planning grants can be found at <http://www.ahrq.gov/qual/liability/>.

5. Will this increased investment of \$250 million provide enough resources to give every state the opportunity to reform their medical liability system?

Answer: All states would have the ability to apply for these competitive grants, which will be awarded and administered by the Department of Justice's Bureau of Justice Assistance (BJA) in consultation with HHS.

6. Can you describe how the Department of Justice will work with the Department of Health and Human Services to ensure that the grant program supports programs that are supported by health care providers and patient groups at the grassroots level and in the community?

Answer: HHS plans to work in close consultation with the Department of Justice's Bureau of Justice Assistance (BJA), which would award and administer these grants. In its work with the Department of Justice, HHS will bring its experience implementing the Patient Safety and Medical Liability initiative, which included significant outreach to stakeholders, including a day-long public meeting in the fall of 2009 with a wide range of stakeholders such as providers and patient safety advocates.

7. I believe the recently released Health and Human Services Department budget documents assume some Medicare and Medicaid saving from Recovery Audit Contracting programs. As you know, Recovery Audit Contracting is now required for all of Medicare and Medicaid under the Affordable Care Act, and is based on the innovative private-sector practice of hiring outside contractors to identify wasteful spending. The contractors are paid a small contingency fee based on the recoveries and through a small Medicare pilot program involving just five states has already recouped a billion dollars.

Do you see Recovery Audit Contracting as the kind of innovation that can reap great returns on investment for your Department? And can similar innovation in preventing and recovering waste and fraud make a difference for our states struggling to keep strong Medicaid programs under the current and severe budget challenges?

Answer: We believe the national program will continue to be a success. FY 2010 was the first full operational year for the national Recovery Audit program. During FY 2010, CMS focused on educational and outreach efforts and establishing an infrastructure for managing and overseeing the Recovery Audit program.

As of July 4, 2011, the permanent FFS Recovery Audit program has corrected \$684.8 million in improper payments. The \$684.8 million consists of \$109.6 million in underpayments corrected and returned to providers and \$575.2 million in overpayments collected and returned to Medicare. CMS continues to improve and the national Recovery Audit program and expects collections to continue and increase as the Recovery Auditors expand their reviews. CMS

monitors the national Recovery Audit program and makes necessary adjustments to maintain a balance between provider burden (both financial and administrative) and increasing recoveries.

CMS supports States' implementation of Recovery Audit Contractors (RAC) in the Medicaid program and has provided guidance to States in the form of a letter to State Medicaid Directors (October 1, 2010) and a Notice of Proposed Rulemaking (published November 10, 2010). CMS expects to publish final regulations regarding the use of RACs in the Medicaid program later this year. In addition, CMS has provided significant technical assistance to States through all-State calls and webinars and has begun the coordination with States that have RAC contracts in place, as required by the statute. CMS intends to grant States flexibility in the design of their RAC programs to the extent possible while still meeting the statutory requirement that States contract with RACs "in the same manner as" the Secretary contracts with Medicare RACs under section 1893(h).

8. I understand that the April 1st deadline for states to implement the Recovery Audit Contracting requirement of the Affordable Care Act has been pushed back. What is the new deadline for states?

Answer: CMS and States are working to develop the Medicaid RAC programs. States were required to submit a State Plan Amendment to CMS by December 31, 2010 to establish their RAC programs, and all States have done so.

CMS published a proposed rule in November and the public comments are currently under review. The proposed rule did include an implementation date of April 1, however in February, CMS communicated with the States that the implementation date would not be April 1. CMS announced that the final rule will indicate the new implementation date, and we anticipate that the final rule will be issued later this year.

9. I understand that the Centers for Medicare and Medicaid Services is only projecting recoupment of a few hundreds of millions of dollars annually through the Recover Audit Contracting program, out of roughly \$47 billion in Medicare annual improper payments. Is CMS pursuing ideas and initiatives to increase the levels of recoupment?

Answer: We believe the national Medicare Fee-for-Service Recovery Audit program will build upon the success of the demonstration. During the demonstration project, the Recovery Auditors corrected \$1.03 billion in improper payments, including approximately \$990 million in overpayments collected. As of July 4, 2011, under the permanent national Medicare Fee-for-Service Recovery Audit program, the Recovery Auditors corrected a total of \$684.8 million in improper payments, including \$109.6 million in underpayments corrected and \$575.2 million in overpayments collected. CMS is working collaboratively with the Recovery Auditors to determine if there are changes that can be made to the program to increase collections.

Currently, CMS may only use recovery audit collections to fund the administrative aspect of the program. However, to address recovery audit major findings within the Medicare program, it would be beneficial if CMS could retain a portion of the recovery audit program collections for corrective actions (including automated edits, provider education, policy updates and additional

prepayment review). A proposal to allow HHS to retain a portion of the recovery audit collections is included in the FY 2012 President's Budget.

10. I was very pleased to work with my colleague, Senator Ensign, on a provision that strengthened employer wellness programs in the Affordable Care Act. Wellness programs, such as the initiatives created by Johnson & Johnson and Safeway, have helped to improve their employees' health outcomes while also helping to reduce health care costs. By harnessing market-based incentives, these programs encourage individuals to participate in programs such as smoking cessation, exercise, and nutrition classes.

What do you think is the best way to ensure that these types of wellness programs are accessible and affordable for small businesses and their employees?

Answer: Good health starts with steps we can all take to avoid getting sick in the first place, from getting regular check-ups, vaccinations, and recommended screenings, to eating a healthy diet and getting enough exercise.

HHS recently announced the availability of \$10 million to establish and evaluate comprehensive workplace health promotion programs across the nation to improve the health of American workers and their families. The initiative, with funds from the Affordable Care Act's Prevention and Public Health Fund, is aimed at improving workplace environments so that they support healthy lifestyles and reduce risk factors for chronic diseases like heart disease, cancer, stroke, and diabetes. Funds will be awarded through a competitive contract to an organization with the expertise and capacity to work with groups of employers across the nation to develop and expand workplace health programs in small and large worksites. Participating companies will educate employees about good health practices and establish work environments that promote physical activity and proper nutrition and discourage tobacco use—the key lifestyle behaviors that reduce employees' risk for chronic disease.

11. The Medicare Improvements for Patients and Providers Act of (MIPPA) required CMS to establish a transition adjustor in the new bundled payment system in a manner that does not take money out of the system. However, I understand from dialysis facilities in my district that the number of facilities that moved immediately into the new PPS may be far greater than the Agency estimated in its Final Rule, which will result in a significant payment cuts. Given the vulnerability of this patient population, it is critical that CMS properly calculate the transition adjustor using the actual number of facilities that will be paid under the new PPS rather than transitioning into the system over time.

Can you tell us when CMS will recalculate the transition adjustor using the actual number of facilities that moved into the bundle earlier this year and when the Agency plans to correct the adjustor?

Answer: On Friday, April 1, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule with comment (IFC) to revise the end-stage renal disease (ESRD) transition budget-neutrality adjustment that had been finalized in the CY 2011 ESRD Prospective Payment System (PPS) final rule.

As you note, the ESRD PPS provided for a 4-year transition but also allowed facilities to make a one-time election to move to the full PPS rates. The law required CMS to make a temporary adjustment during the transition to ensure budget neutrality. To do so, CMS estimated the number of facilities choosing to move to the full PPS rates and calculated a budget-neutrality adjustment based on that estimate.

However, to ensure that Medicare is paying accurately and consistent with the statute, CMS took action to revise the transition budget-neutrality adjustment to reflect the actual election decisions of ESRD facilities to receive 100 percent payment under the ESRD PPS. The revision will be applied prospectively and results in a zero percent transition budget-neutrality for renal dialysis services furnished April 1, 2011 through December 31, 2011 rather than an adjustment of negative 3.1 percent.

12. Can you describe the progress with the implementation of the National Alzheimer's Project Act? Who is the best person in your department to contact with questions about this program?

Answer: The U.S. Department of Health and Human Services (HHS) has a number of programs that address Alzheimer's disease and the challenges it presents to older adults and their caregivers. The National Institute on Aging leads the National Institutes of Health's efforts in clinical, behavioral and social research into Alzheimer's disease, aimed at finding ways to treat and ultimately prevent the disorder. One notable achievement is the Alzheimer's disease Neuroimaging Initiative, a public-private partnership that is developing imaging to facilitate development of interventions to treat the disease, in its earliest, pre-symptomatic, stages. In addition, the Healthy Brain Initiative at the Centers for Disease Control is working to implement their Roadmap: a coordinated, multi-faceted approach that incorporates the promotion of cognitive health into public health practice. Further, the Administration on Aging's Alzheimer's Disease Supportive Services Program is helping states in their efforts to create responsive, integrated, and sustainable service delivery systems. The program helps states implement programs that translate evidence-based interventions into effective service programs and explore innovative approaches to improve the delivery of supportive services at the community level. These agencies worked together to develop "Dementias, Including Alzheimer's Disease" as a topic area within Healthy People 2020, highlighting our commitment to addressing this major public health issue.

The National Alzheimer's Project Act creates an important opportunity to review and coordinate our efforts to help change the trajectory of this debilitating disease. The act requires that the Alzheimer's plan be developed with the advice of a public-private Advisory Council on Alzheimer's Research, Care, and Services. The Advisory Council was established on May 23, 2011. The Federal Register notice announcing the establishment of the Advisory Council and requesting nominations for members was published on June 10, 2011. We are reviewing nominations and hope to announce Advisory Council members shortly.

In addition, an Interagency Group on Alzheimer's Disease and Related Dementias that includes agencies within HHS, as well as the National Science Foundation, the Department of Veterans

Affairs, and the Department of Defense has been convening since April. The group is working to inventory Federal programs focused on research, clinical care, and long-term services and supports for people with Alzheimer's disease and their caregivers. We are identifying areas of overlap, gaps, and opportunities for collaboration. This information will be used to inform the work of the Advisory Council and the development of a national strategy for Alzheimer's disease.

If you have immediate questions, please contact the Office of the Assistant Secretary for Legislation, who can coordinate the response.

13. As you can appreciate, most states are currently facing tremendous budgetary pressure and are looking for ways to run their programs, such as Medicaid, more efficiently. I am pleased to see that the Federal Coordinated Health Care Office is working hand-in-hand with the Centers for Medicare and Medicaid Services to improve the coordination of health care services for low-income adults who participate in both Medicaid and Medicare.

Are there any plans to help provide planning grants to states for the establishment of potentially cost-saving initiatives such as managed care programs for long-term care or PACE programs? What kind of federal assistance will be available to states who are looking to improve the operation of their Medicaid programs?

Answer: I believe the area of improving care for beneficiaries eligible for both Medicare and Medicaid holds significant promise and we do have plans in place to assist States with this important population. In fact, the Federal Coordinated Health Care Office (the Medicare-Medicaid Coordination Office), created by the Affordable Care Act, has partnered with the Center for Medicare and Medicaid Innovation (Innovation Center), to solicit 15 design contracts of up to \$1 million each to design new approaches to better coordinate care for Medicare-Medicaid enrollees. These design contracts will support the development of new models that integrate the full range of acute, behavioral health, and long-term supports and services. The overall goal of this contracting opportunity is to identify and validate delivery system and payment integration models that can be rapidly tested and, upon successful demonstration, replicated in other States. The primary outcome of the initial design period will be a demonstration proposal that describes how the State would structure, implement, and evaluate a model aimed at improving the quality, coordination, and cost effectiveness of care for dual eligible individuals.

In addition, the Medicare-Medicaid Coordination Office is working collaboratively with the Innovation Center to design unique opportunities for integrated care through payment and delivery system reform for Medicare-Medicaid enrollees. On July 8, 2011, the Medicare-Medicaid Coordination Office, in partnership with the Innovation Center, announced the *Financial Models to Support State Efforts to Integrate Care for Medicare-Medicaid Enrollees*. CMS provided initial guidance on two streamlined approaches for States interested in testing models designed to reduce program expenditures under Medicare and Medicaid, while preserving or enhancing the quality of care furnished to Medicare-Medicaid enrollees.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Benjamin Cardin

1. My question involves a provision of CHIPRA that I authored. We know that for various reasons it is difficult for Medicaid and CHIP enrollees to find dental care, and that working parents whose children qualify for those programs are likely to be employed in jobs that do not permit them to spend working hours scheduling health care appointments. Because of numerous examples of parents who had to call several providers before finding one who accepted a public insurance plan, I worked to secure passage of an amendment requiring the HHS Insure Kids Now website to list participating dentists and benefit information for all fifty states and the District of Columbia. My goal was to ensure that parents could easily access provider information. Unfortunately, a November 30 GAO report on children's access to dental services found an alarming rate of incorrect data on this site. GAO called 188 dentists listed on the site and found that 26 had wrong or disconnected phone numbers, 23 were not taking Medicaid or CHIP patients, and 47 were either no longer in practice or no longer performing routine services.

What steps have you taken in the months following the release of the GAO report to fix these errors? What additional resources are needed, and how can we work together to ensure the accuracy of this information?

Answer: At CMS we understand that providing up-to-date, accurate information for families is an essential component of any effective strategy to improve children's access to dental care, and we emphasize our commitment to working with States to further this goal. In response to the GAO report, we issued a State Health Official letter on November 30, 2010 informing State health officials and Medicaid directors that we would be reaching out to their staff with more information about our expectations for improving the quality of data posted on the Insure Kids Now website, and expressed interests in soliciting ideas for how to improve the quality of the information.

Additionally, to maintain and accelerate access to oral health services, CMS has developed a national oral health strategy to provide focus and visibility to our efforts. CMS has been working in coordination with Federal and State partners, as well as the dental and medical provider communities, children's advocates and other stakeholders to improve access to pediatric dental care. This strategy centers on the establishment of new state and national oral health goals to increase use of preventive services for children, which were announced in 2010. CMS and States are now working to develop State-specific action plans to make progress toward the goals. To ensure progress, supporting States' efforts to promote access, developing and measuring the impact of new and improved approaches to delivering care, and coordinating efforts across the Federal government, States, Tribes, providers, advocacy groups, foundations, and other key stakeholders will be critical.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Chuck Grassley

1. Secretary Sebelius, earlier this month Senate Finance Committee Ranking Member Hatch wrote to the Centers for Medicare and Medicaid Services (CMS) about the waivers that were granted to more than 700 companies and unions to delay meeting certain requirements of the Patient Protection and Affordable Care Act. Like the Ranking Member, I am amazed by the 200 percent increase in waivers given out since December and concerned about the lack of transparency in the process – in particular the lack of information that is made available to the public.

The Center for Consumer Information and Insurance Oversight (Center), which recently moved from the Department of Health and Human Services to CMS, is responsible for issuing those exemptions. While the Center identifies the entities that were granted exemptions on its website, it does not provide any information on individual waiver determinations. Nor does it identify the entities that were denied a waiver and the reasons for the denials.

At the Senate Finance Committee hearing last week on “The President’s Fiscal Year 2012 Budget Proposal,” I asked if you would agree to direct the Center to post specific information regarding the waivers on a public website. You only responded that you would provide the requested information to me. Thus, I am reiterating my request.

In the interest of transparency and accountability, I ask that HHS direct the Center for Consumer Information and Insurance Oversight to post the following information on its website: (1) the criteria each entity met to obtain a waiver; (2) a list of entities that applied but were denied a waiver; and (3) the reason for each denial.

Will you, Secretary Sebelius, agree to do that? If you do not intend to direct the Center to post this information on its website, please explain why not.

Answer: HHS has published guidance outlining the criteria for a waiver, which is all posted on our website. Our November 5th guidance explicitly memorializes standards for review. They are:

- **Whether compliance with the restriction on annual limits would result in a significant decrease in access to benefits.** Such a decrease in access could result from the dropping of coverage by a plan or plan insolvency if the waiver is not granted.
- **The policy’s current annual limits.** Plans with higher annual limits would be expected to experience lower premium increases to become compliant with the IFR’s restricted annual limit requirement than plans with lower limits.

- **The change in premium in percentage terms.** The lower the percentage increase estimated to achieve compliance, the less likely compliance with the IFR would be found to be “significant.”
- **The change in premium in absolute dollar terms.** While the percentage increase can be relevant to the determination of whether an increase is “significant,” for policies with very low premiums, an increase in premiums on a percentage basis may still translate to a small increase in absolute dollar terms and therefore may not be “significant.”
- **The number and type of benefits affected by the annual limit.** Some policies have limits on only some essential health benefits, such as prescription drugs. For example, while increasing the annual limits on prescription drugs to \$750,000 may increase the portion of the premium related to drug coverage significantly, it may not significantly increase the overall cost of health insurance for enrollees.
- **The number of enrollees under the plan seeking the waiver.**

Some applicants for waivers of the annual limits requirements received denial letters. Denied applicants generally did not demonstrate that compliance with the minimum annual limits requirements would significantly increase premiums or decrease access to benefits. These applicants are notified of the opportunity to be reconsidered for an approval if they provide additional materials explaining how their plan will experience a significant increase in premium or decrease in access to benefits as a result of the denial of the waiver. Those plans that were approved upon reconsideration are also listed on the public approval list.

As of August 19, 2011, 80 applicants received denial letters. The list of applicants who received denial letters is available on the CCIIO website at:
http://cciio.cms.gov/resources/files/denials_081911.pdf

2. The President’s fiscal year 2012 Budget Proposal would require states “to monitor and remediate high-risk billing activity to identify prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States may choose one or more drug classes and must develop or review and update their care plan to reduce utilization and remediate any preventable episodes where possible to improve Medicaid integrity and beneficiary quality of care.”

What guidelines and assistance will HHS be providing to the states to ensure that they effectively identify and remediate excess utilization of prescription drugs?

Answer: In Fiscal Year 2009, Medicaid spent \$15.8 billion on prescription drugs, net of rebates. Because so many Medicaid recipients rely on prescription drug medication and because the program spends billions each year on providing this benefit, it is imperative that both the Federal and State governments continue efforts to ensure that the benefit is free of fraud and abuse.

As you know, the President’s Budget proposed requiring States to monitor high-risk billing activity in the Medicaid program to identify prescribing and utilization patterns that may indicate

abuse or excessive utilization of certain prescription drugs. Currently, many States use Drug Utilization Review (DUR) Programs and Surveillance and Utilization Review (SUR) Units to monitor overutilization. The President's proposal would make this a standard feature in all State Medicaid Programs.

3. In your recent response to my letter dated October 20, 2010 regarding prescription drug overutilization in the Medicare and Medicaid programs, you indicated that the Medicare Drug Integrity Contractors (MEDIC) identify, among other things, drug-seeking beneficiaries and geographic hot spots where there is high utilization of certain types of drugs and investigate the outliers identified by their analyses. To what extent will findings made by the MEDICs be shared with the state Medicaid agencies to help identify drug classes that should be monitored?

Answer: CMS is committed to effective partnering with State Medicaid agencies to combat improper prescription drug utilization. MEDICs work with state Medicaid agencies in specific situations, sometimes through the use of task forces, and provide states with aggregate Part D data. In addition to the information shared between the MEDICs and States, many States have similar activities focused on drug utilization. In some instances, States are partnering with CMS in these endeavors, for example, the CMS Medicaid Integrity Group is currently collaborating with the State of Ohio to combat improper prescription drug utilization. The diversion of controlled prescription drugs adversely affects not only the State, but the integrity of the Medicaid program and CMS. On March 25, 2010, CMS and the DEA met with both local and State officials in Ohio to discuss the growing problem of drug diversion in the State. In response to the growing concerns, the CMS Medicaid Integrity Group and Ohio have agreed to work collaboratively to reduce improper payments for prescription drugs. Ohio is an example of our commitment to effective partnering with the States.

4. In your written statement on the President's Fiscal Year 2012 Budget before the Senate Finance Committee on February 15, 2010, you stated that "the Budget includes \$78 million, an increase of \$17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate health information technology (health IT) adoption and promote electronic records (EHRs) as tools to improve the health of individuals and transform the health care system. The increase will allow ONC to assist health care providers in becoming meaningful users of health IT."

Last year, I wrote to you regarding patient safety issues associated with health IT. In particular I asked how the Department is ensuring that the health information technologies being developed are safe and effective. I also asked to what extent should Regional Extension Centers play a role in the reviewing and/or monitoring of complex health IT systems.

In April 2010, you responded that "the Department has a wide range of authorities and programs that can be brought to bear to improve the safety of HIT-assisted care." You also stated that the Agency for Health Research and Quality "oversees Patient Safety Organizations (PSOs), which receive reports on patient safety problems that could shed light on issues related to HIT-assisted care."

a. To what extent have the PSOs provided information regarding safety issues related to the use of health IT?

Answer: The Agency for Healthcare Research and Quality (AHRQ), which is responsible for implementing the PSO program, worked in conjunction with the Office of the National Coordinator for Health Information Technology (ONC) and the Food and Drug Administration (FDA) to develop a uniform method to collect information on safety issues related to the use of Health IT. Last October, AHRQ notified the public of the opportunity to comment on this protocol via the Federal Register. The National Quality Forum, a non-profit consensus endorsement organization that brings together national experts on quality measures on safety and other national quality priorities, convened an expert panel to review comments solicited by HHS. AHRQ and FDA completed revisions based upon the feedback and submitted a revised protocol to ONC in March 2011. The revised protocol will be formally included in the next version of AHRQ's Common Formats for hospitals as well as Common Formats for skilled nursing facilities. The protocol will allow hospitals to submit data to PSOs and PSOs to aggregate data nationally regarding safety issues related to the use of Health IT (HIT).

There have not been data collected by PSOs using AHRQ's Common Formats thus far on safety issues related to the use of health IT using the above referenced standardized protocol. The standardized protocol will help facilitate the collection of more detailed information related to patient safety issues and health IT in the future by PSOs.

In your response, you also stated that “the Regional Extension Centers are an important potential source of advice for providers concerning the merits of alternative HIT systems, including their implications for safety.” In addition, you stated that the “Extension Centers will also educate providers about best practices for installing HIT so as to minimize problems that may result in safety issues.”

b. According to the ONC website, ONC has funded 62 Regional Extension Centers (REC) throughout the country. What is the extent of ONC's oversight over the RECs?

Answer: ONC provides a variety of oversight activities to support the Regional Extension Centers. These activities include:

- 1) Milestone tracking: Through the use of a customer relationship management tool, ONC monitors the success of each REC in achieving their key milestones. Each REC identified a specific number of primary care providers in priority settings, that they would 1) enroll, 2) get “live” on a certified electronic health record system and 3), utilize the electronic health record system to meet the meaningful use criteria. ONC tracks this information on a daily basis.
- 2) Bi-weekly oversight calls: ONC project officers have calls with each REC on a bi-weekly basis to monitor their success at achieving milestones and to connect them to technical assistance as necessary.
- 3) Quarterly operation plan submissions: Each quarter, each REC provides ONC with an “operations plan”, which is a report on their key activities, programmatic risks, key

staff/partnership updates, and future milestone projections. ONC uses this information to identify best practices and to shape development of additional technical assistance.

- 4) Financial monitoring: ONC monitors the financial draw downs of each grantee on a monthly basis. It also reviews annual audits of each grantees financials.
- 5) On-site visits: On an annual basis, ONC project officers make site visits to each REC. During the visits they review policies/procedures, milestone back up information and interview providers receiving services from the REC.

c. Is it the ONC that evaluates the performance of the RECs and ensures that the RECs effectively assist health care providers in adopting electronic health records? If not, then who is responsible for doing so?

Answer: ONC uses the milestone reports and operations plans that REC submit on a regular basis to monitor the performance of the RECs in meeting their key milestones.

During their bi-weekly calls and site visits, project officers review with the REC any concerns that they have received about the program. ONC has also hired an external evaluator, to survey providers that are receiving services from RECs and measure their customer satisfaction. This data will be incorporated into the periodic reviews of the REC.

5. Last year, HHS and Department of Justice officials stated that some of the resources supporting the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative will be devoted to expanding the Medicare Strike Forces from 7 cities to a total of 20 cities. In your written statement, you indicated that the fiscal year 2012 Budget request also “supports the expansion up to 20 Strike Force cities to target Medicare fraud in high risk areas.”

What portion of the HHS Budget request for strengthening program integrity activities would support expansion of the Strike Forces?

Answer: HCFAC funding supports prevention-focused activities at CMS and Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiatives:

- HEAT Initiatives (\$181.8 million): Expands Strike Force cities from seven to up to 20; intensifies law enforcement focus on pharmaceutical fraud; increases representation at administrative appeals; expands the integrated data repository; and develops geospatial complaint maps to help target priorities and identify “hot spots.”

The Strike Force model has been very successful. Since its inception, Strike Force operations in nine cities have charged more than 1,000 individuals who collectively have falsely billed the Medicare program for more than \$2.3 billion. These figures include the Medicare Strike Force’s charging 111 individuals with more than \$240 million in false Medicare billing.

6. What is the status of that expansion?

Answer: Strike Force efforts started in Miami in 2007 and expanded to Los Angeles in 2008. In 2009 and 2010 under the HEAT initiative, we continued expanding the Strike Force to Detroit,

Houston, Brooklyn, Tampa and Baton Rouge using the additional discretionary funding that Congress provided in response to the President's budget requests. On February 17, 2011, we announced further expansion of Medicare Fraud Strike Force operations to Dallas and Chicago.

HEAT has enhanced coordination of anti-fraud efforts of DOJ's Civil and Criminal Divisions and U.S. Attorneys' Offices, FBI, HHS/OIG and CMS. The HEAT task force is working to identify new enforcement initiatives and areas for increased oversight and prevention, including how to increase efficiency in pharmaceutical and device investigations.

7. Have HHS and DOJ identified the locations of any of the additional 13 Strike Force cities? If so, what is the expected timeframe for launching the new locations?

Answer: On February 17, 2011, we announced further expansion of Medicare Fraud Strike Force operations to Dallas and Chicago, bringing the total Strike Force locations to nine. Further expansion to additional cities is contingent upon Congress providing sufficient discretionary appropriated resources. Fully funding the FY 2012 Budget Request will allow HHS and our law enforcement partners to continue expanding our Strike Force operations to additional cities where there is an emerging need for this type of law enforcement partnership.

8. In your letter to Governor Brewer of Arizona dated February 3, 2011, you note that "roughly 40 percent of Medicaid benefits spending -- \$100 billion -- was spent on optional benefits for all enrollees, with nearly 60 percent of this spending for long-term care services."

Is it your intention through your letter to suggest to states facing fiscal crisis that they should cut long-term care services in Medicaid?

Answer: No, it is not my intent that States facing fiscal crisis should cut Medicaid long-term care services. As you may know, this Administration has been, and remains, committed to optional home and community-based services (HCBS) for Medicaid beneficiaries. This is reflected in our Year of Community Living campaign as well as our efforts to implement the many HCBS authorities provided in the Affordable Care Act.

On August 5, 2011 we provided guidance to States on this issue by a State Medicaid Director letter. This letter clarifies ways States can make HCBS program modifications that are within the bounds of the maintenance of effort provisions. In addition, it reminds States of the flexibility they have to make modifications to their HCBS waivers. We believe this flexibility can help interested States make modifications to the waivers that can help them preserve coverage instead of dropping a waiver entirely. This letter does not represent a change in policy; rather, it presents clarifications in response to questions we have received from States.

9. On January 20, 2011, I sent you a letter requesting information about what actions you would be undertaking against states that have failed to turn in audits as mandated under Section 1001(d) of the Medicare Modernization Act of 2003.

Can you please provide me an electronic copy of all the audits received to date? In addition to that information, I would also like you to provide for me information you collected to confirm that the audits were completed consistent with the requirements of the statute.

Answer: We are working diligently to ensure that all States submit the required Disproportionate Share Hospital (DSH) audits prior to when CMS is required by law to begin deferring payments. This work includes ensuring that submitted DSH audits meet the minimum submission requirements. In November 2010, CMS mailed a reminder letter to States that had not submitted acceptable DSH audits and reports. The letter provided additional information regarding the DSH audit and report review process and reminded States that Federal funding claimed for DSH expenditures is conditioned upon the timely receipt of the DSH audits and reports. The current status of State DSH audits has been sent, as requested, in an electronic format to your staff.

10. On August 4, 2010, the Government Accountability Office (GAO) submitted a report to Congress titled "Medicaid Managed Care: CMS's Oversight of States' Rate Setting Needs Improvement" (GAO-10-810). The GAO made specific recommendations the Department of Health and Human Services could take to improve the accuracy of payments made in Medicaid.

Can you let me know what actions you have taken to implement those recommendations or why you chose not to implement them?

Answer: It is our goal to see that all medical services are adequately reimbursed, while acknowledging that states have the responsibility for setting rates. CMS identified many of the same issues raised in the GAO report before the study was conducted, and is already taking several steps to ensure better oversight of Medicaid managed care rates.

We have established a managed care oversight team to develop and implement a number of improvements in oversight, including standard operating procedures for review of rates and a compliance checklist. The Affordable Care Act also gives CMS additional authority and responsibility for acquiring and using Medicaid program data, which should enable us to assess and improve the quality of data submissions we receive in support of managed care rates. We also look forward to working with, and learning from, the Medicaid and CHIP Payment and Access Commission (MACPAC) as they undertake work to improve payment accuracy and adequacy.

11. On February 22, 2011, the Washington Post reported the following:

"In another effort to smooth things over with states, Sebelius also will soon provide guidance to states on Medicaid reimbursement rates for doctors and hospitals. Several states are considering reducing Medicaid payments to providers, but there's concern that slicing rates too deeply could cause some doctors to close their doors to Medicaid patients. The HHS guidance is intended to help states decide which cuts go too far."

I assume this action is in conjunction with the position taken by the Administration in the Maxwell-Jolly v. Independent Living Center of Southern California case. In the brief submitted to the Supreme Court, the Solicitor General argued “the Secretary recently disapproved the operative State plan amendment and a formal administrative hearing will now be conducted; and HHS has committed to conducting a rulemaking proceeding over the next year that will result in an authoritative interpretation of Section 1396a(a)(30)(A).

Can you please describe in detail how you plan to implement the interpretation of Section 1396a(a)(30)(A)?

Answer: On May 6, 2011 the Centers for Medicare and Medicaid Services (CMS) published a proposed rule providing additional guidance to States on requirements to ensure compliance with section 1902(a)(30)(A) of the Social Security Act (the Act), which provides that States must, “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area.” Our regulation is not intended to create a Federal payment standard but rather would rely on State information/data collection and a state public process to ensure that Medicaid recipients have access to services. The proposed rule allowed for a 60-day public comment period which closed on July 5, 2011 and CMS is currently reviewing the submitted comments before finalizing the regulation.

12. Do you believe that states paying rates greater than the guidance should reduce payments?

Answer: As noted in our proposed regulation, we do not intend to create a Federal payment standard but rather would rely on State information/data collection and a state public process to ensure that Medicaid recipients have access to services.

13. Do you believe that states paying rates less than the guidance should increase payments?

Answer: As noted in our proposed regulation, we do not intend to create a Federal payment standard but rather would rely on State information/data collection and a state public process to ensure that Medicaid recipients have access to services.

14. Given the potential consequences of this action and the length of time that has passed since Congress amended the statute at Section 1396a(a)(30)(A), do you believe you have any responsibility to consult with Congress BEFORE producing this for the states?

Answer: As always, we appreciate the comments and feedback from Congress on our regulations. We take the comments we receive from Congress very seriously and to the extent that we have received them in this instance, will take them into consideration before finalizing the rule.

15. Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) established an accreditation program for supplies of imaging services. Chairman Baucus and I sent you a letter dated November 19, 2008 clarifying the congressional intent

behind the provision—specifically, that accreditation organizations should meet the standards already in use by the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC). I understand that you are considering The Joint Commission for inclusion as an accreditation organization.

I would like further information on that decision and specifically, if you believe The Joint Commission has the expertise necessary to certify the quality of images at the same level as the ACR or IAC.

Answer: The Administration is committed to ensuring the safety of Medicare beneficiaries by implementing programs that reduce the risk of unnecessary radiation exposure. As the agency that administers the Medicare program, the Centers for Medicare & Medicaid Services (CMS) is responsible for the purchase of high quality, safe, and effective care for Medicare beneficiaries. This responsibility includes the enrollment of qualified suppliers, and the development and implementation of safeguards that ensure that Medicare beneficiaries receive services from a reputable supplier or provider.

I understand that the Joint Commission has over 16 years experience with specific imaging center accreditation and has provided ongoing accreditation of over 100 suppliers and providers to date. Consistent with section 1834(e)(3) of the Social Security Act as amended by section 135(a) of MIPPA, CMS requires accreditation organizations to utilize the following criteria to evaluate the adequacy of suppliers of imaging services: (A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services; (B) standards for qualifications and responsibilities of medical directors and supervising physicians; (C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications; (D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished; (E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier, and (F) any other standards or procedures the Secretary determines appropriate. During CMS' consideration of accreditation organizations, the Joint Commission provided CMS with more than 25 quality standards that meet all of the MIPPA requirements. Accordingly, we view the selection of the Joint Commission as more than appropriate given its specific expertise and quality standards in this area.

16. Could you please provide to me information about the process and policy considerations that resulted in CMS's January 28, 2011 clarification that waterproof dressings for catheter dialysis patients to protect their catheters while showering or bathing at home are covered as part of the bundled payment to dialysis providers?

Answer: The Administration shares your commitment to ensuring that patients with End-Stage Renal Disease (ESRD) receive quality care under the Medicare program. Through various initiatives, including the new ESRD prospective payment system (PPS), quality incentive

program (QIP), and collection of data on infection control, CMS has worked actively to implement reforms that support quality of care in this critical area of the Medicare program.

With regard to the specific issue of waterproof dressings for catheters, the Centers for Medicare & Medicaid Services (CMS) has given careful consideration to this issue. This includes a review of Medicare policies as they relate to dressings used for showering and bathing, meetings with a leading manufacturer of these items, and, most importantly, thoughtful consideration of patients' clinical needs. Longstanding Medicare policy states that the ESRD composite rate is a comprehensive payment for all modes of in-facility dialysis, hemofiltration, and home dialysis except for bad debts, physician's patient care services, and certain laboratory services and drugs that are separately billable. Further, the Medicare Benefit Policy Manual states that dressings, needed as part of dialysis catheter care, are included in the ESRD composite rate and, therefore, are not separately billable. This policy is also reflected in the establishment of the ESRD PPS as set forth in the final rule published on August 12, 2010 (75 FR 49032).

Accordingly, ESRD facilities are responsible for furnishing all medically necessary renal dialysis items and services, including renal dialysis services that are used in the home – all of which are paid through the ESRD PPS or a blend of the composite payment system and the ESRD PPS. To the extent that waterproof catheter dressings are determined to be medically required, an ESRD facility should provide them and be paid by Medicare in this way. Paying for these items through a separate code would represent duplicate payment.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Olympia Snowe

1. Secretary Sebelius, as we discussed during the hearing, I remain concerned that a great many provisions of the health reform law will impose serious repercussions in terms of inhibiting competition in the state insurance markets and actually driving up health costs. A prime example of this is the medical loss ratio (MLR) requirements. Last July – eight months ago – the Maine Bureau of Insurance initially requested a “waiver” in Maine from the MLR requirements, which are defined as the percentage of a premium that the coverage spends on reimbursement for clinical services and activities that improve health care quality. Starting last month, insurers must provide rebates to enrollees if this spending does not meet minimum MLR standards for a given plan year – 85 percent for large group plans and 80% for small group and individual insurance plans.

The Maine Bureau’s waiver request stated that implementation of the federal standard may “disrupt” and have a “serious destabilizing effect” for Maine’s individual health insurance market. I don’t believe that this is a complicated analysis. According to Section 2718(b)(1)(A)(ii) of the new health reform law, the HHS Secretary may adjust the MLR requirement for a state if the Secretary “determines that application of such 80 percent may destabilize the individual market in such state.” A waiver by HHS would allow individuals in Maine to keep the coverage they currently have – a key promise of health reform supporters – and also would protect what little competition that remains in Maine’s individual market. It appears to be a straightforward analysis – specifically, that one of the two remaining carriers providing coverage will not be forced to exit the market, allowing approximately 14,000 Mainers – or 37 percent of the market, to retain their current coverage. *That’s why last November, I sent a letter to HHS echoing the Maine Bureau’s waiver request, but to date, HHS has not granted it.*

Secretary Sebelius, at the Finance Committee hearing you stated that, “with regard to Maine application for a waiver of the medical loss ratio, part of the requirement of the application is to develop some data and we are working with the Maine department on that data. The requirement for data collection just started in January.” My understanding is that on January 25, HHS deemed Maine’s application to be complete. What is the current status of Maine’s request for a waiver from the MLR regulations? When can we expect HHS to render its final decision and grant this waiver? This would provide some certainty that approximately 14,000 Mainers will not be forced out of their current coverage, and it will protect what little competition remains in Maine’s insurance market.

Answer: Maine submitted an initial application for an adjustment to the individual market MLR standard in December 2010. At CCIIO’s request, the State twice submitted additional information to assist us in our determination. After a careful review of all of the evidence presented, and an extended public comment period, CCIIO determined that Maine met the regulatory criteria necessary to receive an adjustment. In the interest of maintaining stability in

the individual insurance market in Maine, an adjustment to the MLR was granted on March 8, 2011.

2. In September, the NIH Office of Research on Women's Health celebrated its 20 year anniversary. In 1989, as co-chairs of the House Congressional Caucus for Women's Issues, Rep. Pat Schroeder and I asked GAO to document inequities in medical research at the National Institutes of Health. GAO found that although NIH had a policy of including more women in clinical studies and expanding the portfolio of women's health research on paper, they weren't even remotely close to meeting their own standard. As a result, the office was created in response to the lack of systemic and consistent inclusion of women in NIH-supported clinical research. And with the launch of the ground-breaking Women's Health Initiative, NIH helped usher in the most far-reaching clinical trials in this area ever undertaken in the U.S. Yet today, despite spending more than \$30 billion per year on NIH research alone, sorting out how to apply our knowledge of prevention, diagnosis, and treatment is often difficult. And according to an Institute of Medicine report released in September 2010, "a lack of analysis and reporting of data separately for males and females continues to limit researchers' ability to identify potentially important sex and gender differences."

How does HHS plan to address IOM's findings? And to what extent will comparative effectiveness research take into account subsets of patients, such as women, who have traditionally been underrepresented in research?

Answer: Since the establishment of the Officer of Research on Women's Health (ORWH) at NIH, and the implementation of the NIH policy on the inclusion of women and minorities as subjects in clinical research, investigators have been required to design NIH-supported clinical research studies to also include women and individuals from racial and ethnic groups. Such inclusion is required unless clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of participants, the purpose of the research, or the condition under study is a sex-specific condition. The NIH further requires NIH-defined Phase III clinical trials to be designed to permit a valid analysis of potential differences in intervention effects based on sex/gender and race and ethnicity. NIH policy states, "*If final analyses are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required.*" In essence, the NIH inclusion requirements facilitate the design and conduct of Phase III clinical trials so that comparative analyses are incorporated and can be performed and that progress in conducting and completing these comparative analyses are reported to the NIH.

The Institute of Medicine (IOM) report released in September 2010 states, "*a lack of analysis and reporting of data separately for males and females continues to limit researchers' ability to identify potentially important sex and gender differences.*" This is based upon the lack of publication in many instances of analyses of comparative or differential results between women and men even though the NIH requires such an analysis as part of the final NIH Progress Report. This disconnect is related to the editorial policies and decisions of scientific journals which may or may not include such analyses or information in what is published.

It is important to note that while the law does not give the NIH the authority to mandate publication of specific research results in scientific journals, NIH policy states, *“the inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and or subgroups analyzed, will suffice.”*

In an attempt to overcome barriers to the publication of research results that include sex/gender analyses, the NIH held a roundtable meeting in 2001 to discuss the impact of the NIH policy requiring analysis by sex/gender of clinical trials data and how this information can best reach the public domain. The *Journal of the National Cancer Institute* changed its editorial policy to require authors to report the results of sex/gender analysis where appropriate; however, many scientific and medical journals still do not have requirements for sex-specific reporting of results.

In response to the September 2010 IOM report, the ORWH is now funding the IOM to convene a workshop to assess the benefits and barriers to scientific journals reporting clinical outcomes in men and women separately, as well as sex differences in basic research.

NIH staff continues to monitor, document, and work with grantees and contractors from the time of application/proposal through close-out of the award to ensure compliance with the inclusion policy. During application/proposal development, program officers/staff provide technical assistance to investigators about the policy requirements. During peer review, review officers introduce and discuss with reviewers the Guidelines/Instructions for reviewing the Inclusion of Women and Minorities in Clinical Research, including requirements for designing Phase III Clinical Trials in order that valid analyses can be conducted for sex/gender and ethnic/racial differences. At the time of award and submission of progress reports, program officials monitor and verify that inclusion policy requirements are met. For Phase III Clinical Trials, this also involves verifying that the plans for valid analysis of sex/gender and ethnic/racial differences are being followed.

Finally, NIH has a long history of performing Comparative Effectiveness Research, and has undertaken numerous ground-breaking studies which have led to significant changes in clinical practice. Comparative Effectiveness Research is a tool that can help women, men, and members of ethnic and racial groups and their families each make better decisions about which therapies will specifically benefit them. Sometimes Comparative Effectiveness Research shows that newer advances work (as for example in an NIH-supported study that showed an implantable defibrillator saved significantly more lives for both women and men than a commonly prescribed medication). Sometimes Comparative Effectiveness Research shows that newer advances don't work (as for example in the NIH study demonstrating that bone marrow transplants did not prolong life in women with advanced breast cancer). NIH continues to invest in the development of innovative Comparative Effectiveness Research trial designs and in statistical, psychometric and modeling efforts in order to better enable accurate mining and analysis of population and sex/gender-based sub-group data.

Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011

The Honorable Jon Kyl

1. Thank you for your February 15 letter to Governor Brewer in which you clarify that Arizona can eliminate its Medicaid coverage for childless adults without violating the maintenance of effort (MOE) provision in the Affordable Care Act (ACA). I am heartened by your responsiveness to the difficult situation in which the Arizona Health Care Cost Containment System (AHCCCS) finds itself, and have a few follow-up questions:

Your letter expressly states that a “reduction in eligibility associated with the expiration of your demonstration for individuals whose eligibility derives from the demonstration (for example, the childless adult population) would not constitute an MOE violation.” This does not address Governor Brewer’s request to reduce coverage for TANF families from 100% FPL to 50% FPL, as that population is not covered pursuant to a demonstration.

a. Can Arizona reduce coverage for TANF families from 100% FPL to 50% FPL without violating the ACA’s MOE provision?

b. If not, will you use your § 1115 waiver authority to allow Arizona to reduce AHCCCS coverage in this manner?

Answer to a & b: As a former Governor, I know the difficult budget pressures facing States. The Administration has a strong track record in our partnership with States during difficult economic times. CMS is ready to offer new approaches, listen to new ideas and conduct business with States in ways that are responsive to the severity and immediacy of these challenges. We are offering States like Arizona technical support and fast-track ways for them to implement new initiatives to help States strengthen their programs over the long run and run more efficient Medicaid programs.

As I stated in my letter to Governor Brewer, we will continue to work with Arizona’s staff as we consider your State’s proposal and our legal options within the Affordable Care Act. We hope we can find ways to balance the State’s fiscal needs with the needs of the most vulnerable low-income populations in the State, like the TANF group. We have received requests from Arizona about your TANF population and our staff is continuing to review your State’s proposal and to determine what is feasible with this population. We look forward to continued discussions with Arizona about ways in which we can support your State during these difficult economic times. CMS will continue to work collaboratively with all States to explore existing flexibility and cost saving ideas that will help States operate their programs in a cost efficient manner and with the best interests of the beneficiaries in mind.

2. In your letter to Governor Brewer, you reference the provider tax proposed by the Arizona Hospital and Healthcare Association as an option that can help fund the shortfall the state faces within AHCCCS. This seems inconsistent with the Administration’s FY12

budget proposal to phase down Medicaid provider taxes beginning in 2015. Does the Administration support the use of provider taxes as a Medicaid financing mechanism?

Answer: Provider fees continue to be a legitimate option for States to explore as they work to ensure the functioning of their State Medicaid programs. In my letter to Governor Brewer, I suggested that a provider fee may be one possible approach, among others specified in the letter, to meeting the State's funding shortfall.

While provider fees are a legitimate funding option, we continually suggest statutory changes to the Medicaid program which we believe will enhance the efficiency and functioning of the program. As you noted, the President's FY2012 Budget proposes to phase down the provider tax threshold over time but does not propose to phase the practice out all together.

We continue to be available to work with the State of Arizona if they wish to pursue the Arizona Hospital and Healthcare Association proposal.

3. Your letter mentioned integration of physical and mental health care as a potential source of cost savings. Last year, the Arizona legislature considered Senate Bill 1390, which would have moved towards such integration within AHCCCS. That legislation was supported by Governor Brewer but, since it ultimately failed, she must explore other ways to achieve integration between mental and physical health care. This is a long-term endeavor that will not generate immediate savings. What are your specific suggestions for more immediate cost savings in AHCCCS?

Answer: I recognize that many States are examining their Medicaid programs to identify the most cost-effective strategies provide needed services to Medicaid beneficiaries. I suggested to Governor Brewer that she may want to consider the Affordable Care Act option to receive a temporary 90 percent matching rate for care coordination services provided by a health home to people with multiple chronic conditions. In addition, I have also identified to all Governors various tools to manage their programs, including modifying benefits, managing care for high-cost enrollees more effectively, purchasing drugs more efficiently, and ensuring program integrity.

4. The medical loss ratio (MLR) requirements in ACA § 2718 require that health insurers in the large group market spend 85% of their premiums on clinical services and activities that improve health care quality. The percentage is 80% in the small group and individual market. The statute empowers you to "adjust" this ratio for any given state's individual market if you determine that that market would be destabilized as a result of the statutory ratio requirement.

I am told that Iowa, Maine, Florida, and South Carolina have already requested adjustments. Are there any others?

Answer: All applications for an adjustment to the medical loss ratio provision of the Affordable Care Act can be found on the CCIIO website at www.cciio.cms.gov. To date, CCIIO has issued determinations for Maine, New Hampshire, Nevada, Kentucky, North Dakota, Iowa, Guam and

Delaware. CCHIO has yet to issue determinations for Florida, Georgia, Louisiana, Kansas, Indiana, Michigan, Texas, North Carolina and Oklahoma.

5. The HHS implementing regulations released in November clarified the criteria for an adjustment request, but did not clarify what it actually means to “adjust” the MLR. What is your definition of an “adjustment?” Would you simply reduce the 80% to the state’s existing MLR, if any? Or would you implement a different MLR of your own choosing?

Answer: The regulation allows States to request a lower medical loss ratio (MLR) standard, below 80 percent for the individual market, for up to three years – effectively a State-based transition – if they foresee plans withdrawing from the individual market and this withdrawal could serve to destabilize the individual market. This approach adheres to NAIC recommendations and supports State-specific and market-specific transitions.

The criteria for these requests are laid out in the regulation and are consistent with the criteria detailed in the letter sent by the NAIC to Secretary Sebelius on October 13, 2010. The regulation also allows for several other types of adjustments to the MLR standard, including a special circumstances adjustment to certain types of plans, such as so-called mini med plans and expatriate plans. In addition, a health insurance issuer may apply a credibility adjustment for plans with fewer than 75,000 members to address the volatility in their claims experiences that may have an impact on their MLR. The standard to calculate these adjustments to the MLR standard is set forth in the MLR interim final rule.

6. If a state can apply an adjusted MLR in its individual market, will it be allowed to use its existing MLR calculation formula, or will it have to apply the NAIC recommended formula?

Answer: The State must apply for an adjustment to the federal MLR percentage and HHS will approve the specific adjustment requested by the State only if it is determined that meeting the 80% Medical Loss Ratio standard may destabilize the individual market and that the State’s requested adjustment amount does not exceed the adjustment amount that is necessary to avoid the likelihood of market destabilization. If HHS determines that the State’s requested adjustment amount exceeds the amount that is necessary to avoid the likelihood of market destabilization, HHS will make its own determination concerning the MLR adjustment applicable in that State. In order to qualify for this adjustment, a state must demonstrate that requiring insurers in its individual market to meet the 80% MLR has a likelihood of destabilizing the individual market and result in fewer choices for consumers. A state’s request for an adjustment to the MLR standard is a public document. The Secretary invites public comment regarding a state’s request. However, public comments must be submitted within 10 calendar days of HHS posting a state’s complete request online. The public comment period is designed to give all interested parties full opportunity to present relevant information to the Secretary, which will be considered in making a timely determination on whether an adjustment to the statutory MLR standard is justified for the state applicant’s individual market.

7. Will all the states applying for relief receive the same adjustment?

Answer: Each State's insurance market is unique, so what is determined appropriate for Maine or Nevada may not necessarily translate to another State with a different insurance market. CCHIO is committed to evaluating any other State request in a transparent manner, in accordance with the criteria laid out in statute and regulation, while taking into account the unique aspects of each State's insurance market that may contribute toward market destabilization.

**Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011**

The Honorable Pat Roberts

1. In your testimony you say that you “took a magnifying glass to every program in our department and made tough choices. When [you] found waste, [you] cut it. When [you] found duplication, [you] eliminated it. When programs weren’t working well enough, [you] reorganized and streamlined them to put a new focus on results. When they weren’t working at all, [you] ended them.”

Do you have a list of all of these changes? And did any of them result in regulatory changes?

Answer: As part of the FY 2012 Budget process, we identified ways to streamline our operations and target our investments more effectively. The Department is committed to continuing to review the Department’s programs and eliminating overlap and duplication wherever we find it. For FY 2012, the HHS discretionary budget is slightly below the FY 2010 level. The Department is contributing to deficit reduction and to meeting the President’s freeze to non-security programs with over \$5 billion in targeted reductions within the total. Examples of such cuts relating to eliminating duplication or ineffective programs include: discontinuing the \$74 million HRSA State Health Access Grant program which has helped 13 states expand coverage, but is duplicative with work the Department is doing under the new health law to expand access to affordable care; discontinuing the \$23 million Healthy Communities Program, the \$39 million Racial and Ethnic Approaches to Community Health Program, the \$3 million Built Environment Program, and the \$100 million Preventive Health and Health Services Block Grant in CDC, which are duplicative of other Community Health and Public Health Infrastructure and Community Transformation Programs; and discontinuing the \$10 million Rural Community Facility Program in ACF, which is duplicative of efforts in EPA and USDA. In addition, the Budget proposes to reduce the HRSA Rural Hospital Flexibility Grants by \$15 million since investments in Health Centers and Health Professions continue to support health access activities in rural communities.

Furthermore, about \$44 million of decreases are proposed within CDC to eliminate duplicative or disease-specific funding in areas such as prion disease; climate change; genomics activities; and informatics, and laboratory science activities. The President’s Request also reduces \$33 million from the Budget while consolidating existing asthma, healthy homes, and childhood lead poisoning prevention activities into one new comprehensive program that recognizes and mitigates an expanded range of home-based hazards. In FY 2012, CDC plans to consolidate activities from eight programs (Nutrition, Physical Activity, and Obesity; School Health; Health Promotion; Heart Disease and Stroke; Diabetes; Arthritis and Other Chronic Diseases; Cancer; and Prevention Research Centers) into a Comprehensive Chronic Disease Prevention Program that will focus on the top five leading chronic disease causes of death and disability, including heart disease, cancer, and diabetes. Similarly, the Budget consolidates over 23 birth defects, disability, and health projects into three comprehensive programs. Due to concerns about

effectiveness, the Budget eliminates \$23 million for the Agricultural, Forestry, and Fishing Sector of the National Occupational Research Agenda. In addition, the FY 2012 Budget for CDC includes a \$100 million in administrative savings from FY 2010 by reducing travel and contracts.

Within SAMHSA, \$25 million is proposed to be saved from efficiencies garnered from the consolidation of various public awareness activities and multiple performance systems. Within ASPR, \$3 million is cut in the request to eliminate the International Early Warning Surveillance program since it is duplicative of activities supported elsewhere in the Department. Additionally, within ACF, less effective Developmental Disabilities programs addressing Voting Access and Projects of National Significance have been reduced by \$23 million; and, because fewer than 40% of mentoring matches endure more than 12 months, the Mentoring Children of Prisoners Program has been cut by \$24 million while modifications are made to improve its effectiveness. Also, \$17 million is proposed to be cut to eliminate the Adolescent Family Life Program given the recent addition of the Pregnancy Assistance Fund.

Furthermore, NIH is proposing to create in FY 2012 a new organization, the National Center for Advancing Translational Sciences, and eliminate the existing National Center for Research Resources, following an assessment that drug development and other translational research activities could be more effectively organized across NIH.

2. The Senate recently agreed that 1099 provisions should be repealed.

However, the budget seems to only address the repeal of the requirement for goods would continue the requirements for services.

What is the Administration's position on the repeal of the 1099 provisions? And, if has been stated before the President continues to support the repeal of this onerous and costly mandate on businesses across the country, please address the inclusion of the requirements for services in the budget?

Answer: A bill repealing this provision was signed into law on April 14, 2011.

3. In your testimony you mention "historic private market reforms including eliminating pre-existing condition exclusions for children" however I am surprised that you didn't mention the loss of the child-only market in 20 states.

Can you please comment on the impact of your regulation on the private market?

Answer: In March of 2010, the insurance industry said they wanted to make discriminating against children with pre-existing conditions a thing of the past. Several months later, they reneged on their commitment and unfortunately, many insurance companies simply stopped selling child-only insurance policies. We stand ready to work with private insurers to facilitate their ability to offer child-only health care policies. Already we have offered to work with the private plans to have special open seasons and have advised them of other options available to limit adverse selection, such as adjusting rates for health status or permitting child-only rates to

be different from rates for dependent children, consistent with state law. We hope that insurers in the affected States will examine all of the flexibility available to them to continue to offer child-only policies and reconsider their decision not to offer child-only policies.

Additionally, CCIIO will continue its work to ensure that Pre-Existing Condition Insurance Plans (PCIPs) in all States offer coverage for children at a premium based on the standard rate for children. The PCIP program includes coverage of pediatric benefits, prescription drugs, and inpatient, outpatient, and mental health services.

4. In your testimony you discuss how you are reducing health care costs. Specifically you cite an “enhanced review of premium increases.”

Does HHS plan to have actuaries review these premiums to determine if they are justified?

Answer: For too long, insurance companies have been able to operate with little or no public oversight of their rate setting. As a result, consumers and employers have been subjected to unexplained premium increases that far outpace overall inflation and average wage increases, leaving families and companies to spend higher and higher proportions of their income to insurance companies.

Forcing insurance companies to publicly justify their rate increases will finally shed light on industry practices that have long squeezed the family budgets of American families. This unprecedented new transparency in the health insurance market will encourage insurers to do more to control health care costs and discourage insurers from charging exorbitant premiums. Reviewing rate increases will go a long way toward ensuring that consumers finally get the value they deserve for their premium dollars.

Under the final rate review rule, States with effective rate review programs will review rate increases that are subject to review and make determinations on whether these increases are unreasonable. HHS actuaries will review rate increases at or above the rate review threshold in State insurance markets where current State practices fall below the regulatory-defined criteria of an effective rate review program.

This approach is consistent with the Affordable Care Act requirement that HHS establish a rate review process for unreasonable rates in conjunction with States. Under this final regulation, HHS’ role in reviewing rates above the rate review threshold is confined to insurance markets that do not have an effective rate review program. In the case of effective review States, current review and approval practices will satisfy the regulatory requirement concerning the review of such rate increases that are subject to review under a rate review threshold.

5. Does HHS plan to use, and has HHS used, actuaries to determine if the expected reductions in premiums that the Department cites in a number of press releases are accurate?

Answer: Under the final rate review rule, States with effective rate review programs will review rate increases that are subject to review and make determinations on whether these increases are

unreasonable. HHS actuaries will review rate increases at or above the rate review threshold in State insurance markets where current State practices fall below the regulatory-defined criteria of an effective rate review program.

This approach is consistent with the Affordable Care Act requirement that HHS establish a rate review process for unreasonable rates in conjunction with States. Under this final regulation, HHS' role in reviewing rates above the rate review threshold is confined to insurance markets that do not have an effective rate review program. In the case of effective review States, current review and approval practices will satisfy the regulatory requirement concerning the review of such rate increases that are subject to review under a rate review threshold.

6. In the HELP Committee recently you mentioned, in response to my question, that the move of the Office of Consumer Information and Insurance Oversight to CMS, was in an effort to conserve funds.

Can you tell us how much HHS is expected to save with that move?

Answer: There are many efficiencies to be gained from the move, mainly in program support areas such as budget, management, contracting, and information technology. Instead of having each of these functions in two separate agencies, the reorganization allows for them to be combined and allows OCIO to benefit from more mature CMS structures

There is a joint CMS/OCIO transition team that is working to fully integrate OCIO as a new center in CMS. Part of this team's work will be to assess opportunities to achieve the efficiencies of combining the two agencies, such as shared IT systems, regulatory functions, legislative affairs office functions, contracting functions, and other resources. The exact financial impact of this move is contingent upon this assessment.

7. In relation to the SGR extension, why are you only proposing a 2 year extension? And what does HHS and the Administration see as a possible solution for a long-term solution?

Answer: The Administration supports permanent, fiscally responsible reform to the SGR so that seniors and their doctors can depend on stable, predictable physician payments. The President's FY 2012 budget proposes ten years of SGR relief for physicians. To that end, the budget includes a down-payment of this proposal: offsets that would more than cover two years of an extension to prevent dramatic cuts in physician payments.

We're committed to working with Congress to identify additional offsets to cover the costs of long-term physician payment stability.

8. What solution or strategies would you provide or suggest for the TANF reauthorization?

Answer: The Administration would be interested in exploring with Congress a variety of strategies to strengthen the program's ability to improve outcomes for families and children, including helping more parents succeed as workers by building on the recent successes with

subsidized employment; using performance indicators to drive program improvement; and preparing the program to respond more effectively in the event of a future economic downturn.

One area we are particularly interested in exploring is subsidized employment. The Recovery Act provided states with funding that could be used for subsidized employment programs. States took this opportunity and ran with it – and many had significant success working with employers, creating subsidized jobs where parents contributed to the business, and placing some subsidized job participants in unsubsidized jobs. Last June I met Christy Webber who owns a landscape business in Illinois. She was one of the many employers in Illinois who was able to hire parents who needed a job and, in turn, expand her business during the recession. The parents gained real skills and the dignity that comes from working. HHS also talked with participating employers who said their businesses were strengthened by the subsidized employment program and that the employees were a real asset to their businesses. We should consider whether there are ways to make subsidized employment a more important part of TANF.

Another area we would like to explore is performance indicators. The cliché that what gets measured gets done is often repeated because it is true. But right now in the TANF program we don't measure performance in areas where we all agree we need to see better outcomes. We want to work with you to explore performance indicators that would help us understand how well the TANF program is working and, more importantly, would offer important information to states about where they should direct their energies to improve performance.

We think there are many areas where there can be constructive, bipartisan work done to improve the program and we look forward to working with Congress to strengthen the TANF program.

9. How much is the Department expecting it will cost to make the changes suggested by the Administration to the 510(k) approval process? In other words how much will it cost to implement? And does that estimate include what sounds like a continuous retraining of staff on the new rules and review process?

Answer: FDA believes it can implement the actions it committed to take in 2011 to improve the 510(k) program with current resources.

**Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011**

The Honorable Michael Enzi

1. The Department of Health and Human Services Budget (HHS Budget) calls for 75,808 employees in 2012. This is an increase of nearly 4,800 employees over the FY 2010 level.

How many of these employees will be hired to implement the new health care law?

Answer: The Affordable Care Act made a number of changes to current programs that are under the purview of HHS. It is difficult to separate the full time equivalents (FTE) working on health reform specific activities in FY 2012 from those working on activities that are the normal course of business for these programs. However, the Act did establish funding sources which could be used to pay for new staff. As of December 31, 2010, HHS has hired 672 people from the \$1 billion appropriation provided in the Act for implementation. In addition, over 350 staff across the Department are supported by other appropriations in the Act.

2. The HHS Budget estimates the number of full time equivalents at the Centers for Medicare and Medicaid Services (CMS) will increase by over 1,000 FTEs in 2012.

Please provide a detailed accounting how many of those employees are being hired to work on PPACA implementation including a breakdown of how many individuals are hired to work on Medicare and how many are being hired to work on private insurance.

Answer: As shown on page 12 of CMS' FY 2012 Congressional Justification (CJ), CMS' FTEs increased by 1,013 between the FY 2010 enacted level and the FY 2012 Budget Request. This chart below, extracted from the CJ, displays staffing levels within CMS by funding source.

	FY 2010 Enacted 1/	FY 2011 CR Level 2/ (P.L. 111-322)	FY 2012 Budget Request
CMS FTEs:			
Direct (Federal Administration)	4,276	4,278	4,917
Reimbursable (CLIA, CoB, RAC)	126	115	118
Subtotal, Program Management FTEs	4,402	4,393	5,035
Affordable Care Act (Mandatory)	0	3	37
ARRA Implementation (Mandatory)	100	130	160
Total, Program Management FTEs	4,502	4,526	5,232
Affordable Care Act (Mandatory)	5	188	248
Medicaid Financial Management (HCFAC; Mandatory)	90	97	100
MIP Discretionary (HCFAC; Discretionary)	25	53	55
Medicaid Integrity (State Grants; Mandatory)	100	94	100
Total, CMS FTEs 3/	4,722	4,958	5,735

The footnotes below have been renumbered and modified from those in the FY 2012 CJ in order to explain the chart extract.

- 1/ The FY 2010 staffing level reflects staffing estimates at the time our FY 2010 appropriation was enacted, with the addition of 5 mandatory FTEs for ACA-related activities.
- 2/ Reflects the annualized Continuing Resolution level of funding provided under P.L. 111-322.
- 3/ Excludes staffing funded from the ACA Implementation Fund in fiscal years 2010 and 2011.

CMS' FY 2012 Congressional Justification can be accessed at the following link:
<http://www.cms.gov/PerformanceBudget/Downloads/CMSFY12CJ.pdf>

3. Also include which of these FTEs will come "from other funding sources" as stated in the footnote.

Answer: As of December 31, 2010, HHS has hired 672 people from the \$1 billion appropriation provided in the Act for implementation. In addition, over 350 staff across the Department are supported by other appropriations in the Act.

4. Please also explain the footnote in the budget that states, "fiscal years 2010 and 2011 exclude staffing funded from the Affordable Care Act Implementation Fund."

Answer: The staffing that is excluded from the fiscal years 2010 and 2011 totals are funded out of the Health Insurance Reform Implementation Fund (HIRIF), established by Section 1005 of the Health Care and Education Reconciliation Act of 2010. The full time equivalents (FTE) from HIRIF were left out of the fiscal years 2010 and 2011 totals so that the staffing levels for all three fiscal years could be directly comparable. As the footnote states, all three fiscal years include FTE funded out of annual appropriations and other discretionary and mandatory sources.

5. How many staff are currently working at the Center for Consumer Information and Insurance Oversight (CCIIO) both a full time and part time capacity?

Answer: As of August 8, 2011, CCIIO has 212 staff members.

6. How many staff do you expect will be working at CCIIO at the end of FY 2011?

Answer: As of August 8, 2011, CCIIO has 212 staff members and will continually evaluate staffing needs in order to effectively implement the Affordable Care Act insurance provisions.

7. How many staff do you expect will be working at CCIIO at the end of FY 2012?

Answer: The FY 2012 CMS Congressional Justification assumes 272 FTE for CCIIO in FY 2012. CMS is reviewing the most effective allocation of staff across the agency.

8. During the recent hearing before the Committee on Health, Education, Labor, and Pensions, Secretary Sebelius was asked about this decision to disestablish the Office of

Consumer Information and Insurance Oversight (OCIIO) and establish a new Center for Consumer Information and Insurance Oversight (CIIIO). In regard to the decision, Secretary Sebelius stated “we did that to maximize, I think, efficiencies. It was going to be an independent office; and once we looked at overhead costs of duplicating everything, from the front office help to legal staff, it was seen...as an expedited way to maximize and leverage our assets”.

It falls to Congress to ensure taxpayer dollars are spent appropriately and oversee the implementation of the new health care law. As part of this effort, I would ask that you respond to the following questions.

Who in President Obama’s Administration was the first to suggest disestablishing OCIIO and establishing CIIIO? When did the Department first consider disestablishing OCIIO and establishing CIIIO?

Answer: The senior leadership at HHS began to discuss options for moving the office into an operational phase for continued implementation of the Affordable Care Act late in December 2010.

9. Please provide a list of the number of staff detailed to OCIIO from other offices within the Department of Health and Human Services and other Departments of the federal government. Include whether the staff previously working at OCIIO will now work at CIIIO.

Answer: As of August 31, 2011 there are 6 detailees working in CIIIO: 2 from CMS, 1 from DOJ, 1 from HRSA, and 2 OS employees. With the announcement in January 2011 of the transfer of OCIIO out of the Department to CMS, OCIIO staff have been reassigned to CIIIO in CMS.

With the announcement in January 2011 of the transfer of OCIIO out of the Department to CMS, Departmental staff from have been reassigned to CIIIO in CMS.

10. Provide a list of all contracts OCIIO signed with outside entities to conduct any activities on behalf of OCIIO.

Answer: As is typical in the commercial market, CIIIO contracted with certain entities to perform a unique function, so that CIIIO gained from entities’ experience and expertise and did not waste time or resources reinventing already established process. For example, for the federally-run PCIP program, CIIIO drew upon OPM and the National Finance Center’s experience to implement billing and enrollment systems. PCIP also used a competitive bid process to select GEHA to administer the program’s benefits. Additionally, 27 State-based contractors run the PCIP State programs.

For the information technology (IT) and program operations of the ERRP program, CMS works with the contractor who manages the Retiree Drug Subsidy Program. CIIIO was able to maximize the efficiency of the ERRP program operations by taking advantage of the expertise

the contractor built while implementing the Retiree Drug Subsidy. The ERRP IT/Operations contractor established the ERRP public website (<http://www.errp.gov>) in June 2010 to communicate with program stakeholders. The contractor also implemented and maintains secure systems and software to make reimbursements to sponsors, store data, and report program data. Additionally, the contractor supports CMS in delivering valuable and timely education, training, and outreach materials to sponsors.

The ERRP Contact Center contractor responds to telephone and email inquiries, refers technical issues to the IT/Operations contractor, and conducts special outreach projects as needed. The contractor also participates in testing systems developed by the IT/Operations Contractor.

Other contracts include analytic support from George Washington University for the comments CCIIO received from its Request for Comments and Notice of Proposed Rulemaking about the Health Insurance Exchanges, actuarial support from ARC and operational and IT support for Healthcare.gov.

11. What is the status of the five components that were a part of OCIIO (the Office of the Director, the Office of Oversight, the Office of Insurance Programs, the Office of Consumer Programs, and the Office of Health Insurance)?

Answer: The division of responsibility and five component offices within CCIIO at CMS remains unchanged from their roles and responsibilities under OCIIO at HHS.

The five main program offices remain the same:

1. The Office of the Director provides policy support and guidance to the CCIIO programs and activities.
2. The Office of Oversight ensures compliance with the new insurance market rules (for example, prohibitions on rescissions absent fraud or intentional misrepresentation and on pre-existing condition exclusions for children that took effect last year). It also oversees the new medical loss ratio rules and will assist states in reviewing insurance rates.
3. The Office of Health Insurance Exchanges provides guidance on and oversight of the creation of the state-based Affordable Insurance Exchanges.
4. The Office of Insurance Programs manages the temporary pre-existing condition insurance plan programs, a national early retiree reinsurance program, and is developing the Consumer Oriented and Operated Plan (CO-OP) program.
5. The Office of Consumer Support provides citizens with comprehensive information on coverage options currently available so they may make informed choices on the best health insurance for their family and oversees implementation of new appeals requirements.

More information on each of the Offices can be found at:
<http://cciio.cms.gov/resources/about/index.html>.

Functions in CCIIO such as IT infrastructure, regulatory support, Federal and State relations, contracting, human resources, and communications have been incorporated within existing CMS' existing organizational structure.

12. Provide a detailed accounting of all federal dollars allocated to OCIIO, including a description of how the funds were used. Provide a detailed accounting of the process used to transfer funds from OCIIO to CCIIO. Include a detailed accounting of the costs incurred to disestablish OCIIO and establish CCIIO. Provide a detailed accounting of all funds that have been allocated to CCIIO and how the Department plans to spend said funds during the current fiscal year.

Answer: Attached is information related to CCIIO appropriations, budget, and spending through March 31, 2011.

Effective April 2011, CCIIO funds were transferred to CMS. Bi-weekly meetings were held with financial management staff from CMS, the Department, and the HHS Program Support Center to co-ordinate the effort. The Department requested that the Treasury Department create allocation accounts within the following OCIIO accounts:

- 75-0111 – Health Insurance Consumer Information
- 75-0112 – Grants to States for Premium Review
- 75-0113 – Temporary High-Risk Health Insurance Program
- 75-0114 – Temporary Reinsurance Program
- 75-0115 – American Health Benefit Exchanges.

For these five accounts, the Department has transferred, from its jurisdiction to CMS, amounts for the second half of the fiscal year. Once obligations for the first half of the year have been finalized, the Department will transfer any additional amounts that remain available for obligation to the CMS allocation accounts. In addition, the Consumer-Operated and Oriented Plan (CO-OP) program account (75-0118) will be administered by CMS, but not as an allocation account. CMS established an accounting structure for these six Treasury accounts and has made the necessary systems changes in the CMS Healthcare Integrated General Ledger Accounting System (HIGLAS). Please see the attached chart entitled "CCIIO Outlays through March 31."

13. Provide all financial estimates justifying the claim that disestablishing OCIIO and establishing CCIIO would lead to administrative savings and increased efficiencies.

Answer: The Department did not calculate or quantify the amount of savings that would be achieved through merging OCIIO into CMS. This is because the efficiencies to be achieved are from a future organization that had not been fully established. Instead, qualitative analyses led to the conclusion that there would be fewer resources needed overall by sharing administrative structures, processes and personnel, such as those involved in budgeting, contracting, legislative relations and management oversight.

14. Did the Administration initially consider establishing OCIIO within CMS? If so, what was the determining factor that prompted the Department to create OCIIO within the Office of the Secretary?

Answer: A number of options were considered, including CMS, when OCIIO was first established within the Office of the Secretary because it primarily served a policy function. As the organization transitions to a fully operational phase of implementation, the decision has been made to merge OCIIO into CMS.

15. Will the Department renew the lease for more than 70,000 square feet of office the Department leased in Bethesda, Maryland to accommodate OCIIO? Did the government agree to pay \$51.41 per usable square foot?

Answer: In 2010, the Department agreed to a five-year lease for the Bethesda office space used by CCIIO. Press reports have erroneously asserted that CCIIO is paying more than the market rate for its rentable space. In fact, the rent paid for the rentable space in the Bethesda office is \$43.42/square foot, which is on par with downtown Bethesda rental prices and is actually more than \$12/square foot cheaper than rentable space in the District. CCIIO saved between \$8-9.5 million by moving into offices that already had office furniture and were built out.

16. Unfortunately, the new health care law writes HHS a blank check and appropriates "such sums as may be necessary" to implement the health insurance exchanges. Your budget request asks for \$249 million in FY 2011 and \$400 million FY 2012. This is an increase of \$151 million.

Can you please tell me how much you expect the Department will spend on health insurance exchanges since the time the health care bill was signed into law until 2014 when the exchanges are supposed to be fully operational?

Answer : To clarify, the "such sums" appropriation is related only to activities States will perform to set up an Exchange, and is available only through December 31, 2014. Given the current fiscal situations in many States, this financial support is of paramount importance to having Exchanges ready to enroll consumers leading up to January 2014. States will build much of their Exchange infrastructure in FY 2012, including information technology (IT) systems.

CMS negotiates with States and Territories to ensure Exchange planning and establishment grant budgets are well justified. We are also encouraging the most efficient and effective use of these funds through encouraging collaboration and sharing of knowledge across States. For example, we require the awardees of the "Early Innovators" grant program for Exchange IT systems to make their models available to all other States so we do not pay for the same IT development multiple times.

17. Will you commit that during this time of unprecedented federal debts and deficits, you will cap the amount of money the federal government will spend implementing this part of the health care law?

Answer: We are committed to staying within the funds allotted by Congress for the implementation of the Exchanges and other parts of the Affordable Care Act, and using those funds efficiently. Through March, \$53.7 million in Exchange planning grants have been awarded to States and Territories. Another \$241.6 million has been awarded to seven “early innovator” grantees who have committed to building information technology systems that can be replicated in other States, thereby avoiding the costs associated with re-inventing information technology systems for every State. As of March 31, 2011, \$2.5 million in administrative costs had been spent by CCIIO on Exchanges. Please see the attached chart entitled “CCIIO Budget in Obligations.”

18. The HHS Budget states spending for the early retiree reinsurance program totaled \$3.6 billion in fiscal year 2011 and proposes spending \$1.4 billion in fiscal year 2012. Despite several requests our office has still not been informed of how many claims were paid in calendar year 2010 and how many claims HHS expects to pay in calendar year 2011. The HHS Budget states 5,000 unions, local governments, and businesses have signed up for the early retiree reinsurance program.

Please provide a detailed accounting of who these entities are, which have filed claims, how many claims have been paid, how many claims have been denied, how much of the original \$5 billion allocated for the program has already been spent, and how much money has been spent on administrative costs?

Answer: As of March 2011, approximately 5,850 applications, submitted by nearly 5,400 plan sponsors, have been approved for the program. These applications represent a variety of for-profit companies, schools and other educational institutions, unions, State and local governments, religious organizations, and other non-profits.

As of March 17, 2011, program reimbursements provided to over 1,300 participating state and local governments, commercial and nonprofit entities, union plans and religious organizations total nearly \$2 billion. ERRP funds disbursed so far have been used to reimburse expenses of covering over 100,000 individuals who have each incurred health plan costs that exceed the program’s \$15,000 threshold. These reimbursements also benefit millions of early retirees, their spouses, surviving spouses, and dependents, and even active workers covered under the same plan as retirees, by helping to preserve the availability of health benefits, and by reducing the out-of-pocket costs that most participating plans indicate would otherwise be charged to enrollees for coverage.

A full list of entities that received funding can be found in our March 31, 2011 progress report at: http://cciio.cms.gov/resources/files/errp_progress_report_3_31_11.pdf.

19. The HHS Budget projects spending nearly \$3 billion on the high risk pool program in FY 2011 and 2012.

How much of the \$5 billion appropriated for the program will be used on administrative expenses?

Answer: As of March 31, 2011, CCIIO spent \$4 million in administrative costs for the Pre-existing Condition Insurance Program. Some of these expenses were spent on one-time start-up costs that will benefit PCIP through the next three years, including establishing enrollment processes, premium billing systems, and call center services. As required by law, we are carefully monitoring the State and Federal PCIP programs to be sure that administrative costs stay within the 10 percent threshold for the lifetime of the program.

20. What does the Department project enrollment to be in this program in FY 2012 and FY 2013?

Answer: Based on data reported as of June 30, 2011, Pre-existing Condition Insurance Program had 27,489 members. Of these, 19,933 were enrolled in State-run PCIPs and 7,556 were enrolled in the Federally-run PCIP. Between the November and June enrollment releases, the number of people covered by the Federally-run PCIP increased by more than 400 percent (6,058 people).

We expect enrollment to continue to increase. In an attempt to increase enrollment, CCIIO launched a targeted outreach effort to inform potentially eligible people about PCIP. Also, on May 31st, 2011, HHS announced steps to reduce premiums and make it easier for Americans to enroll in PCIP. PCIP premiums dropped as much as 40 percent in 18 States where the Federally administered PCIP operates. In addition, starting July 1, 2011, people applying for coverage in the Federally-administered PCIP can simply provide a letter from a doctor, physician assistant, or nurse practitioner dated within the past 12 months stating that they have or, at any time in the past, had a medical condition, disability, or illness. Applicants will no longer have to wait on an insurance company to send them a denial letter. HHS also sent letters today to the 27 States running their own programs to inform them of the opportunity to modify their current PCIP premiums.

To further enhance the program, beginning this fall, HHS will begin paying agents and brokers for successfully connecting eligible people with the PCIP program. This step will help reach those who are eligible but un-enrolled. Several States have experimented with such payments with good success. This is a part of continuing HHS outreach efforts with States, insurers, providers, and agents and brokers to reach more eligible people and let them know that coverage is available. HHS is also working with insurers to notify people about the PCIP option in their State when their application for health insurance is denied.

Our goal is to provide health coverage to as many eligible people as possible (subject to the \$5 billion cap) until 2014 when the law forbids insurance companies from denying an individual coverage based on a pre-existing condition and consumers will have access to affordable health insurance choices through the Exchanges.

21. Does the Department expect to spend any of the \$5 billion appropriated for the high risk pool program on creating, running, or administering CCIIO?

Answer: The \$5 billion in funding for the Pre-existing Condition Insurance Program is appropriated for claims and administrative costs related to administering the program. PCIP funds are used for the program, as directed by the law.

22. Why were the State high risk pools reclassified as a discretionary program in FY 2011 and FY 2012?

Answer: Since FY 2003, the State High Risk Pool Program has been funded with a combination of mandatory and discretionary appropriations. In recent years, CMS has sought and Congress has chosen to fund the program via discretionary annual appropriations. In both FY 2010 and FY 2011, approximately \$55 million in discretionary annual appropriations funding was provided by Congress for this activity. The President's FY 2012 Budget continues to request \$44 million for State High Risk Pools, to bridge the gap until 2014 when insurance companies can no longer deny an individual coverage based on a pre-existing condition.

23. Within nine months of the new health care bill becoming law, the Department of Health and Human Services published 18 regulations. Twelve of the 18 regulations were issued as interim final rules. This means that two thirds of the health care regulations were issued without an opportunity for the public to comment on them.

Can you make a commitment to me that the Department of Health and Human Services will insist that federal agencies publish a notice of proposed rulemaking in the Federal Register, and give the public at least a 30 day opportunity to comment on all the regulations issued implementing the new health care law?

Answer: Across the administration, we have worked hard to implement the Affordable Care Act as efficiently and effectively as possible. As you know, many important protections, including the Patients' Bill of Rights, went into effect just a few months after the Affordable Care Act became law. It was important to give consumers, health plans and States the information they needed to implement those requirements in a timely fashion, which required the Administration to promulgate Interim Final Rules with comment period. We carefully reviewed the comments that we received in response to these rules, and have amended and clarified several of the rules based on those comments.

This Administration is committed to an open process and seeking feedback from interested parties and stakeholders. The regulations implementing the Affordable Care Act have been published, where possible, as proposed rules with comment periods before being finalized.

24. Additionally, despite numerous requests, Congress has not been given a schedule of when additional health care reform regulations will be published.

Can you please provide a schedule of when you expect upcoming health care regulations will be published?

Answer: As you know, each spring and fall the Administration publishes a list of upcoming regulatory actions. This is the best source of information on upcoming rules.

25. Also, senior Administration staff have previously indicated that many of the interim final rules will be reissued as final rules.

Is this your understanding? If so, please include the dates you expect the interim final rules will be reissued as final rules as part of the schedule mentioned above.

Answer: As you know, each spring and fall the Administration publishes a list of upcoming regulatory actions. This is the best source of information on upcoming rules.

26. Under current law, the Centers of Medicare and Medicaid Services (CMS) is allowed to use Medicare Trust Fund dollars for specified activities relating to quality improvement and fraud and abuse prevention.

Concerns have been raised that CMS could use this so-called apportionment authority to fund some of the implementation activities associated with the new health care law. Any diversion of these funds would represent a serious breach of faith with the Medicare beneficiaries who have contributed to the Medicare Trust Fund through their Medicare payroll taxes.

Will you commit that you will block any effort to divert Medicare Trust Fund dollars to any purpose other than providing care for Medicare beneficiaries and funding the existing Medicare quality and fraud prevention programs?

Answer: I share your concern that Medicare Trust Fund dollars should be spent to provide Medicare beneficiaries with high quality care. The Administration is committed to protecting the integrity of the Medicare Trust Funds and fully complying with all applicable laws that govern the use of Trust Fund dollars. The Medicare Trust Fund can be used to finance quality improvement activities, as well as activities to prevent fraud and abuse. CMS' use of apportionment authority will continue to fall within these parameters.

27. Please explain exactly how much money will be spent by HHS, the Department of Treasury, and the Office of Personnel Management on implementation of PPACA and how the funds will be expended.

Answer: The FY 2012 President's Budget estimates obligations of \$538 million to HHS and \$252 million to the Department of Treasury and the Office of Personnel Management for FY 2011. In FY 2012, the Budget estimates obligations of \$82 million to Treasury. For HHS, many of these expenses are initial start-up costs, such as new IT systems. As depicted on page 489 of the FY 2012 Office of Management and Budget Appendix, the majority of funding for all agencies will be spent on advisory and assistance services, or contracts, and salaries and benefits.

28. Do you anticipate other agencies will be involved with implementation of PPACA? If so, what agencies and how will their PPACA implementation activities be funded?

Answer: Treasury, HHS, and the Department of Labor share responsibility for the implementation of the Affordable Care Act with respect to employment-based plans. My

understanding is that the Department of Labor responsibilities are being funded by its own appropriations, which fund its general enforcement authority [under the Employee Retirement Income Security Act] over private-sector benefit plans, including 2.6 million health plans, and supplemented by the funds provided from the Implementation Fund. To date, no other agencies have received Implementation Funding. The Department of Homeland Security and the Social Security Administration also have responsibilities under the Affordable Care Act.

29. Please explain why \$128 million was obligated from the PPACA implementation fund in FY 2011, why \$790 million will be spent in FY 2012, and why \$82 million will be spent in FY 2013.

Answer: The correct years for obligation reflected in the President's Budget are FY 2010, FY 2011, and FY 2012, respectively. \$128 million was obligated from the Implementation Fund in FY 2010. The Budget projects that \$790 million will be obligated in FY 2011 and \$82 million will be obligated in FY 2012. The \$128 million obligation in FY 2010 is an actual number.

HHS has used the funds to primarily support salaries, benefits, contracts, and infrastructure for various health reform initiatives. The funds will allow HHS to improve and enhance its existing programs including quality reporting and incentive payments, health plan oversight, provider and beneficiary outreach, administrative simplification, and information technology infrastructure. This funding will also support implementation of new insurance market reforms and oversight programs, new State and Federally-coordinated Affordable Insurance Exchanges that must be built before 2014, and outreach and education for a new and broad cohort of consumers.

The Department of Treasury required funding to implement multiple tax changes, including the Small Business Tax Credit, expanded adoption credit, W-2 changes for loan forgiveness, excise tax on indoor tanning services, charitable hospital requirements, and planning for Exchanges.

The Office of Personnel Management (OPM) required funding to plan for implementing and overseeing Multi-State Plan options for the Exchanges. At least two Multi-State Plans will be offered on each Exchange beginning in 2014. OPM is also assisting HHS by implementing an interim Federal external appeals process prior to the establishment of a permanent Federal appeals process.

30. Do you expect to cap your spending in FY 2013 at \$82 million? Do you expect to spend federal taxpayer dollars on PPACA implementation in FY 2014? If so, from what accounts do you expect the funds will be allocated?

Answer: Treasury is estimated to spend \$82 million in FY 2012 from the Implementation Fund. Beginning with the FY 2012 President's Budget, agencies requested funding for implementation and regular operations through the appropriations process. Some implementation activities are funded from mandatory appropriations.

31. The President issued an Executive Order titled, Improving Regulation and Regulatory Reviews. I was pleased to see the President acknowledge some regulations "have gotten out

of balance, placing unreasonable burdens on business – burdens that have stifled innovation and have had a chilling effect on growth and jobs.”

According to the Government Accountability Office 43 major rules imposing new costs on the private sector were adopted during the last fiscal year. These rules imposed \$28 billion in new costs to Americans.

Please provide a status update on your activities related to the government-wide review of current regulations. In addition, please describe how HHS will quantify the economic consequences of the regulations you review.

Answer: The President’s Executive Order 13563 asked federal agencies, including HHS, to develop a plan for retrospective review of its significant regulations. HHS finalized its plan on August 22, 2011 and posted it on the HHS OpenGov website (<http://www.hhs.gov/open/execorders/13563/index.html>). For the initial retrospective review, existing resources do not allow the Department to undertake a detailed analysis on each regulation proposed for review, so the priority was first, to identify regulations that agencies could easily modify, streamline, or rescind to address regulatory burdens or inefficiencies, and second, to identify regulations that may be ripe for review because of changes in circumstance. These proposed candidates for review were then divided into categories in accordance with the guidelines set forth by the President in Executive Order 13563, including those candidate regulations that:

- Require updating in recognition of changing technology;
- May be revised to reduce the reporting and recordkeeping burdens;
- Can be cleaned up to eliminate outdated provisions; or
- Can be modified to increase flexibility and reduce burdens on states.

HHS has already completed several regulatory activities identified in Appendix A of its Final Retrospective Regulatory Review Plan, including regulations providing greater flexibility for rural and critical access hospitals to provide patient access to physicians and other providers at other hospitals by using telemedicine, aligning the reporting for electronic prescribing requirements under the electronic prescribing program and EHR Incentive Program in Medicare, and providing greater flexibility for states to repay the federal government for Medicaid overpayments. Additionally, HHS has established a cross-agency Analytics Team, lead by the Assistant Secretary for Planning and Evaluation, to establish greater consistency across agencies in regulatory impact analysis and other analytic tools to improve communications related to the benefits and costs of a given regulation.

On an ongoing basis, agencies will review other regulations more thoroughly to determine their regulatory impact according to a predetermined set of criteria aligned with the President’s objectives in support of developing a streamlined, robust, and balanced regulatory framework. In particular, HHS will emphasize a review of its regulations that will have the greatest potential to alleviate unnecessary burdens and costs or to promote flexibility and create jobs.

**Secretary Sebelius Questions for the Record
Senate Committee on Finance
February 15, 2011**

The Honorable Tom Coburn

1. You said on page 1 of your testimony that “we can’t build lasting prosperity on a mountain of debt.”

Are run-away government spending or our health care entitlements the largest contributors to our dangerously high national debt and annual budget deficits? How does this budget solve either one?

Answer: The Affordable Care Act includes many provisions to control health care costs, and implementing the Act will lead to more efficient care and to savings by, for example, adjusting hospital payments based on readmission rates or hospital acquired conditions and facilitating the establishment of Accountable Care Organizations. Further, the President’s Budget includes efforts to improve budget discipline and will realize health savings by focusing on program integrity, efficiency, and accountability while maintaining benefits and access for beneficiaries. Moving forward, difficult decisions will need to be made to continue to bring down health care costs in Medicare and Medicaid that are the largest contributors to long-term deficit. The Affordable Care Act takes action to slow rising health care costs, and the President’s Budget proposals take important steps that will cut spending and deficits in a way consistent with core values. We look forward to continued work with Congress on bringing down health care costs and tackling the long-term deficit.

2. You said on page 1 of your testimony that the 2012 Budget means “giving more families and business owners...more freedom from rising health costs.”

However, isn’t it true that the independent Joint Committee on Taxation has said that many of the \$560 billion dollars in tax hikes from the controversial health law passed last year will “be passed directly to consumers”?¹ Hasn’t the CBO found that, under the law, premiums for millions of Americans purchasing coverage on their own will be 10-13 percent higher than they otherwise would be?²

Answer: The Congressional Budget Office (CBO) produced estimates of the impact of the Affordable Care Act on premiums. For people purchasing non-group coverage through the Exchanges, it estimated savings of 7 to 10 percent resulting from the increase in the size of the insurance pool as well as the nature of the new enrollees, who, in light of the premium tax credits and the individual responsibility provisions, are likely to be healthier than existing enrollees. An additional 7 to 10 percent savings would result from providing the same set of services to the same group of enrollees – primarily because of the new rules in the market such as eliminating

¹ Joint Committee on Taxation, “Technical Explanation of the Revenue Provisions of the ‘Reconciliation Act of 2010,’ as Amended, In Combination with the ‘Patient Protection and Affordable Care Act,’” March 21, 2010, <http://www.jct.gov/publications.html?func=startdown&id=3673>

² Congressional Budget Office, “An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act,” November 30, 2009, <http://www.cbo.gov/ftpdocs/107xx/doc10781/11-30-Premiums.pdf>

insurance underwriting. CBO also credits some of the savings to increased choices and competition. Together, these savings range from 14 to 20 percent when comparing comparable coverage.

3. According to CBO, Medicaid payment rates for physicians are about 40 percent lower than private payers. As a result, about 40 percent of physicians do not accept Medicaid patients. In some places – like Santa Cruz county, CA, for example – about 60 percent of physicians do not take Medicaid patients.

Do you expect the number of physicians that take Medicaid patients to increase or decrease under the health care law, when 16 to 18 million new Americans are enrolled in Medicaid? To ensure that Medicaid patients have the best access to care, would you enroll in Medicaid?

Answer: For millions of Americans, the Medicaid program provides a source of regular health care that would not otherwise be available to them due to cost or through an employer. As we work with States to achieve continual improvement of the Medicaid program, we know that research has found individuals with Medicaid have similar access to care as individuals with private health insurance, and that Medicaid enrollees are more likely than the uninsured to have a usual source of care and are less likely to not get needed care due to cost. For millions of Americans, the Affordable Care Act Medicaid expansion will mean access to the quality health care that Medicaid provides.

4. The FY2010 Financial audit of the Department found that HHS is not in compliance with federal financial management law. According to the HHS Inspector General’s review of Ernst & Young’s financial audit of HHS, “HHS’s financial management systems are not compliant with the Federal Financial Management Improvement Act of 1996.”

Why are you and your employees not complying with the law? Do you think taxpayers should be concerned about this?

Answer: In FY 2004, the Department began its implementation of a commercial web-based of-the-shelf product modified to replace five legacy accounting systems and numerous subsidiary systems with one modern accounting system with three components. While the Department systems are not fully integrated, steps have been taken to update the systems.

In addition, the Consolidated Financial Reporting System (CFRS) was deployed in the first quarter of FY 2011. CFRS address the Department’s recurring CFO Act findings and the *Federal Financial Management Improvement Act of 1996 (P.L. 104-208)* system non-compliance. The system eliminated the OPDIVs’ manual intervention for the consolidation process.

5. The FY2010 Financial audit of the Department found that nearly \$2 billion taxpayer dollars are stuck in limbo – not helping anyone. “As of September 30, 2010, the audit identified approximately 102,500 transactions totaling an approximate \$1.8 billion that were more than 2 years old without activity.”

Since these funds are clearly old and not being used, would you publicly support legislation transferring those funds to reduce the deficit?

Answer: In FY 2010, this identified issue primarily relates to a limited number of Operating Divisions that did not adequately identify, research and clear differences noted in their Treasury Account Reconciliations timely. The issue is not necessarily that the accounts were not cleared, but that the processes in certain divisions were not regularly executed to identify and clear differences. This reconciliation is a key control in financial management, and should be conducted regularly to ensure proper financial stewardship. In the audit report, uncleared differences were \$3 billion at the end of the third quarter of FY 2010 indicating a lack of regular monitoring; however, the differences were evaluated and significantly reduced to \$400 million at year end. The Department's Office of Finance is working closely with the Operating Divisions, to monitor, investigate and clear the differences in a more timely manner. In FY 2011, we have reviewed these Operating Divisions' Treasury Accounts, and have found improvement in the accounts for FY 2011. The Office of Finance plans to continue regular on-site visits throughout the year to ensure continuous monitoring of this issue.

To further illustrate the issue, HHS is required to reconcile its accounts with Treasury monthly, and promptly resolve the differences in each account. HHS has approximately 500 accounts with Treasury that must be reconciled monthly. To resolve this audit finding, management's approach is to address the material or largest items first, and then continue to work the numerous, smaller backlogged items as we progress. We are committed to sound financial management controls, and note that the \$400 million identified by the auditors is representative of the uncleared backlogged amounts, which we are continually working to resolve and clear.

6. The FY2010 Financial audit of the Department found that nearly \$800 million dollars "could not be explained" differing between HHS' records and Treasury Department records. It also found that some processes and procedural manuals have not been updated since the 1980s.

When HHS bureaucrats cannot do their basic job and are using technology two decades old, what is supposed to make the American people believe you can manage one-sixth of the economy?

Answer: We have implemented a financial management review process in the Department's Office of Finance to ensure that discrepancies such as those noted by the auditors are regularly monitored, investigated and cleared in a timely manner. The amount noted in the FY 2010 annual audit report is attributable to a limited number of Operating Divisions within the Department. The Department's Office of Finance is working with those divisions to improve business processes and system configurations to resolve this issue during FY 2011.

Unlike commercial accounting, Federal government financial reporting has two types of accounts: budgetary and proprietary. These accounts are regularly compared to ensure that all

transactions have been properly reflected in both the standard commercial reports (i.e., balance sheet and statement of net cost) and the uniquely Federal reports (i.e., Statement of Budgetary Resources). Some transactions cross the two types of required Federal reporting, and other transactions are unique to either the budgetary or proprietary reporting and have no associated accounting transaction in the other types of accounts. The discrepancies between the two transactional accounts must be monitored and reconciled on a timely basis throughout the year.

Numerous controls enable the Department to address discrepancies such as these record and account for taxpayer funds in accordance with uniquely Federal guide.

7. Starting the year after next (2014) the new health spending law would impose a tax on all health insurers based on their market share of net premiums written. A few years later (in 2018), the fee amount would grow at the rate of premiums). This tax is does not apply self-funded ERISA plans, non-profit insurers that meet specific criteria, and certain voluntary employee benefit associations. Yet this tax is estimated by CBO to raise \$60 billion over 10 years.

Do you have concerns that the burden of this tax will fall heavily on 1) businesses that purchase insurance – including small businesses that fully insure their workforces, and 2) all individual and families who purchase coverage in the individual market?

Answer: The health insurance industry is expected to gain millions of new customers under the Affordable Care Act. The CBO estimates that the Affordable Care Act extends coverage to 34 million more Americans by 2021. Right now, it has expanded coverage through policies to allow young adults to purchase coverage through their parents' health plans, the Pre-existing Condition Insurance Program, and the Early Retiree Reinsurance Program. Given these policies to shore up and expand private health insurance, the industry is well positioned to pay the annual fee without cost shifting to customers.

8. As part of your confirmation hearing May 31, 2009, I asked you which programs within the Department, if any, do you think can be eliminated because they are ineffective, duplicative, unnecessary, or have outlived their purpose? At the time, you said it was "premature to announce a series of programs that should be eliminated"

The President's 2012 budget includes over a dozen program terminations or reductions at the Department of Health and Human Services that would save the taxpayers hundreds of millions of dollars. Would you publicly support legislation to enact each of the terminations and reductions for your agency?

Answer: We endorse all of the proposals for program terminations or reductions identified in the FY 2012 President's Budget request. All of the proposed terminations and reductions could be adopted in the FY 2012 appropriations bill.

10. Currently the Institute of Medicine (IOM) will soon issue a list of specific mandatory benefits to meet the health care law's essential health benefits requirement. According to a recent New York Times article, Administration officials have indicated that they expect these services to include contraceptives.

Will the administration force employers, such as religious organizations, to pay for items that violate their religious beliefs?

Answer: On August 1, 2011, HHS announced new guidelines that will ensure that women receive preventive health services at no additional cost. Developed by the independent Institute of Medicine, the new guidelines require new health insurance plans to cover women's preventive services such as well-woman visits, breastfeeding support, domestic violence screening, and contraception without charging a co-payment, co-insurance or a deductible.

New health plans will need to include these services without cost sharing for insurance policies with plan years beginning on or after August 1, 2012. The rules governing coverage of preventive services which allow plans to use reasonable medical management to help define the nature of the covered service apply to women's preventive services. Plans will retain the flexibility to control costs and promote efficient delivery of care by, for example, continuing to charge cost-sharing for branded drugs if a generic version is available and is just as effective and safe for the patient to use.

The administration also released an amendment to the prevention regulation that allows religious institutions that offer insurance to their employees the choice of whether or not to cover contraception services. This regulation is modeled on the most common accommodation for churches available in the majority of the 28 states that already require insurance companies to cover contraception. HHS welcomes comment on this policy.

11. President Obama said that taxpayers "end up subsidizing the uninsured when they're forced to go to the emergency room for care, to the tune of about a thousand bucks per family."³ But according to CDC data, patients on Medicaid use hospital ERs more frequently than uninsured patients.

With 16 million additional Americans in Medicaid under the new law, don't you think Americans could be paying hundreds of dollars more each year for the new Medicaid patients who will use the ER frequently?

Answer: Ensuring that Medicaid recipients have regular access to care is of great importance to both States and CMS. Reducing the inappropriate use of hospital emergency departments is important to both the quality of care for all patients and for the fiscal health of the Medicaid program. As we move to expand eligibility in the Medicaid program as required by the Affordable Care Act, we are also implementing a number of Affordable Care Act provisions and policy updates which will help provide for a regular source of care for Medicaid patients. In

³ President Barack H. Obama, "Remarks by the President on Health Care Reform," The White House, March 3, 2010. <http://www.whitehouse.gov/the-press-office/remarks-president-health-care-reform>

particular, on May 6, 2011, CMS published a proposed regulation providing States with additional guidance on requirements to ensure compliance with section 1902(a)(30)(A) of the Social Security Act (the Act), which provides that States must, “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area,” and we are working on implementing section 1202 of the Health Care and Education Reconciliation Act which will increase payment for primary care services delivered to Medicaid recipients and help promote better access to non-emergency care.

