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# PRESIDENT'S FISCAL YEAR 2011 HEALTH CARE PROPOSALS

## HEARING

BEFORE THE

## COMMITTEE ON FINANCE UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

FEBRUARY 3, 2010

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# CONTENTS

## OPENING STATEMENTS



## ADMINISTRATION WITNESS



## ALPHABETICAL LISTING AND APPENDIX MATERIAL

# PRESIDENT'S FISCAL YEAR 2011 HEALTH CARE PROPOSALS

**WEDNESDAY, FEBRUARY 3, 2010**

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

The hearing was convened, pursuant to notice, at 3:30 p.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Rockefeller, Lincoln, Wyden, Stabenow, Carper, Grassley, Hatch, Snowe, Kyl, Enzi, and Cornyn.

Also present: Democratic Staff: Bill Dauster, Deputy Staff Director and General Counsel; Elizabeth Fowler, Senior Counsel to the Chairman and Chief Health Counsel; David Schwartz, Health Counsel; Alan Cohen, Senior Budget Analyst; Deidra Henry-Spires, Professional Staff; and Tony Clapsis, Professional Staff. Republican Staff: Kolan Davis, Staff Director and Chief Counsel; Mark Hayes, Health Policy Director and Chief Health Counsel; Emilia DiSanto, Special Counsel and Chief Investigative Counsel; Rodney Whitlock, Health Policy Advisor; Michael Park, Health Policy Counsel; and Christopher Armstrong, Investigator.

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

The CHAIRMAN. The committee will come to order.

Mahatma Gandhi said, "Every worthwhile accomplishment has its stages of drudgery and triumph; a beginning, a struggle, and a victory." The effort to enact comprehensive health care reform has certainly seen its struggle, and even its stages of drudgery.

As we look back at the progress that we have made and look ahead at the short distance that we have yet to go, I remain confident that we will soon move to the stages of triumph and victory. We are on the brink of accomplishing real health care reform. We are on the brink of reform that will help millions of Americans to afford health care coverage. We are on the brink of reform that will improve the quality and efficiency of health care delivery for all.

Every day reminds us of the need for reform. The latest report by the nonpartisan Congressional Budget Office warns once again that the growth of Federal health care spending represents the "single greatest threat to budget stability." That is because health care costs continue to rise faster than the growth in the economy and faster than the growth in wages of American families.

In the last 8 years, average wages have increased just 20 percent, but the average cost of employer-sponsored health care cov-

erage has doubled more than 5 times, and health insurance premiums have tripled. The high cost of health care means that 1 in 4 Americans lives in a family that has spent more than 10 percent of its income on health care in 2009, and 4 out of 5 of these families have health insurance.

The high cost of health care also diminishes the ability of American companies to compete, and the high cost of health care makes it hard for small businesses that provide health coverage to hire new workers or stay afloat. America spends nearly twice what the next highest spending country spends on health care, but U.S. health care far too often produces uneven quality and poor outcomes.

More than 46 million Americans lack any form of health coverage. Another 23 million are under-insured. According to the CBO, within a decade, 54 million Americans will be uninsured. The CMS Actuary's Office thinks that that number will go even higher, reaching 57 million by the year 2019.

We have tried incremental reform. We created rights and protections in 1996 for people who purchased group health coverage, and we covered millions of uninsured children with the 1997 enactment of the Children's Health Insurance Program. But we have reached a point where it is increasingly difficult to fix this system one step at a time. We cannot add 46 million uninsured people to a broken health system, and we cannot meaningfully control the growth of health spending without covering the uninsured.

Over the past year we have learned how hard it is to reform the health care system, but just because it is hard does not mean that the task is any less necessary. Just because it is hard does not mean that we should look the other way, and just because it is hard does not mean that we have to compromise so much that we fail to address the problems at hand.

Madam Secretary, thank you for all of your hard work over the past year and the work of your department in helping us to craft health care reform. Thanks to your guidance and leadership, we know that we can start covering the uninsured with preexisting conditions this year through a high-risk pool. We know that we can provide immediate assistance to bridge the Medicare drug coverage gap, the so-called donut hole. We know that we can jump-start quality improvement policies in Medicare and Medicaid, and we know that we can make immediate progress on insurance market reform.

I am pleased to see that the President's budget assumes enactment of health reform. The budget accurately reflects that health reform has the potential to reduce the budget deficit by $150 billion over the next decade. As the President said in the State of the Union address, reform also has the potential to reduce the deficit by $1 trillion over the second 10 years.

This year the Finance Committee faces a full agenda: we will work on creating jobs, growing the economy, and reducing the deficit. But given the daunting long-run fiscal challenges that we face, we cannot give up on the quest for health reform that addresses the interconnected problems of cost, quality, and access.

I urge my colleagues on both sides of the aisle, both sides of the Capitol, and both ends of Pennsylvania Avenue to not give up. We can—we must—succeed in reforming our health system.

Of course, we face other daunting challenges. The Medicare physician payment formula needs reform. HHS took an important step by removing drugs from the formula. Just last week, the Senate recognized that a long-term solution will require a short-term investment by exempting part of SGR, or Sustainable Growth Rate, from the new statutory pay-go rules. I hope that this push will aid us in finding a permanent solution for the sake of our seniors who need continued access to medical care.

Beyond health care reform, Congress must reauthorize the Temporary Assistance to Needy Families, otherwise known as TANF, this year. We have more work to do to improve our child welfare program. The President's budget did not assume a 5-year reauthorization, so we must use this year to lay the groundwork for reauthorization.

Let me conclude where I began. I agree with President Obama: we cannot give up on enacting comprehensive health care reform this year. We have gone well past this effort's beginning. We have endured our share of struggle. Now let us, at long last, bring this bill to victory. With your help, Madam Secretary, and certainly with the help of the President, I feel quite confident that we will accomplish that objective.

Senator Grassley?

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

Senator GRASSLEY. Yes. Thank you, Mr. Chairman. Thank you, Secretary Sebelius, for being with us today, particularly in these very extraordinary times.

Our Nation is beginning a slow recovery from one of our worst economic downturns. Now, maybe more than any time in history, people are focused on our Nation's economic challenges, and they are worried. Words that come out of my town meetings, people say to me, "I'm scared." They have watched unemployment soar, the auto industry go into bankruptcy, banks shutting their doors, and families struggling to make ends meet.

As our constituents have tightened their belts and tried to reign in their own household spending, they have seen some in Washington support spending increase after spending increase. They have watched as the Federal debt has increased by $1.5 trillion since President Obama took office. On the heels of that, they have just seen the debt ceiling raised by another $1.9 trillion to make way for even more deficit spending.

So as I travel around Iowa, my constituents know these facts, and they know the figures affecting our economy, as well as the debt. They know it more than many Washington insiders. They also know that this budget only takes minor steps towards a very major problem. They know that under this budget the amount of debt held in 2008 will double to $12.3 trillion by 2013, and then triple to $17.5 trillion by 2019.

The question they keep asking is, when will Washington come to its senses and realize that we cannot afford all of this, all of the

bail-outs, all of the stimulus, all of the new spending that is paid for with our constituents' hard-earned dollars? They seem to express concern about it, and they want to know what we are going to do about it. They fail to see the return on investment that some have promised, and as a result they have lost faith in government spending.

As we consider the 2011 budget with you, we need to be thinking about how we can restore that trust. That trust begins, I believe, with transparency and accountability. In my years serving the U.S. Congress, I have made it my mission to ensure that transparency and accountability are more than just buzz words. They have to be meaningful.

I have held both Republican and Democratic administrations to the same standard. When President Obama was running for office, he pledged to make government "open and transparent." He also promised "to provide a window for all Americans into the business of government."

Actions speak louder than words, and unfortunately, a year into this administration, we have seen that this principle is not always put into practice the way it was talked about in the campaign. Transparency and accountability require an open and frank dialogue between people's representatives in Congress and those in the administration.

At this time, I have over 10 responses overdue from the Department of Health and Human Services on matters ranging from health care fraud to public safety, and those are listed up there and the number of days that we have been waiting for answers. I think my oversight efforts are often resisted, held up, frustrated, and impeded, impeded by bureaucrats who seem more interested in covering up than in opening up.

While this lack of transparency and accountability is nothing new in Washington, the American public was led to believe that more could be expected when they voted for the President who wanted change. Promises were made. Principles based on transparency and accountability were repeated over and over again, and obviously the vast majority of Americans believed.

Well, I want to continue to work on the American people's behalf to hold government accountable for its actions and ensure that the administration conducts its business in the open and transparent manner that was suggested.

While these accountability and transparency problems persist, I am pleased at least to see that addressing fraud, waste, and abuse in Medicare, Medicaid, and CHIP has a prominent role in this year's budget proposal, as it should. If we learned anything during the health care reform debate, it was that fighting health care fraud, waste, and abuse is really a bipartisan priority.

We all have seen the staggering estimates of around $60 billion of taxpayers' money being lost. This seems to be a conservative estimate. So I look forward to hearing from you, Madam Secretary, today on the proposals to strengthen fraud, waste, and abuse prevention, detection, and enforcement. But before Congress can weigh the merits of your legislative proposals, as well as your requests for increased funding, we need to know what and how you are doing with what you all currently have.

I mentioned earlier, Congress has the duty of government oversight. This includes reviewing annual reports that you are required to produce. One of these annual reports is on payment error rates. The latest one was due last November, but Congress has yet to see payment error rates for specific types of providers.

Obviously this seriously impedes our ability to conduct oversight, and it limits our ability to evaluate how the Federal Government is addressing fraud, waste, and abuse, so I look forward to hearing from you today on the status of that report.

Mr. Chairman, in regard to that, I ask unanimous consent that the slides on payment error rates from CMS be entered into the record.

The CHAIRMAN. Without objection.

Senator GRASSLEY. Thank you.

[The information appears in the appendix on p. 42.]

Senator GRASSLEY. In addition to fraud, waste, and abuse proposals, the budget also assumes a 6-month FMAP extension to States. While I do agree the States still need assistance to make ends meet, I think it is time for Congress to cut the strings attached to the aid that we are sending them.

As States struggle to balance their budgets, having the Federal Government provide them assistance that prevents them from touching Medicaid does not make much sense. We should give States control of their budgets so that they can be more innovative and efficient with how they provide access to care. And, of course, you are a former Governor, so I hope you would agree with that, that flexibility is very important to being a good Governor or State legislator. I look forward to discussing this, and other issues with you.

Thank you.

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

I would like to welcome our witness, the former Governor of Kansas, now HHS Secretary. We are honored to have you here, Madam Secretary.

As you know, your full statement will be included in the record. I just urge you to summarize it. We usually have a 5-minute rule here, but we will give you a few more than 5 minutes.

So, why don't you proceed?

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

Secretary SEBELIUS. Thank you, Senator Baucus, Ranking Member Grassley, and committee members. I am glad to be here today to discuss the President's 2011 budget as it regards the Department of Health and Human Services.

I think you will find the budget builds on some themes the President laid out in his State of the Union: strengthening security and opportunity for America's working families, investing to build a foundation for future growth, and bringing a new level of accountability and transparency to government. It abides by the President's pledge to try to identify programs that are redundant, obsolete, or ineffective.

As you know, Health and Human Services provides the health services that Americans depend on, and delivers human services to many of our most vulnerable populations. We think that it is important to make some of the investments our country has been putting off for years, including investments in fighting health care fraud, strengthening our public health infrastructure, and getting more focused on prevention and wellness.

So I would like to give a brief overview of Department priorities, focusing specifically on areas of Medicare, Medicaid, and CHIP. I know that we will have a chance to deal with some questions and look forward to working with all of you as we move this forward.

I will start with fraud and abuse. As Ranking Member Grassley has already noted, taking this seriously is something that is long overdue. It is something that the President feels very strongly about, which is why he asked the Attorney General and me to work together in the creation of a new anti-fraud focus, which is known as the Health Care Fraud Prevention and Enforcement Action Team, better known as HEAT.

We have already had some unprecedented success with, now, seven strike forces in cities around this country, with a new data sharing system, where we can monitor and observe changing patterns of billing practices, and a whole host of new prevention tools, which we anticipate will be enormously effective. So the President has included resources for new systems and new personnel to focus on this effort, and this is one of the efforts that we know actually returns significantly more than any investment we make.

Tomorrow will be a year from the date that the Children's Health Insurance Program was expanded. We know that in 2009, more than 2.5 million children who were previously uninsured got coverage from Medicaid and CHIP. One of the efforts that our department takes very seriously is the outreach effort provided by congressional funding, and we intend to work with State and Federal partners to identify and enroll the estimated 4 to 5 million children who are eligible right now but still not enrolled. The budget does extend the FMAP enhanced match that Congress applied in the Recovery Act.

As a former Governor, I can tell you, this is one universally welcomed relief for States who still have not seen their budgets recover. Since Medicaid is one of the most significant expenditures that any State in the country makes in terms of the percentage of the budget spent on health care, having an enhanced Federal match is something that is supported, I think, by Republican and Democratic Governors.

We ensure access to up-to-date health care for seniors and people with disabilities who depend on Medicare with new operations in CMS that will help us change from a relatively antiquated claims processing system into an actively purchasing quality care system, seeking the next generation in health care technology to help providers raise the quality of care for all Americans.

We continue to fund patient-centered research projects, which empower providers and patients to get the most up-to-date information about strategies and protocols that work well.

Chairman Baucus referenced the physician payment rate. The budget assumes a zero-percent update for physician payments, re-

flecting the last number of years that Congress has taken care to make sure that seniors did not see a dramatic decrease in the provider rates for their doctors. We support the longer-term strategy and look forward to working with Congress to that end so this does not continue to be a yearly debate.

There is a continued investment in neighborhood community health centers, following up on the Recovery Act investment, but an additional investment that will provide 25 new sites and will eventually provide care for about 20 million people a year, 3 million more than were served in 2008, with high-quality, low-cost preventive care.

There is a continued investment in our health care workforce, recognizing that health care delivery falls short unless you have the providers who actually deliver that care. The Indian Health Service continues to be a presidential priority, trying to live up to the commitments made generations ago to American Indians and Alaska Natives, and trying to reduce the woeful health disparities that we continue to find.

Our budget includes new funding for a 21st-century food safety system through the Food and Drug Administration. We, right now, live in a global food marketplace. Just for example, half of our fruit and nearly two-thirds of our seafood comes from overseas, yet we have a 20th-century inspection operation. So, redesigning a food safety system which gives American consumers the confidence that the food that they serve to their children is safe is something that we, again, take very seriously.

Following the signing last year of the tobacco legislation, the budget makes a serious investment in the battle against smoking. We saw dramatic decreases in smoking rates for years in America, but they now are holding steady at 20 percent, and frankly that is way too high. So, additional focus on better ways to stop smoking, new research, and community-based projects, is part of this ongoing effort to try to lower the dramatic costs that are underlying a lot of the chronic health conditions and are directly related to smoking.

Public health security continues to be a focus. We know that we need to be better prepared for our public health emergencies, whether it is caused by natural disaster or by attacks by our fellow man. We know that medical countermeasures stand at the front of those readiness efforts, the vaccines, treatments, and respirators that help reduce the spread of infections. This flu season we have all had a bit of a wake-up call, responding to the first pandemic in 40 years, having an opportunity to look at where our system worked well and where there were gaps.

So we continue to believe that funding new strategies, new technologies, new research through NIH, work at the FDA on scientific breakthroughs, but also looking at a whole host of medical countermeasures, is more important now than ever. I have asked my Assistant Secretary for Preparedness and Response to actually use the 2009 H1N1 experience as a template to look at where the gaps in our responsiveness system are and what kinds of strategies on a multi-year basis we need going ahead and to provide me a report by the end of the first quarter of this year. I look forward to shar-

ing the report with you, Mr. Chairman, and members of your committee.

Finally, Mr. Chairman, I wanted to mention some of our critical programs that do not deal directly with health care but deal with the human service side of our budget. We know that investments in children, particularly at-risk children, continue to be a terribly critical factor in how well and prosperous they may be in later life. So, this budget focuses on Early Head Start and Head Start, providing enough resources to serve about 66,000 more young children than just 2 years ago.

But what we know is that middle-class families are not just taking care of their kids these days; often they are also dealing with aging parents. So, there is a new family caregiver program, recognizing the fact that about 80 percent of long-term care services are provided by family members. Often that is great news for the elderly family member who gets to be cared for by loved ones, but it can be financially and physically exhausting for the caregiver.

So, this provides, through our Administration on Aging, additional support for everything from counseling for caregivers, assistance, and adult daycare centers for periodic stays, to respite care and transportation help to assist families who are trying their best to balance these caregiving roles.

States and communities are also part of the focus on some additional relief under the TANF program for some of the essential services that they are providing.

So, Mr. Chairman, those are some brief highlights of the Health and Human Services budget, focusing on the health and well-being of Americans and delivering essential human services. I think that we continue to work to improve the everyday lives of Americans. I look forward to working with you to advance the health, safety, and well-being of the American people, and having an opportunity to answer some questions about this budget.

The CHAIRMAN. Thank you, Madam Secretary.

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

The CHAIRMAN. I would like you to explain to all of us why health care reform creates jobs and how it saves jobs. Certainly the President went to New Hampshire and other States to help encourage more job promotion in our country. We in the Senate will soon pass a jobs bill. Clearly, to get the economy moving again, we have to do all we can to create new jobs.

Because health care costs are rising so much higher than wages, 5 times faster in the last 8 years, and premiums are rising 3 times faster than wages, it just seems quite clear that there is a trade-off there. For an employer who is providing health insurance, who has to pay for health insurance, their costs are going up so much. That is lost wages. The more we can get health care reform passed here to lower the rate of increase in health care costs, the more that that's going to help the employee get higher wages.

If you could just expound on that a little bit, Madam Secretary, just to help explain to all of us, and to the country, basically why health care reform really is a job creator and it helps businesses and employees keep jobs?

Secretary SEBELIUS. Mr. Chairman, not only is the health care sector a huge part of our overall economic picture—it represents about one-sixth of the overall Gross Domestic Product in America, in and of itself—doctors, nurses, health care providers, health IT workers, a whole host of workers in the system are certainly part of our economy.

But just focusing on small business owners who are often regarded as the critical engine of the American economy and produce more jobs in the long term, I hear over and over again as I travel around the country about the crushing costs of health care for employees. Small business employers are often in a Catch-22 situation: if they do not provide coverage for their employees, they lose good employees. They cannot retain the best and the brightest, who follow health care to the bigger company or the bigger market.

The CHAIRMAN. And there are incentives in this bill to help small business too, is that not correct?

Secretary SEBELIUS. There is absolutely a major incentive. In fact, it would go into effect in 2010. It is one of the early deliverables in health reform, to assist small business owners to essentially stay in the health care market, or come into the market. Eventually there would be not only that assistance, but an opportunity for lower-income workers to have coverage. You not only would have more productive companies, but we would be more globally competitive. We would be able to, by reducing overall health care costs and not shifting them from industry to industry, have an opportunity in this global marketplace to compete more effectively, whether it is selling cars or widgets, with competitors around the world.

I think the third aspect that is a jobs aspect is really about having a more productive workforce. Health and wellness, prevention of illness, prevention of long-term chronic illness, keeping employees in the workforce, and reducing sick days all have a direct positive impact on our workforce. We have poorer health results than many countries around the world. We have employees who live sicker and die younger than many places, so having those kind of investments from health reform and a more productive workforce, I think, in the long run makes America more prosperous.

The CHAIRMAN. But is health care reform not necessary for the administration and HHS to start implementing some new ways to reimburse providers, to get at reimbursement based more on quality as opposed to quantity? That is, limiting excessive readmissions from hospitals, value-based purchasing for hospitals, and accountable care organizations. Do you not need legislation in order to begin to enact a lot of these reforms, which will clearly begin to reduce the rate of growth of health care costs, and at the same time improve quality?

Secretary SEBELIUS. In both the House and Senate bills there is a major directive to begin shifting a payment system to quality outcomes through prevention and wellness incentives. Both bills include elimination of what Americans now pay in co-pays for preventive care. This will encourage screenings and early detection, which will save lives from cancer and other chronic illnesses that can be identified early.

Also, hospital-based infections are a serious concern. We have 100,000 Americans each and every year dying, not because of what brought them to the hospital, but what happens to them in the hospital. Our focus on hospital-based infections directs our payment system to first provide incentives for hospitals that do very well, but eventually stop paying for care that is poorly delivered or makes people sicker.

The CHAIRMAN. Thank you very much. My time has expired, but I appreciate all that. Thank you, Madam Secretary.

Senator Grassley?

Senator GRASSLEY. Last week, I wrote to express my frustration with the lack of responsiveness to my requests from HHS and its subordinate agencies. I am still waiting for responses to more than a dozen letters that I sent last year to HHS, FDA, CMS, and CDC. In my letter last week, I asked you to get back to me by January 29th, but I have not received a response from you. So I would, please, like to have you let me know when I will be getting a complete response to all of my outstanding requests.

Secretary SEBELIUS. Senator, I share your interest in transparency and openness. I know that we are now on a regular briefing schedule with your staff members. We are attempting to respond as quickly as possible and as thoroughly as possible to the information you requested. It is my information that we have given you complete responses to a number of the requests, a majority of the requests. Some, we are still working on.

What I can assure you is that, as quickly as we get the information together, we will get it to you. I know that the staff correspondence often is ongoing and conversations are ongoing to try to clarify and make sure we are getting you exactly what you want.

Senator GRASSLEY. Well, it seems to me that one of the problems is expediting the clearing process within the Department and its agencies so that letters from Congress are answered thoroughly and delivered in a timely fashion.

What are your plans to expedite that clearance process? I mean, the letters are written. They are sitting on somebody's desk for approval.

Secretary SEBELIUS. Well, Senator, as you know, we have a large agency, which is not an excuse for untimely responses. I have met on a regular basis with our executive secretariat, and actually now receive at my request a weekly report on the status of correspondence, where it is, who has it, and following it through the pipeline. So I am taking this very seriously and very personally.

Senator GRASSLEY. All right. Well, you can see up here——

Secretary SEBELIUS. Actually, I cannot. [Laughter.]

Senator GRASSLEY [continuing]. How many have not been responded to and how many days it has been we have been waiting for responses. It seems to me like the list keeps getting longer and longer. If we answered our letters as Senators like that, we would not get reelected.

Let us go on to another issue. As I mentioned in my opening statement, I am a strong supporter of transparency and accountability. As President Obama mentioned the other day, he is disappointed that there has not been more transparency in the health care debate. The budget assumes comprehensive health care will be

enacted. In order for that to occur, I am assuming negotiations between Congress, the White House, and stakeholders are continuing to take place.

Could you commit to me today that, going forward, any negotiations involving any of your senior staff, in an effort to pass comprehensive health reform, will be done in an open and transparent manner?

Secretary SEBELIUS. Well, Senator, I do not know what conversations with senior staff you are talking about. Our staff is available to you and your members, and they meet with them regularly. They are available to other members. I do not control the negotiations that go on between the House and the Senate, or the conversations. Our staff provides technical support across the board.

Senator GRASSLEY. So you are saying that your staff is not there for anything more than just technical support? They are not involved in any negotiations representing the White House, or anything like that?

Secretary SEBELIUS. Sir, I have conversations on a regular basis with Republicans and Democrats, but I do not convene the House and the Senate, and I am not a principal in the negotiations, nor are my staff.

Senator GRASSLEY. All right.

I wrote to you in December asking you to explain why Congress did not receive the fiscal year 2009 Comprehensive Error Rate Testing report, or CERT, as it is called. That report was supposed to be out in November. The annual report shows national payment error rates for Medicare fee-for-service programs. This report shows improper payment rates for each type of provider, like hospitals or durable medical equipment suppliers. Congress relies on this report to evaluate how well or how not-so-well Medicare is doing when making payments.

I also asked you to tell me when I can expect the final report. You have not responded to that letter. I have before me, as I already showed the chairman for putting in the record, CMS's November presentation to committee staff on fiscal year 2009 Medicare improper payment rates. Each member here at the dais has copies.

Everyone, I hope, would turn to page 8 of the slides. You will see that in November of 2008, the error rate for durable medical equipment was 7.3 percent; in November of 2009, that number jumped to 51.9 percent, a very significant jump. If you go to page 10, that number goes up even higher, to 73 percent. Seventy-three percent is the rate that CMS got when it used the "most stringent" criteria for calculating the error rate, the criteria that it is supposed to be using.

So, question number one: how do you explain sitting on these numbers, especially when this country is in the midst of health care reform discussions regarding legislation that would delegate more authority to the Department on a broad range of financing and delivery system changes and new payment models?

Secretary SEBELIUS. Well, Senator, I think, a couple of things. First of all, I think that we took very seriously the previous criticisms by the Inspector General that the previous administration, under HHS, was not being accurate about its payment rates.

Senator GRASSLEY. I agree with you.

Secretary SEBELIUS. I am pleased to hear that. So the result of the change this year, using the criteria that we agree should have been used for years, was a new system. I would like to also point out—I know you are well aware of this since you follow this closely, but just to make this clear to other committee members—that an error rate is not a fraud rate. They are different issues. It could be as little as the doctor's signature not being legible, or something in the wrong column. But again, we think it should be accurate.

We are working diligently under this new system. We put out the global numbers in November at the time the report was due. We hope, by the end of this week, to have the underlying numbers, but the shift has not been one that has been necessarily very quick, because it has been a change from a traditional system and we needed to recalculate every single error rate. We wanted to get it right. We wanted to abide by what the Inspector General said we should have been doing all along. I promise it will be hand-delivered to you, but I have been told by the end of this week we should have all the underlying numbers ready to go.

Senator GRASSLEY. Thank you. And I hope you realize, 73 percent is still a very, very high rate of error.

Secretary SEBELIUS. No, I understand.

Senator GRASSLEY. Senator Rockefeller, it is your turn.

Senator ROCKEFELLER. Thank you, Senator Grassley.

Secretary Sebelius, I am glad to see you. A couple of points I would like to make. One, with respect to what Senator Grassley, who is my dear friend about whom I have said some very good things in his election years in the Omaha—what paper?

Secretary SEBELIUS. It would not be Omaha. Des Moines, maybe.

Senator GRASSLEY. I was concerned about something else. I did not give you the proper respect. Would you please repeat it?

Senator ROCKEFELLER. No. [Laughter.]

I got the wrong state.

Secretary SEBELIUS. The *Des Moines Register*.

Senator ROCKEFELLER. The *Des Moines Register*. That was the point. That was the point.

I was just saying that he and I have a good relationship.

Senator GRASSLEY. We do have a very good relationship.

Senator ROCKEFELLER. We do. But it also occurs to me that sometimes in this question of—I think you have 70,000 employees. You have responsibility over an enormous array of things; I do not know how many letters I write you. But I often find that it is a good thing, and so does my staff, sometimes just simply to call either you, in my case, or in their case, some of your staff people.

Letters can actually be very inefficient. Number one, they take a much longer time to get over to you and then get back to us, and they have to go through a process and sometimes they are put in general language. Sometimes just a phone call, and as you indicated, staffs being in touch with staffs is, what I have found, the best way to try to work problems out. I am just saying that, for whatever it is worth.

Is it not true that health care is, at this particular point, the single greatest economic engine in the United States' economy, that is, in terms of rapidity of growth of jobs?

Secretary SEBELIUS. I think that is an accurate statement, Senator.

Senator ROCKEFELLER. My understanding is that over the past 2 years there have been 631,000 new jobs simply in something called the health care sector, and that there have been, just the last month, 22,000 new jobs, which is interesting, because the economy is not doing very well, as it has been explained, and people are frustrated by that.

We are all trying to work on, how can we create more jobs? Well, if we can just do health care reform, get it done, we will have contributed enormously to that, and it is already producing an enormous number of jobs. So to me, it is one of the best—and I think that is according to the Bureau of Labor Statistics, so I am not doubting what they say.

Let me shift just a bit. There are over 100 community health centers that applied for the American Recovery Act funding and received—in my own State, the applications that we had, they received about a 90-percent score on their proposals for the Facilities Investment Program, but they were left unfunded due to funding limitations.

Now, you talk about the important link between health care investments and economic growth. Do you not think it is also possible that we come back with a jobs program—I mean, these are very important. It is like Health Service Corps people. If you do not have them, you suffer. If you do have them, your people, particularly in rural areas, which Iowa and West Virginia have a great number of, gain enormously.

If there are shovel-ready projects—and I am thinking right now again of community health centers—if we get some more money for that, it would be possible to do more with that, particularly with people who score 90 percent or over on your own criteria.

Secretary SEBELIUS. As you know, Senator, the American Recovery Act provided a major investment in community health centers, and they were wildly overwhelmed by beneficial projects that just were not able to be funded based on the amount of money available. But no question, having a health center produces workers in that area, and they operate as a community center, often, and have a huge beneficial effect on neighborhood well-being, on workers, and on jobs.

It is a construction project, and then a long-term service project. So we appreciate the continued investment in the FY 2011 budget. I think it is definitely a jobs program that also yields better health results for the communities in which they are located. Twenty million Americans have low-cost preventive health care for themselves and their families based on these community health centers. Often, the strain on hospitals and community hospitals is reduced as a result because people are accessing health providers more appropriately, not going through an emergency room door, but actually getting help through a health center. So, I think it has lots of beneficial ramifications.

Senator ROCKEFELLER. Good. My time is up for the moment.

Senator GRASSLEY. Thank you, Senator Rockefeller.

Senator Wyden is next, then Senator Enzi, then Senator Cornyn, then Senator Hatch.

Senator WYDEN. Thank you, Senator Grassley, and welcome, Secretary Sebelius.

Secretary Sebelius, we are obviously all paying attention today to the fact that the budget assumes that comprehensive health reform is enacted and there would be savings of about $150 billion over the next decade. Now, the President has said that an essential part of comprehensive health reform is expanding consumer choice and competition, and I share the President's view. One way the President seeks to promote choice and competition is by creating a working marketplace, in effect a set of exchanges, kind of like farmer's markets where people could compare the various products.

How would, in your view, creating these health insurance exchanges contribute to the savings that are envisioned in the budget by enacting comprehensive health reform?

Secretary SEBELIUS. Senator, I think that having a new marketplace, as you say, with competing private sector plans, which is what is envisioned, not only has a beneficial effect for individual purchasers, but small business owners, self-employed Americans, and others who often struggle with the high cost of care right now, would also have some choices, would have some options.

In addition, I think in the long term, competition holds down costs. It is a great market strategy, that if you have competition versus a monopoly, you really have an opportunity for the market to work. So, my experience running a State employee health plan in Kansas was that we made sure that employees had at least one other choice, at least two choices, wherever they lived in the State. Some were actually created by the State system to provide competition.

What we found is, that got us the best prices at the lowest cost. People wanted access to that pool of workers. In Kansas, we had the largest health pool in the State, 90,000 covered lives. People wanted access to that. They ended up being very competitive in terms of the prices and services that they offered. That would operate within States and in multi-State areas, and I think give folks choices right now that they do not have right now.

Senator WYDEN. I want to continue to work with you and the President on this, as you know. My concern has been that most Americans do not have choices today. Of course, a member of Congress can fire their insurance company. They can say, in 2009, if you are not treating me well I can go somewhere else in 2010. So, I intend to work very closely with you, the President, and Chairman Baucus and Senator Grassley on this, because there is not a marketplace today, and we need one.

Secretary SEBELIUS. That is right.

Senator WYDEN. Let me ask you, if I might, about another area that I know we share similar views on. That is the treatment of those who are chronically ill. The evidence shows that somewhere in the vicinity of 75 percent of the health care budget goes for a relatively small percentage of the population, maybe 10 percent. There are bipartisan bills here in the Senate—Senator Burr and I, for example, have one here—and also in the House—Ed Markey and Chris Smith—to promote what is called independence at home.

There, you would have, in effect, a coordinated team of practitioners who have, in effect, agreed to take lower payments, so that

does not add to the deficit in order to give better care for people at home. You all do not have that in the budget, and I would just like to hear your thoughts about what kind of priority the independence at home effort would be for you and the Department in the years ahead.

Secretary SEBELIUS. Senator, I think that concept would be embodied in one of the health reform components, in the Centers for Innovation. It is certainly one of the strategies that is operational in some areas. In fact, in the northeast corner of the country we just added Medicare to a provider coordinated care strategy that is under way in Vermont and northern Massachusetts, which operates very much along that way. I think it is a huge priority.

Back to the State issue: as a former Governor, the dual-eligible population, those who are poor enough to qualify for Medicaid and those who are old enough to qualify for Medicare, are again the fastest-rising cost in the Medicaid budget of any State operation and often are chronically ill, often have multiple issues. States are way out ahead of the Federal Government right now in looking at ways to deliver better care at a much lower cost, and certainly the independence at home is one of those strategies. It has been a huge priority for me.

Senator WYDEN. Thank you.

The CHAIRMAN. Senator Enzi? Thank you. Thank you, Senator.

Senator Enzi?

Senator ENZI. Thank you, Mr. Chairman. I would ask consent that my statement be made a part of the record.

The CHAIRMAN. Without objection.

Senator ENZI. Thank you.

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

Senator ENZI. Madam Secretary, under the President's budget, community health centers receive an increase of $290 million for the 2010 budget, which is on top of the $2 billion they received in the stimulus package. In addition, as Senator Wyden noted, the budget assumes that the health reform is passed, and that would provide mandatory and unlimited funding for community health centers.

In the President's State of the Union address he said, "Families across America are tightening their belts and making tough decisions. The Federal Government should do the same." How is mandatory and unlimited deficit spending for community health centers, with an additional increase of $290 million, plus on top of the $2 billion provided in the stimulus package, representative of those comments?

Secretary SEBELIUS. Senator, I think that the experience of health providers, of patients, of community leaders across America is that the investment in community health centers has been a great way to lower health care delivery costs. Regardless of where they are in the country, the delivery of highly effective preventive care at a significantly lower cost than the sort of competing systems has been proven. The ability to reach out, in this case, to lots of Americans who either do not have insurance coverage at all or who have very modest coverage, again, has been very effective in terms of preventive care delivery.

So I think that the increased footprint of community health centers, working in tandem, which they do in many parts of the country, with the primary delivery system, with community hospitals, with provider groups, has been a wonderful way, whether people have insurance or not, to deliver health care using a very cost-effective strategy.

Senator ENZI. I have been a supporter of the community health centers, but this seems to go quite a ways. I know that some private entities have sprung up in the meantime, like some MinuteClinics at CVS that are supplementing this. Then this seems to me to be quite a huge increase.

But to move on to a little different subject, since we have limited time, I think your Chief Actuary, Richard Foster, said that the Medicare payment cuts in the Senate bill could lead to as many as 20 percent of all hospitals, nursing homes, and other Medicare providers to have to operate at a loss. How many jobs would be lost if one out of every five health providers is losing money, and therefore goes out of business? Do you think that Mr. Foster's analysis is correct, that the level of Medicare cuts in the Senate bill may be unsustainable?

Secretary SEBELIUS. Senator, as you know, there have been lots of different analyses of the various strategies regarding Medicare. I think the most obvious point about Medicare right now is that it is unsustainable on its current course. It is scheduled, with the current situation, to be totally out of funds within 9 years, and those numbers change every year, so it is clear that doing something is necessary.

One of the things that I think our department took very seriously was looking at strategies for areas where we are over-paying for various services and goods, over-subsidizing private insurance companies for various kinds of Medicare Advantage programs, not taking fraud and abuse seriously, which again returns money. We have already, in the less than 1 year I have been at the head of HHS, had over $4 billion returned to the Medicare trust fund based on various kinds of settlements and fraudulent activities that we have shut down. So we are taking all of that very seriously.

I think that, clearly, if you had some significant reduction in providers within the Medicare system, there would certainly be a job loss. But again, the most imminent loss of jobs is a 21-percent pay cut that is facing Medicare providers if Congress does not fix the SGR rate. That would be a dramatic job loss, I think, that would impact the seniors around this country.

Senator ENZI. I know that Medicare needs more funds. I know that the half-trillion dollars that we were talking about could go to Medicare to fix some of those things, and I am hoping that we will take a look at that.

I also have additional questions I would like to ask on the health IT. Of course, I am looking forward to my report on Dr. Gruber, who represented himself as an independent academic expert while he was making $400,000 from the Department, and that that did not show up on the list that I got earlier in the year when I had requested it. So, I am looking forward to that. Thank you.

The CHAIRMAN. Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman.

Madam Secretary, let me ask you about improper payment rates in Medicaid. You talked to Senator Grassley about that. Under the President's budget, an additional $26 billion would be spent on the Medicaid program, but, according to some figures I have seen, as much as 10 percent of Medicaid payments are improper payments, which cost taxpayers $3.6 trillion over 10 years. Of course, as you know, since this is a shared expense program, the State and the Federal Government share in that expense.

I have been trying, my staff has been trying, to get from your staff, since July, a detailed statement about improper payment rates. So far, we have been refused that information. You may not be aware of that, so I wanted to bring that to your attention. I would like to ask you, would you see that that information is provided to us so we can make a better-informed decision about your proposal to spend an additional $26 billion on the Medicaid program?

Secretary SEBELIUS. Yes, Senator, I would. I am not specifically aware of your request. I assure you, I will check into it. As you know, though, our department does not pay the Medicaid providers directly. That really is done at the State level. The contracts are let at the State level. Each State has a different kind of arrangement. The Kansas Medicaid program did not look like Iowa's, or Nebraska's; our providers were different.

So, one of the difficulties, Senator, may be that collecting that data from 50 States around the country, updating it, and making sure it is accurate may be one of the challenges, because we do not hold that data in the Department of Health and Human Services.

Senator CORNYN. Well, of course, about 60 percent, roughly, of those are Federal tax dollars in my State.

Secretary SEBELIUS. We pay a match, but we do not have direct contact with the providers.

Senator CORNYN. I understand. Well, I would think that your department would have an interest——

Secretary SEBELIUS. Absolutely.

Senator CORNYN [continuing]. In whether Federal tax dollars, as well as State dollars, are being squandered.

Secretary SEBELIUS. Senator, that is one of the efforts in the fraud and abuse area. We have a whole series of new initiatives that will be worked out with our State partners to look at fraud and abuse and waste and error rates in the Medicaid program.

Senator CORNYN. I heard you say that earlier, and I would like to get to that in a second. But that is why we need State-by-State numbers, which is what we requested from your agency. We would like to know whether those improper payment rates are provider payment errors or errors in determining eligibility. That is simply why we want to get information. We are not reaching any judgment yet, we would like to get the information. I appreciate your commitment to work with us to get that information promptly.

But I would like to talk to you just a second about fraud and abuse. As a former State Attorney General, I can tell you that neither the Federal Government nor State governments have enough resources to chase the fraudsters and the people who are trying to cheat the taxpayer after the fact, and we need to do a better job,

I think, on the front end of certifying providers and stopping it on the front end.

I would just ask you to look at one piece of legislation that I have introduced, along with other Senators, called the Seniors and Taxpayers Obligation Protection Act—you may be familiar with it—which does exactly that, tries to stop it on the front end as opposed to chasing it on the back end. I am not being critical of the improved enforcement efforts, that is important, but I do not think you will ever have enough resources, either at the State or Federal level, to chase all the fraudsters down. I think that is why we need to start on the front end.

Secretary SEBELIUS. And Senator, I absolutely agree with that. I will definitely take a look at your legislation. We have begun some new certification practices. Durable medical equipment was one that we had a huge increase in some erratic billing, so we have instituted third-party verifications, more provider numbers. But I agree, every scheme we come after at the back end, there will be a new scheme at the front end. So, I look forward to looking at your legislation.

Senator CORNYN. Well, thank you very much for that. I appreciate it.

Secretary SEBELIUS. Sure.

Senator CORNYN. You talked about the fact that Medicare will become insolvent in less than a decade. Of course, that has been the subject of a lot of concern by the American people as they see us spending more on programs, our failure to meet our responsibilities to deal with current unfunded liabilities.

While we have heard that health care reform is entitlement reform, we know from Dr. Elmendorf in the Congressional Budget Office that the health care bills, reform bills, cannot be used to both pay for health reform and address the solvency of the Medicare program.

He said the key point is, the savings to the Hospital Insurance Trust Fund under health reform 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.

Since, at least under Dr. Elmendorf's opinion, you cannot double-spend that money, can you talk to us about your proposals or the administration's proposals to deal with these $38 trillion in unfunded liabilities for Medicare?

Secretary SEBELIUS. Senator, I think that health reform actually does include a number of proposals which would certainly slow the growth rate of the Medicare trust fund spending without violating any of the benefits that are currently relied upon by not only seniors, but some of our most disabled citizens.

They not only look to save money in the overall purchase of prescription drugs, they look to make sure that we are not paying for, or over-paying for, services and procedures that are not cost-effective. They slow the growth rate by having competitive bidding in areas like durable medical equipment, getting a better bang for our buck while still delivering the services to beneficiaries.

But also I think there is an enormous amount in health reform that anticipates prevention and wellness and having a different

kind of strategy so that you do not wait until a senior enters Medicare and is paying for acute services, but hopefully lowering the underlying conditions for chronic diseases.

The CHAIRMAN. Senator Snowe? Thank you very much, Senator. You are next. Thank you, Senator.

Senator SNOWE. Thank you, Mr. Chairman.

Madam Secretary, welcome. One of the first questions I wanted to ask you is regarding low-income fuel assistance, which is a critical program for my region, and throughout the country, depending on the severe circumstances of the weather.

Senator Reed of Rhode Island and I sent a letter, along with 46 other Senators, concerning the methodology that was used to distribute the low-income fuel assistance funding, the release of the emergency funding, for example. Forty million of the 490 that was released was set aside for heating degree days, and our State received 80 percent less, and Rhode Island received 50 percent less, for example.

On the heating degree funding, States like Florida—and I understand it was unusually cold in Florida this year—received $3.9 million emergency assistance; Texas received $10.8 million; Alaska, Minnesota, and Maine received nothing because of the calculation of these heating degree days. So, while Florida would have 30 heating degree days, last December, Caribou, ME would have had 1,376 heating degree days, 44 times the energy required.

So I am trying to make sense of, what was the methodology used in this distribution? I am not arguing that Florida and Texas should not have received any funding, I am arguing the point about why there was such a radical difference in the amount of funding that cold weather States—severe cold weather States—received in the release of this emergency funding.

Last year, Maine received $29 million, this year it is $4 million. Rhode Island lost more than 50 percent of its funding. If you use unemployment as a calculation, Rhode Island has the second highest in the country. So we submitted a letter to you, and I would appreciate if you have a response here today, to understand better why the money was distributed in this fashion.

Secretary SEBELIUS. Certainly, Senator. We will get the detailed formula to you, but there were several factors this year that were looked at. One is that the cost of heating oil is significantly lower this year than last, which affected some of the costs in the northeast States which rely heavily on heating oil. I think it was over $100 last year and it was down below $80 this year, so there was a significant wave.

As you have already said, some of the southern States had particularly cold snaps, which again was not a factor a year ago, and needed to be calculated in. Third, the formula not only included the overall look at the heating issues, but also unemployment numbers. So, those three factors were the formula used this year to redistribute the funds. Detailed information on how the funds were distributed is now available on ACF's website: *http://www.acf.hhs.gov/programs/ocs/liheap/funding/fy2010_contingency_information.html*.

Senator SNOWE. Well, I think you would agree that that is a dramatic change, given the enormous cost in heating oil that could be

$60, $70, $80 a barrel, as it has been this winter. It is more than $2,000 for a season in a State that has very low wages. So, I think that is true for a number of the States that have signed this letter as well, from the Senators who represent those States. I hope that we can have further discussion in the future concerning it.

Secretary SEBELIUS. Absolutely.

Senator SNOWE. I understand the exigencies that occurred in these other States, and I am not denying that they should have had funds. I do not want to create a regional fight here, because that is not what this is all about. I just want to make sure that we have a fair and equitable consideration, especially during these very difficult times. The fact is that home heating oil is a very expensive proposition in our State, where 80 percent depend on it, frankly.

On the issue of health care reform, we talk about jobs. The reverse is true as well. That is what I am hearing in my State among small business owners, who are very concerned about the calculation of the potential costs that could arise from the assumptions made with health care reform.

It was one of the big issues that I had with a number of reforms in Maine that was cited repeatedly, the potential for raising the cost of doing business, where they would hesitate to invest in future capital equipment or add any jobs. I heard that repeatedly. Particularly when we talk about Medicare tax, there is a 62-percent increase that was included in the legislation, an employer mandate.

So there are a number of issues that could potentially raise the cost of doing business. I have a deep concern that that is going to depress the ability of small businesses, especially, to turn around the economy. We talk about those tax credits, and they are important, but it also requires small businesses to pay up front. They are going to have to lay down some money in order to get the benefit of that tax credit. They might not even be in that position.

So I think that we have to look at the overall calculation in all of this. There are some things that we could do short of this comprehensive reform immediately. There is legislation that Senator Lincoln and I have introduced on small business exchanges, along with Senator Durbin, on a bipartisan basis. It would help to open the doors to small businesses, at the very least. That should have been done long ago. But I also think we have to calculate the impact of health care reform as it has already been designed on small businesses and the potential to lose jobs as well.

The CHAIRMAN. Senator Lincoln?

Madam Secretary, did you wish to respond? Senator Snowe's time has expired, but I just want to be fair and courteous and give you an opportunity to briefly respond.

Secretary SEBELIUS. No. I think the jobs calculation for small business owners is huge. As you know, I did a couple of forums in Maine, heard from some of your constituents directly. I do think that the look, the lens—the small business tax credits in both the Senate and House bills would kick in in 2010. There would be then a more affordable market down the road. There would be fixes in the system along the way.

So at least, while I think it is always important to look at the impact, I think there is no question that the group being squeezed in the current health care marketplace is often self-employed and small business owners who have no choices, higher prices, and fewer options and often lose employees based on the fact that they cannot keep them.

The CHAIRMAN. Thank you very much, Senator.

Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman.

I want to thank my colleague from Maine for bringing that issue up, because I do believe that the largest percentage of the uninsured do fall into that category of small businesses, working for small businesses, self-employed, independent contractors. I think it is a great step forward in terms of what we could do that would be meaningful in this overall health care debate. I certainly enjoy working with her; she does a great job. I am pleased with what she does.

Just a couple of questions I would like to throw out, and maybe you could answer them. I think I have about four here. I just want to touch on the technological divide between rural and urban America. In your original Federal Register notice on health IT, you were going to preferentially fund rural States, those with underserved areas and those that needed to catch up.

Unfortunately, in your funding for health information exchanges and other grants like the Beacon Community Grants, it appears that the funding is on a per-person ratio or funding communities that are more advanced in their implementation. The problem with that is that we never get started in rural America.

So, I just would like to see some assurance that the health information technology is going to be available to all Americans, particularly rural citizens like those in my State, and make sure that this digital divide does not contribute to the increasing health disparities that exist in rural America between rural and urban citizens. So I hope that you all will focus on that and help us in terms of making sure that everyone is going to have a fair shot at that health IT.

The Older Americans Act. The nutrition programs were provided with an urgently needed $100 million under the Recovery Act. However, the fiscal year 2011 budget only totals about $8 million. My concern is that the recovery funds are going to be expended, and I am hoping, or really questioning why the elderly nutrition programs are not included in the recovery extensions in the President's budget. I think that is something important to focus on. The elderly are one of our most vulnerable groups.

I was pleased to hear Senator Wyden bring up coordination of care and all of those different efforts. I am hoping that you can elaborate a little bit on the coordination of care demonstrations. I have been working very, very diligently on those over the past several years and understand the importance that that plays in us getting the biggest bang for our buck, but also getting better outcomes, particularly in Medicare.

One other thing was that the Department released a draft of the Healthy People 2020 Report. In its 216 pages, it contained 556 objectives, which is great. We are glad we are focusing on so many

things. But I was a little bit concerned, or disappointed, I suppose, that the words "Alzheimer's" or "dementia" were never mentioned.

Of the top 10 causes of death in the United States, Alzheimer's disease is only one of the 10 without its own topic area in the draft report. Noting that it affects about 5.3 million Americans, with the number expected to rise by mid-century to as many as 16 million Americans, it is certainly a growing public health crisis.

I hope that you can look at the possibilities of perhaps, before the publication's final report, looking at additions that could at least include a separate topic area, perhaps, on Alzheimer's disease, just as the other top 10 causes have, in that report. I think it would be a very strong message, that we are focused on that in this country.

Then the last would be the Medicare extenders. I want to compliment the chairman for working with us on the Medicare extenders and these different issues that obviously we feel are going to fall off the edge of the cliff, whether it is therapy caps, physical therapy, speech, language, and occupational therapy, the pathologists also, the ambulances, rural hospitals, and others.

I know that you and I visited on the phone about that, and I understand your position. But if the administration does not have the legal authority to extend those policies, what do you believe you can do to be helpful to us if in fact we cannot get those moved down the road? How can we be helpful to those providers? That is a lot, but I just wanted to get it all out there. Any of that you can jump on would be great.

Secretary SEBELIUS. Let me assure you that health IT has a variety of strategies looking at different areas. But the health extension offices which will be established throughout the country are very much focused on under-served areas, are very much focused on assets that need to be brought in. That really is one of their primary objectives, to make sure that there are not sort of forgotten areas of the country, forgotten providers, smaller hospitals, smaller provider groups, so that footprint is very much aimed at that.

I know that there is some concern that the nutrition aid for older Americans is not enhanced along with some others. I would say that there are a variety of new strategies for older Americans, including the caregiver strategy and some others, which have new funding in the budget. But I hear your concerns at this tough time, that we need to keep seniors who rely on those programs in our sights.

In terms of 2020, what I would love to do, I am going to carry that suggestion to Dr. Howard Koh and have him follow up with you about that.

Senator LINCOLN. That is great.

Secretary SEBELIUS. I think that is one that is very appropriate. He is much more intimately involved with those 500 recommendations than I am, and I think this is a great time to provide that input.

The Medicare extenders. As I have suggested, Senator, we do not feel we have the administrative flexibility to merely push them down the line. As we talked about, there are strategies about holding bills, but that can only be done for a period of time. I assume that eventually, if it is fixed legislatively, we could do some retro-

active repayment. But at this point our general counsel has looked at this very carefully and feels that we really would be in violation of the law if we just ignore what the deadlines are for those.

The CHAIRMAN. Thank you. Thank you, Senator, very much. I might say, Senator, we are thinking of putting therapy caps in the extenders package, in the jobs bill.

Secretary SEBELIUS. Yes.

Senator LINCOLN. Certainly. That is why I said, you have done great. You have been wonderful to work with.

Secretary SEBELIUS. That is what I understand. Whatever vehicle is there.

The CHAIRMAN. I think it will be in that legislation. Thank you.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman, very much.

Welcome, Madam Secretary.

Secretary SEBELIUS. Thank you.

Senator STABENOW. Thank you for your leadership on health care and health insurance reform.

First, just a comment. Thank you to the chairman for working hard on helping to change the way we pay physicians through what has been dubbed the SGR. I know we are going to be doing something there, which is very important.

I want to just urge you, Madam Secretary, this payment system does not work. I was pleased to author the legislation to repeal it. I still believe we need to do that, and I hope the administration will work with us, long-term, to do that. I appreciate your efforts to take the cost of prescription drugs out of that formula, which was a very important first step, but I am hopeful that you will, as well, look for other ways in which you can fundamentally change that. We changed the incentives in health reform. If we are able to move that forward, I think that is one of the positive things in there, but I would just urge you to continue to work with us.

Secretary SEBELIUS. I look forward to it. As you know better than many, given your long efforts in this area, the uncertainty for providers and for patients about the future of their medical care really undermines the confidence in a great health care system. I really look forward to a long-term fix to making sure that we can live up to the trust that we have committed to beneficiaries, that they will have a provider, they will have services delivered.

Senator STABENOW. Right. Thank you. We need to get that done.

I wanted to speak about and ask you about graduate medical education, which we know is so important. We need to get more students, more physicians into primary care. Of course, again, that is another focus of what we have been working on with health care reform. We know that there is a broad primary care crisis.

But I do want to note that we have hospitals that want to train more physicians in Michigan, in my State, and I know in Maine, Florida, and in other places. But they have been frustrated by the CMS regulation on new residency programs and Medicare's graduate medical education program.

Unfortunately, the process was changed. I am sure you are aware of this, but originally in the Balanced Budget Act of 1997 there was concern expressed about flexibility and hospitals moving forward. They were going to expand their residency programs. CMS

initially allowed hospitals to qualify for residency slots under a cap when they created new programs, and they defined the programs that would receive initial accreditation. It was a very straightforward process, and hospitals moved forward, and so on.

Then in August of 2008, there was a new regulation that penalized programs that received the initial accreditation. Unfortunately, this has resulted in revoking funding for programs that today are ready, willing, and able to go forward to be able to train our primary care physicians.

In fact, we have programs in Michigan that may close as a result of the lack of funding. So, given the fact that we need more physicians, we need more primary care physicians, as we know, I am asking if you would work with us to address this change that was made over a year ago and be able to allow hospitals to proceed to do what they have been authorized to do.

Secretary SEBELIUS. Well, Senator, I would look forward to—August 2008 was a bit before my time and the new team's time.

Senator STABENOW. I am aware.

Secretary SEBELIUS. But I would be glad to go back and revisit that and actually take a look at that with your staff. Absolutely.

Senator STABENOW. Thank you.

And then finally I would just briefly urge and ask about your focus on mental health services. I have felt that one of the positive things that we have done in crafting our health reform initiatives was to include mental health——

Secretary SEBELIUS. You bet.

Senator STABENOW [continuing]. And substance abuse services, both in definitions on chronic care, as well as prevention, and so on. Yet, we are seeing States making drastic cuts in mental health services.

So I am wondering, what areas of the President's budget would improve or expand on these critical health care services?

Secretary SEBELIUS. Actually, the new regulations for the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 are now out, and we look forward to making sure that they are enforced around the country, and that certainly is as a result of lots of good effort. We have a wonderful new administrator with the Substance Abuse and Mental Health Services Administration (SAMHSA), Pam Hyde, who comes with private sector and public sector experience in various parts of the country and is already engaged in a lot of across-government efforts.

We are working with the Department of Defense on homelessness for veterans, and we are working with the Department of Housing and Urban Development on chronically homeless individuals. We are looking at substance abuse services as critical. In prevention, there are some exciting new studies about the ability to actually prevent mental illness and work on this, and preventive care.

So there are actually investments in the 2011 budget which add behavioral health services to a number of community health clinics, which had no mental health services in the past but now will have an infusion of investment to make sure that, along with primary care, there will be behavioral health services available, and more mental health professionals.

So we are looking at areas across our agency and across the government where we can actually make sure that mental health is not a silo off to the side, but is part of the whole look at health care moving forward in a much more holistic approach.

We have a significant dialogue under way with the Administration for Children and Families, knowing that a lot of the prevention of substance abuse really starts at a very young age, making sure that we have those services available, and Head Start and Early Head Start programs also.

Senator STABENOW. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Madam Secretary, there is a lot of concern about fraud in Medicare and Medicaid, and other programs administered by HHS. I think you would agree, our intuitive sense is that a lot of those allegations are probably true. That is, there is a lot of waste, under the headline of fraud, that we just do not stop.

Senator LeMieux came to me a couple of days ago with an interesting idea. He is pretty concerned about waste and fraud in Florida, and in the country generally. I remember a couple, maybe 3 months ago, we were looking at home health care outlier payments, and the percentage in Florida and some of these counties is way, way, way above the per capita incidence of seniors in those same counties.

Secretary SEBELIUS. Right.

The CHAIRMAN. But his idea is this. Maybe we can take a page from the credit card companies. As we know, the credit card companies have put together these very sophisticated mathematical algorithms about their credit card holders, just like Google does. Google knows what books you buy, and they want you to buy similar books based upon your purchasing pattern. But the thought Senator LeMieux had is this: just as a credit card company will notify you as a credit card holder if there is some charge that is an outlier—say some charge is made down in Brazil and you have not been in Brazil.

Secretary SEBELIUS. And I was here.

The CHAIRMAN. And you were here. But they call you up and say, did you make this charge? Is this something that you bought? They ask you first. You can either authorize or not authorize it. But they know because they have pretty sophisticated computer systems.

So the thought is, maybe we can do some of this in Medicare and Medicaid and some other Federal programs. Now, that gets into prompt payment, and how long does it take for a provider to be reimbursed, and so forth. But on the surface, I think it has some appeal. Senator LeMieux told me that he called a credit card company and talked to the people in charge, and was trying to see to what degree their system might work here. Often, it is the private sector that comes up with pretty efficient ways of doing things.

Secretary SEBELIUS. Right.

The CHAIRMAN. After all, they have the bottom line to worry about, and they have to compete with, say, another credit card company, for example. So I doubt that you have given a lot of thought to that; maybe you have. But anyway, I was kind of intrigued with his idea. Any comments?

Secretary SEBELIUS. I had a conversation with Senator LeMieux about this notion recently because, as you know, we have set up our second strike force in Florida, and it is a hotbed of activities. But I think it has some real interest. I have asked our folks—he has a piece of legislation—to have some conversations with him, but I think the kind of real-time data sharing that he is talking about, looking at aberrant patterns, the way they identify some of these things in a credit card; if 90 percent of my charges are from Washington, DC and suddenly something shows up, or I have never been abroad and something shows up and they flag it, that is exactly what we are trying to do with sharing data with the Justice Department, watching billing patterns.

In Florida, Senator, just for instance, 10 percent of the patients getting home health care live in the State of Florida; 95 percent of the patients who have $100,000 or more in billing of home health care live in Florida. So we matched those quickly and kind of went after it, but that is exactly the kind of—but I hope to learn what the credit cards are doing.

The CHAIRMAN. I encourage you to pursue this aggressively.

Secretary SEBELIUS. Yes. Absolutely.

The CHAIRMAN. I do not want to be corny about this, but we are talking about the taxpayers' money here.

Secretary SEBELIUS. You bet. You bet.

The CHAIRMAN. If we can stop a lot of this, it is going to enhance the credibility of the program.

Secretary SEBELIUS. And getting out in front of it is absolutely right.

The CHAIRMAN. Yes, that is right, rather than at the back end, as you have said several times.

Secretary SEBELIUS. You bet. Yes.

The CHAIRMAN. I appreciate that.

Secretary SEBELIUS. Pay and chase is not as effective as trying to stop it in the first place.

The CHAIRMAN. That does not work. That does not work. They are pretty clever. They find new ways to cut and run.

Secretary SEBELIUS. Right. Right.

The CHAIRMAN. Could you kind of outline for us, remind us of what some of the early deliverables would be of health care reform? Some people say, gee, it is not going to go into effect, once it is passed, for several years. Would you outline for us some of the, fancy term, "early deliverables"?

Secretary SEBELIUS. Assuming the passage of health reform soon, in the year 2010 it is anticipated that we would have States put together high-risk pools to provide affordable coverage for the uninsured, chronically ill folks. A number of the significant insurance reforms would occur, so people would no longer be able to eliminate insurance coverage for children with preexisting conditions. They would have to be covered.

You would have to remove the payment caps that currently interrupt cancer treatments and chronically ill services for people who have insurance coverage. Children could stay on their parents' policies, the twenty-somethings. I have to tell you, as a mom of a 25-year-old, that is really important to me. But until 26 to 27, you could be covered as a dependent under your parents' coverage.

We would begin to institute medical loss ratios for insurance companies so you would know how much money they are spending on benefits for patients and how much is going to overhead and CEO profits, which right now is unable to be determined. Also, preventive care would cease having co-pays right away in 2010.

The CHAIRMAN. So there are significant early deliverables here?

Secretary SEBELIUS. Absolutely.

The CHAIRMAN. Right away. Right away.

Secretary SEBELIUS. And the fraud and abuse prevention would start right away, to really crack down on the system.

The CHAIRMAN. Thank you. Thank you very much.

Senator Carper?

Senator CARPER. Thanks.

The CHAIRMAN. Welcome to the committee.

Senator CARPER. Thank you. It is good to be here. I apologize for arriving late.

The CHAIRMAN. No, I love to have you here.

Senator CARPER. I had the pleasure of welcoming to Delaware, on Monday, a number of high school students, exchange students from countries all over the world. I was struck—we basically had a Q&A session in the Senate, the State Senate, our legislature, general assembly legislative hall in Dover.

They asked a lot of questions, and one of the questions we got into, and issues we got into, was health care. They were curious about health care and health care reform, and were curious as to why we spend so much more money than any other country. They are curious as to why we do not get better results. There were three students there from Japan, a couple from Okinawa, and they basically said, we spend half as much as you do.

I think we spend about 16 percent of GDP, they spend, in Japan, about 8 percent. According to different kinds of measurements that we have for wellness, healthiness, life expectancy, infant mortality and so forth, they actually beat us hands down. They spend half as much, and they cover everybody. They do not do it through a socialist system. I think they have private insurance companies. I believe they have private providers. But I was struck by that conversation.

Today, when I came down to Washington on the train, as I do almost every morning of the week, the train goes by in Newark, DE, just almost before you hit the Maryland line, there is a big Chrysler plant. Well, it used to be a Chrysler plant, and it is closed, where 4,000 people used to work every day. Today, nobody works there.

Today, in a time in which we are really concerned about trying to make sure that people have jobs—again, the loss of manufacturing jobs, the exodus of manufacturing jobs from this country—can you help us—and you may have already done this, but I am going to ask you to do it again—just connect the dots for us here. Affordable health care, quality health care. How does it connect with the need to create jobs and maintain and create a nurturing environment for job creation and preservation?

Secretary SEBELIUS. Senator, I think that there is no question we spend almost twice as much and get worse health results than any other developed nation. Part of it is that we continue to pay more

than anybody in the world for health issues that really do not result in people being healthier, so we over-pay for products and services, we pay for procedures and not for quality outcome, which encourages, I think, more testing, more protocol, and sometimes people would suggest even more hospitalizations, but not necessarily keeping people well in the first place.

We have not invested, as many people have, in health and wellness. A large part of that health and wellness is a huge gap in who has access to preventive health services, follow-up home health care. So when we have 46 million Americans without health insurance at all, they enter the health system in more serious shape, with more chronic conditions, and use emergency rooms more often, which is the least effective, most expensive way to get health care treatment. Some of it clearly has to do with diet. We do not eat nearly as much tuna as the Japanese, and that would probably make all of us a little healthier.

But the jobs, I think, are directly related, because our manufacturing sector has been the first to be absolutely uncompetitive in a global marketplace, when Chrysler was competing with companies around the world who were not layering on $3,000 in health care costs on every car that was sold, or not trying to compete.

So we have to get to a strategy where we have a healthier Nation and a more equitable share of health expenses, paying for outcomes and quality, and finding ways to lower the deficit in the long run, which will make us not only healthier and more prosperous, but certainly more competitive.

Senator CARPER. Thank you. I think I have shared this with you before. I held, back in the August-September time frame, a number of town hall meetings, different than any I have ever held before. We did telephone town hall meetings. In the first one, we had 4,000 people on the call, the second one, we had 6,000 people on the call. I was just struck by the hunger of the people in my State about what was really going on, what we were really doing.

One of the aspects of the legislation that we are passing is something that is designed to help better ensure that we go after fraud, particularly with respect to Medicare and to Medicaid. There is a provision in our bill, supported certainly by Senator Baucus, by Senator Wyden, all my colleagues, that says we need to incentivize the States.

Previously, the States had 60 days to identify fraud, to go out and collect the money and be able to turn half of it over to the Federal Government. As a result, they did almost none of it. If they could not do all that in 60 days, and few of them could, they just let it go. What we are doing, we do under the legislation, is change it to say you have a year to identify it, go after the money, go after the fraudsters, get the money, get it back, and then split it with the Federal Government. That is in our legislation that the Senate passed.

You, I think, have in the administration's budget about a $250-million increase in additional resources to fight waste and abuse in Medicare and in Medicaid. Would you talk about that a little bit? Because we all know it is huge out there. I think we are using private contractors to go out and recover, at least in three States, in the last couple of years, money fraudulently taken out of Medicare.

We recovered, I am told, $700 million last year alone. I think we are taking that to all 50 States.

Could you talk about that, and how these resources and the partnership with the private sector will help us get back more money?

Secretary SEBELIUS. Senator, the President takes very seriously that we be good stewards of taxpayer dollars. Certainly anyone stealing out of Medicare or stealing from the State partnership with Medicaid is stealing taxpayer dollars and jeopardizing the trust we have with seniors. So this budget has an 80-percent increase in resources, new data systems, new sharing with the Justice Department.

The Attorney General and I, at the President's request, are now leading a joint Justice-HHS effort where we now have strike forces in seven different cities to try to not only send a very strong signal that we take this very seriously, but have been enormously effective so far. This will give us a much bigger footprint around the country.

As I was sharing with Chairman Baucus, we can share data realtime, watching aberrant billing practices and go after them. We are going to invest in State partnerships at the Medicaid level, knowing that having those footprints on the ground, having U.S. Attorneys, as well as the States' Attorneys General who can be very aggressive partners in pursuing fraud, is all to the good.

We know that there is a huge return. It is estimated to be anywhere from $2 back for every dollar we spend to $4 back, which is what the Attorney General says, to every dollar we spend. So, this is money that not only makes sure Medicare and Medicaid will be there long-term, but also allows us to prosecute the criminals and prevent fraud in the first place.

Senator CARPER. One of the things I have always been fascinated with, and my colleagues have heard me say this before, is how do we harness economic forces? How do we harness market forces to drive good public qualities and behavior? A good example of that is the Medicaid deal. Before now, or really even now under current law—because we have not passed the Senate-passed bill, it has not been signed into law—the States are not really incentivized to go after Medicaid fraud.

The CHAIRMAN. I want to give Senator Wyden a chance here, too.

Senator CARPER. Oh, I am sorry. I am sorry. Can I just close with one quick comment?

The CHAIRMAN. Senator Wyden has been very gracious. He is letting you proceed.

Senator CARPER. Yes. If I may.

There is, I think, a provision under current law that says that private citizens, health care providers, are encouraged to report fraud if they see it in Medicare. They are encouraged to report it. They do not have to, they are encouraged to.

One thing I would like for us to think about, again, is incentivizing behavior. Rather than just saying we encourage you to report it, why do we not say we want you to report it, you are expected to, or required to report it? But also say, if you do, just like we do with whistle-blowers now, we actually incentivize whistleblowers because we allow them to keep some percentage of what was recovered. We may want to do that in terms of people who

blow the whistle in Medicare fraud and make sure that we incentivize them, not just to do the right thing, but if they do, they will also benefit from that financially.

Secretary SEBELIUS. Actually, Senator, I think that is a great idea, and we will take a look at it. We have a great sort of "seniors' army" that trains volunteers, who go then to their friends at meal sites and neighborhoods, and they have become a tremendous sort of strike force. We figure we have 20 million undercover cops on the ground.

If there is anybody who takes stealing from Medicare seriously, it is those Medicare beneficiaries who are very aggressive in their efforts. That has been a huge help to tipping us off to bad billing practices, to fraudulent activities, to people who would steal IDs, a whole host of issues.

Senator CARPER. Good. Keep it up.

Mr. Chairman, thank you. Senator Wyden, thanks for your patience with me. Thanks.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. It has been a very good hearing. We have gotten a lot out of it, and I thank you for having it.

The CHAIRMAN. We are going to do more.

Senator WYDEN. Absolutely. And I will be here with you.

The CHAIRMAN. Good.

Senator WYDEN. Thank you.

Madam Secretary, I want to ask you about one other area, and that is that an enormous amount of expense and frustration for the millions of people who use our health care system, especially the providers and the patients, is the staggering array of different billing systems that we have for American health care.

As you know, getting a standardized billing system has almost been the longest-running battle since the Trojan War. I was actually reading some history on this recently. One of your predecessors, Lou Sullivan, made this a top priority. This is what Lou Sullivan, a wonderful physician, wanted to get done. Here we are, practically eons later, and we are still wrestling with this.

I think it would be very helpful if you would do two things. One, give us an update on where we are at this point in getting a standardized billing process. Second, I am curious whether you all and your staff are taking a look at some of the efforts around the country that look like they are bearing fruit.

The one that I have been interested in is Minnesota. Minnesota seems to have come up with a standardized billing process, and then it limits the insurance companies from coming up with sort of exceptions, which invariably jack up the rates and make things more complicated.

But start, if you would, by giving us almost a state of where we are, 2010, on getting a standardized billing process so that we end this bureaucratic water torture for the providers and the patients, who constantly tell us about all these forms and different papers, and the like. Where are we today?

Secretary SEBELIUS. Senator, I think the good news is that there are administrative simplification mandates in both the House and Senate health reform bills, which I would suggest will greatly ac-

celerate progress in this area. Absent some kind of a lever, it is a difficult task. It is one that I know personally well because I worked on it in Kansas, and I think I am safe in saying that Kansas now, like Minnesota, is about to have a uniform billing system.

But it is not easy. Everybody is fine with doing it and wants to come to the table to talk about it, as long as you use their system. As soon as you begin to deviate a little bit—I am convinced that it is a huge cost saver and a huge, as you say, torture saver for providers and patients, and one that we have been anticipating implementing through the health reform strategy, because I think that that gives leverage to then have a congressional mandate and follow-ups and make sure that we can get the providers. You need the providers and the payers all at the table simultaneously to figure out the strategy of time tables that work, but it is something that I take very seriously and really look forward to working with you to implement.

Senator WYDEN. I think the provisions in the legislation, both the bills, are good. What concerns me is that absent the kind of leadership you are talking about, we will take another 8, 10 years just working through those models, and somebody else will be in your seat and we will ask almost the same questions.

Secretary SEBELIUS. We do not intend to take nearly that long, Senator.

Senator WYDEN. I like that part.

Secretary SEBELIUS. And States are well ahead.

Senator WYDEN. I like that part.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

It is true, we hear it all the time, as do you, that all the paperwork, all the forms, it is a mess. I remember in the early 1990s, 1993 or 1994, during the last health care reform era, I just happened to go to a Montana hospital. One floor was filled with people doing paperwork. I went up to Canada to poke around. I was up at Edmundston, Hospital. There are three people in the whole hospital, much larger than any Montana hospital, doing paperwork. Three people. That is all there was. We all know about the administrative costs in the American system, how much higher it is than in other countries.

I urge you to solve this thing. We have to, once and for all, so we are not talking about this all the time. You said States are doing much better. Well, you can find the State that is doing the best job, and really do it. Clearly, we have to pass health care reform to help make this happen. Once health care reform is passed, it is going to force more simplification because more insurance companies are going to be forced to simplify—have fewer different alternatives, options, and co-pays and deductibles, pre-existing conditions, all that stuff, frankly.

So, I really urge you to just light a fire under people to get this done. We know how bad it is. We know the American people are fed up with it, and rightly so. It is basically the question that Senator Wyden just asked. So I am just urging you, in the strongest terms possible, just to get this done. We want to work with you. This is a shared effort.

Secretary SEBELIUS. I appreciate that.

The CHAIRMAN. This is a shared effort here, but we need to, together, get it done.

Secretary SEBELIUS. You bet. Yes.

The CHAIRMAN. Get it done. So you need to tell us what you need, whether it is legislation, whatever it is. I just strongly urge you to do that.

Now, I think we are going to get health care reform passed. I am very confident we are going to pass health care reform this year. But I am going to ask you this. If you could, say on a biannual basis, just give us a progress report on standardizing forms and getting rid of a lot of this paperwork, it would make a huge difference. The point is not to put you on the spot, the point is to let us know what the progress is so that, together, jointly, we can solve this.

Secretary SEBELIUS. Sure. And Senator, I think you took a big step. I mean, one is paperwork and one is the numerous forms.

The CHAIRMAN. Right.

Secretary SEBELIUS. So electronic health records and standardization, as you launched in the Recovery Act, will go a huge way down to eliminating a lot of the paperwork and standardizing operations and driving protocol. But that does not get rid of the 15 different forms, so if you fill them out electronically it still drives providers crazy.

The CHAIRMAN. Right. Right.

Secretary SEBELIUS. So we have to do both simultaneously.

The CHAIRMAN. Right. But I personally want you to quantify it. One of the major drivers in getting results is quantifying.

Secretary SEBELIUS. All right.

The CHAIRMAN. Benchmarks, standards. Quantifying. Numbers.

Secretary SEBELIUS. All right.

The CHAIRMAN. How many forms? How many lines? All that kind of thing.

Secretary SEBELIUS. A lot.

The CHAIRMAN. I know.

Secretary SEBELIUS. Thirty cents out of every dollar, we figure, is for overhead costs.

The CHAIRMAN. I am just urging you, on a biennial basis, to get back to us.

Secretary SEBELIUS. Yes. All right.

The CHAIRMAN. Let us know what your plan is, the benchmarks you are setting out for yourself, and the progress you are making or not making, because it is something we just need to do.

Secretary SEBELIUS. Yes, sir.

The CHAIRMAN. Thank you.

Second, the same with waste, fraud, and abuse. A lot of questions here have been about waste, about fraud, about abuse. So I would like you to, again, on a biennial basis, just quantify what you think, your best guess as to what the waste is in all the programs under your jurisdiction, what the fraud is and how you quantify abuse. You have to quantify the number of dollars. Again, we have to work together so we get improvement. I would like you also to just give us a goal. Zero is unattainable.

Secretary SEBELIUS. Sure.

The CHAIRMAN. But if you could give us a goal, like what percent by what date, give us some benchmarks. That is how we are going to get results around here. It is one thing to talk about things.

Secretary SEBELIUS. Right.

The CHAIRMAN [continuing]. But it is something else to quantify it with numbers. People understand numbers. We are working together, on a 6-month basis. You will be back here again, I am sure, sometime in the next couple, 3 months, and we will have a chance to talk about this.

Secretary SEBELIUS. Sounds good.

The CHAIRMAN. But again, we want to work with you. This is not to put you on the spot, this is just to work together.

Secretary SEBELIUS. That is great. I look forward to it.

The CHAIRMAN. Good.

Senator Carper?

Senator CARPER. Could I have a last point? I just want to come back to that point. We have a lot of Federal property that we do not use in our inventory. Senator Baucus knows, we are trying to confirm an administrator for GSA, the General Services Administration, which manages thousands of Federal properties across the country. But we have a lot of them that are vacant, or not used, or under-utilized. We pay the utilities, we pay the security, all kinds of other costs that relate to the facilities.

Agencies, even if they want to sell them, they might need to spruce them up or fix them up or something in getting ready to market them. Then the property is sold and the agency does not get any money back. They do not get any money to pay their costs, their fix-up costs. They do not get any money back to help underwrite the costs of some of their programs, so as a result we end up just carrying on our books not just hundreds, but thousands of properties which are really a drain on our treasury.

At least one agency has figured out how to use, and has been given permission to use, market forces. We incentivize the Veterans Administration. We allow them to keep 20 percent of the proceeds from the properties that they sell. They use that money to help pay for the fix-up costs, they use that money to also go into their programs to help supplement the appropriated funds. That is the kind of thing I think we need to be doing more of. I think I learned all that stuff in new Governors' school, and you probably did, too. We need to put more of those kinds of lessons to work.

Secretary SEBELIUS. Entrepreneurial spirit.

Senator CARPER. There you go. There you go.

Thanks very much.

The CHAIRMAN. You bet.

I also encourage you to break it out according to major categories, such as departments and so forth, so it is not just a gross number.

Secretary SEBELIUS. All right.

The CHAIRMAN. The tyranny of averages sometimes prevents effectiveness. And do not go across all these departments and all your stuff. I do not want you to overdo it, but figure out some reasonable way to segment each, how much, which department has X fraud and which departments have Y waste, and so forth. Just kind of break it down a little bit in some manageable way.

Thank you.

Secretary SEBELIUS. It sounds reasonable. Thank you, sir.

The CHAIRMAN. This is a great hearing. I deeply appreciate you taking the time to come and talk to us.

Secretary SEBELIUS. I look forward to working with you.

The CHAIRMAN. We have a lot of things we have to do.

Secretary SEBELIUS. Absolutely.

The CHAIRMAN. All right. Thank you very much.

Secretary SEBELIUS. Thank you.

The CHAIRMAN. The hearing is adjourned.

[Whereupon, at 5:27 p.m., the hearing was concluded.]

# APPENDIX

## ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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**Hearing Statement of Senator Max Baucus (D-Mont.)**
**Regarding President's Fiscal Year 2011 Health Care Proposals**

Mahatma Gandhi said: "Every worthwhile accomplishment . . . has its stages of drudgery and triumph; a beginning, a struggle, and a victory."

The effort to enact comprehensive health care reform has certainly seen its struggle, and even its stages of drudgery. But as we look back at the progress that we have made, and look ahead at the short distance that we have yet to go, I remain confident that we can before long move to the stages of triumph and victory.

We are on the brink of accomplishing real health care reform. We are on the brink of reform that will help millions of Americans to afford health care coverage. And we are on the brink of reform that will improve the quality and efficiency of health care delivery for all.

Every day reminds us of the need for reform. The latest report by the nonpartisan Congressional Budget Office warns once again that the growth of federal health care spending represents the "single greatest threat to budget stability." That's because health care costs continue to rise faster than the growth in the economy, and faster than the growth in wages of American families.

In the last 8 years, average wages have increased just 20 percent. But the average cost of employer-sponsored health coverage has doubled. And health insurance premiums have tripled.

The high cost of health care means that one in four Americans lives in a family that spent more than 10 percent of its income on health care in 2009. And four out of five of these families have health insurance.

The high cost of health care also diminishes the ability of American companies to compete. And the high cost of health care makes it hard for small businesses that provide health coverage to hire new workers or stay afloat.

America spends nearly twice what the next-highest-spending country spends on health care. But U.S. health care far too often produces uneven quality and poor outcomes.

More than 46 million Americans lack any form of health coverage. Another 23 million are underinsured. According to CBO, within a decade, 54 million Americans will be uninsured. And the CMS Actuary's Office thinks that number will be even higher — reaching 57 million by 2019.

We've tried incremental reform. We created rights and protections in 1996 for people who purchase group health coverage. And we covered millions of uninsured children with the 1997 enactment of the Children's Health Insurance Program.

But we've reached a point where it's increasingly difficult to fix the system one step at a time. We cannot add 46 million uninsured people to a broken health system. And we cannot meaningfully control the growth of health spending without covering the uninsured.

Over the past year, we've learned how hard it is to reform our health care system.

But just because it's hard does not mean that the task is any less necessary. Just because it's hard does not mean that we should look the other way. And just because it's hard does not mean that we have to compromise so much that we fail to address the problems at hand.

Madam Secretary, thank you for all of your hard work over the past year — and the work of your department — in helping us to craft health reform.

Thanks to your guidance and leadership, we know that we can start covering the uninsured with pre-existing conditions this year through a high risk pool. We know that we can provide immediate assistance to bridge the Medicare drug coverage gap — the so-called donut hole. We know that we can jump-start quality improvement policies in Medicare and Medicaid. And we know that we can make immediate progress on insurance market reform.

I'm pleased to see that the President's budget assumes enactment of health reform. The budget accurately reflects that health reform has the potential to reduce the budget deficit by $150 billion over the next decade. And as the President said in his State of the Union address, reform also has the potential to reduce the deficit by $1 trillion over the second 10 years.

This year, the Finance Committee faces a full agenda. We will work on creating jobs, growing the economy, and reducing the deficit.

But given the daunting long-run fiscal challenges that we face, we cannot give up the quest for health reform that addresses the interconnected problems of cost, quality, and access.

I urge my colleagues, on both sides of the aisle, and both sides of the Capitol, not to give up. We can and we must succeed in reforming our health system.

Of course, we face other daunting challenges as well.

The Medicare physician payment formula needs reform. HHS took an important step by removing drugs from the formula. And just last week, the Senate recognized that a long-term fix will require a short-term investment, by exempting part of that fix from the new statutory pay-go rules. I hope that this push will aid us in finding a permanent solution — for the sake of our seniors' continued access to medical care.

And beyond health care reform, Congress must reauthorize the Temporary Assistance to Needy Families, or TANF, program this year.

And we have more work to do to improve our child welfare program. The President's budget did not assume a five year reauthorization. We must use this year to lay the groundwork for reauthorization.

But let me conclude where I began. I agree with President Obama: We cannot give up on enacting comprehensive health care reform this year.

We have gone well past this effort's beginning. We have endured our share of struggle. Now, let us at last bring this bill to victory.

###

**Statement of Michael B. Enzi**
**Senate Committee on Finance Hearing**
**"The President's Fiscal Year 2011 Health Care Proposals"**
**February 3, 2010**

Mr. Chairman, the federal credit card is maxed out, yet we keep on spending.

The President's budget includes $3.8 trillion in fiscal year 2011 spending and $1.4 trillion in fiscal year 2011 deficit. This is the third year in a row of trillion plus deficits. The fiscal year 2010 deficit is now projected to reach $1.56 trillion.

As a percentage of the economy, our deficit is 10 percent of GDP. This is the highest it has been since the end of the Second World War.

I worry about the country that I am leaving for my children and grandchildren. Our nation is being buried under a mountain of debt, which poses a deadly threat to the wellbeing of our nation.

The current levels of debt are simply not sustainable. If not addressed, the current levels of federal debt will prevent the creation of new jobs, slow business growth, increase mortgage rates and limit our ability to address other national priorities.

As one of the largest purchasers of U.S. government bonds, the Chinese government has already made it clear that they are growing apprehensive about our ability to pay our increasing national debts. As China's apprehension grows, the interest rates we pay on our debt will grow. That means that it will soon cost us considerably more to allow Washington to continue to borrow the money it needs to fund its current spending binge.

We are failing on our most fundamental duty as Members of Congress, which is to wisely manage the power of the purse for our nation. According to David Walker, the former head of the Government Accountability Office, at the end of fiscal 2000, the federal government had about $20.4 trillion in total liabilities, and unfunded commitments for Social Security and Medicare.

That number rose to $56.4 trillion at the end of fiscal 2008, which represents a 176 percent increase in just eight years. By the end of this year, that number is expected to have risen to $63 trillion. It is imperative that we stop spending money we don't even have on programs we can't afford.

A newspaper columnist, Diane Badget from Lovell, Wyoming said it best when she wrote how her mother would react to what's happening in Washington today. Diane wrote, "Momma always said, 'If you don't have enough money to buy a quart of milk you don't take someone else's hard-earned cash and buy ice cream.' "

Any serious effort to address our national debt must focus on the health care entitlement programs like Medicare and Medicaid, whose costs are growing at a rate far above the rest of our economy. We need to get a handle on these costs if we ever hope to be able to reduce the deficit.

Spending on Medicare, Medicaid, and other mandatory health care programs reached over $761 billion in 2009. The President's budget estimates that we will spend $900 billion on these programs in 2011. We cannot continue on this path.

We must fix Medicare and Medicaid so they don't bankrupt our grandchildren. By 2020, the CBO estimates these programs will cost $1.5 trillion, which will be about 28 percent of total federal spending.

As a first step, I hope we can agree to not take money out of existing entitlement programs and use it to create new entitlement programs. This is the worst kind of government accounting shell game. Both the Congressional Budget Office and the Chief Actuary at CMS have recently criticized these types of accounting gimmicks, which do not reduce our long term debts.

We need to work together to identify real solutions that will slow the growth of health care costs and make health insurance more affordable for every American. The single greatest challenge in our current health care system is how to slow the growth of ever escalating costs.

This is true for government programs and for private health insurance. Many businesses that purchase health insurance face double digit premium increases. If we don't address the problems driving this cost growth, more and more Americans will lose their health insurance.

Mr. Chairman, I thank you for holding this hearing today and I look forward to hearing any ideas the Administration has to address these challenges.

###

United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

Opening Statement of Sen. Chuck Grassley
Finance Committee Hearing on the President's Fiscal Year 2011 Budget
Wednesday, Feb. 3, 2010

Thank you, Mr. Chairman. And thank you Secretary Sebelius for being here today to discuss the President's proposal for the 2011 budget. I think we can all agree that these are extraordinary times. Our nation is beginning a slow recovery from one of the worst economic downturns in history. Now, maybe more than any time in history, people are focused on our nation's economic challenges … and they're worried. They've watched unemployment soar, the auto industry go into bankruptcy, banks shutting their doors, and families struggling to make ends meet.

And as our constituents have tightened their belts and tried to reign in their own household spending, they've seen some in Washington support spending increase after spending increase. They've watched as the federal debt has increased by 1.5 trillion dollars since President Obama took office. And on the heels of that, they've seen the Senate vote most recently to increase the debt ceiling by another 1.9 trillion dollars to make way for more deficit spending. As I travel around Iowa, my constituents know these facts and figures about our economy and debt better than many Washington insiders. They also know that this budget only takes minor steps to tackle a major problem. They know that under this budget, the amount of debt held in 2008 will double to 12.3 trillion dollars by 2013 and then triple to 17.5 trillion in 2019. And the question they keep asking is, when will Washington come to its senses and realize we can't afford all this? All of the bailouts, all of the stimulus, all of the new spending is paid for with our constituents' hard-earned dollars -- and they're tired of it. They fail to see the return on investment that some have promised, and as a result they've lost faith in government spending.

As we consider the 2011 Budget, we need to be thinking about how we restore that trust. That begins with transparency and accountability. In my years serving in the United States Congress, I've made it my mission to ensure that transparency and accountability are more than just buzz words. They've got to be meaningful. I've held both Republican and Democratic administrations to the same standard of openness.

When President Obama was running for office, he pledged to make government "open and transparent," and his administration has promised to "provide a window for all

Americans into the business of government." Actions speak louder than words and unfortunately, a year in to this administration, we have seen that this principle is not always put into practice. Transparency and accountability require an open and frank dialogue between the people's representatives in Congress and those in the administration.

At this time, I have over ten responses overdue from the Department of Health and Human Services on matters ranging from health care fraud to public safety. In Departments across the federal government, my oversight efforts are often resisted, held-up, frustrated, and impeded -- impeded by bureaucrats who seem more interested in covering up than in opening up. While this lack of transparency and accountability is nothing new in Washington, the American public was led to expect more from this administration. Promises were made. Principles based on transparency and accountability were repeated over and over again—and America believed.

I intend to continue to work on the American people's behalf to hold the government accountable for its actions and ensure that the administration conducts its business in an open and transparent manner. While these accountability and transparency problems persist, I am pleased at least to see that addressing fraud, waste and abuse in Medicare, Medicaid and CHIP has a prominent role in this year's budget proposal – as it should.

If we learned anything during the health care reform debate, it was that fighting health care fraud, waste and abuse is a bipartisan priority. We all have seen the staggering estimates of around $60 billion dollars of taxpayer money being lost. And this is a conservative estimate. So I look forward to hearing from you today on proposals to strengthen fraud, waste and abuse prevention, detection and enforcement.

But before Congress can weigh the merits of your legislative proposals, as well as your request for increased funding, we need to know what and how you are doing with what you currently have. As I mentioned earlier, Congress has the duty of government oversight. This includes reviewing annual reports you are required to produce. One of these annual reports is on payment error rates. The latest one was due last November. But Congress has yet to see payment error rates for specific types of providers. This seriously impedes our ability to conduct oversight. And it limits our ability to evaluate how the federal government is addressing fraud, waste and abuse. So I look forward to hearing from you today on the status of this report.

In addition to the fraud, waste and abuse proposals, the budget also assumes a six-month FMAP extension for states. And while I do agree the states still need assistance to make ends meet, I think it is time for Congress to cut the strings attached to the aid we are sending them. As states struggle to balance their budgets, having the federal government provide them assistance that prevents them from touching Medicaid doesn't make much sense. We should give states control of their budgets, so they can be more innovative and efficient with how they provide access to care. I hope you as a former governor would agree. I look forward to discussing this and other issues with you during the question and answer period. Thank you.

CMS

# November 2009
# Improper Medicare FFS Payments:
# *Summary of Findings*

***November 16, 2009***

CMS

# Medicare FFS IPIA Overview

- Reducing Medicare waste, fraud and abuse is one of HHS's highest priorities to ensure that the program remains strong for current Medicare beneficiaries and future generations.

- To this end, CMS has significantly revised and improved the way that it calculates the Medicare fee-for-service error rate. The improved methodology provides a more accurate assessment of unsubstantiated claims. CMS and its partners cannot reduce waste, fraud, and abuse unless it has an accurate assessment as possible.

- These improvements are consistent with recommendations CMS has received from the Office of Inspector General (OIG).

CMS

# Medicare FFS IPIA Overview – cont.

- As a result of these improvements and more complete accounting, this year's error rate will be higher than last year, 7.8 percent compared to 3.6 percent for last year. This change is NOT necessarily due to more fraud in the program. In fact, the error rate is not a measure of fraud. The two areas with significant increases in errors were inpatient services and durable medical equipment (DME). Both of these areas had substantial changes to their medical record review methodologies based on recommendations from the OIG.

- As result of the higher error rate, CMS will work closely with its contractors to reduce the error rate by ensuring that Medicare fee-for-service claims receive more vigilant review before being processed. The result of this more vigilant review will result in more accurate claims and reductions in Medicare waste, fraud and abuse.

- CMS will also work closely with the healthcare industry to ensure that providers and suppliers understand CMS policies and medical record requirements in order to further reduce errors.

CMS

# National Error Rates by Year 2003 - 2009

| Year | Error Rate | Total Medicare FFS Payments | Total Improper Payments |
|---|---|---|---|
| Nov 2003 | 6.4%* | $199.1 B | $12.7 B* |
| Nov 2004 | 10.1% | $213.5 B | $21.7 B |
| Nov 2005 | 5.2% | $234.1 B | $12.1 B |
| Nov 2006 | 4.4% | $246.8 B | $10.8 B |
| Nov 2007 | 3.9% | $276.2 B | $10.8 B |
| Nov 2008 | 3.6% | $288.2 B | $10.4 B |
| Nov 2009 | 7.8% | $308.4 B | $24.1 B |

* These entries have been adjusted to account for the high provider non-response rate in 2003. Had the adjustment not been made, the improper payments would have been $21.5 B and the national paid claims error rate would have been 10.8%.

CMS

# National Medicare Fee-for Service Error Rates by Year 1996 - 2009

| Year | Error Rate | Total Dollars Paid | Total Improper Payments |
|---|---|---|---|
| 1996 | 14.2% | $168.1 B | $23.8 B |
| 1997 | 11.8% | $177.9 B | $20.9 B |
| 1998 | 8.4% | $177.0 B | $14.9 B |
| 1999 | 8.6% | $168.9 B | $14.5 B |
| 2000 | 9.4% | $174.6 B | $16.4 B |
| 2001 | 8.8% | $191.3 B | $16.8 B |
| 2002 | 8.0% | $212.8 B | $17.1 B |
| 2003 | 6.4%* | $199.1 B | $12.7 B* |
| 2004 | 10.1% | $213.5 B | $21.7 B |
| 2005 | 5.2% | $234.1 B | $12.1 B |
| 2006 | 4.4% | $246.8 B | $10.8 B |
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* These entries have been adjusted to account for the high provider non-response rate in 2003. Had the adjustment not been made, the improper payments would have been $21.5 B and the national paid claims error rate would have been 10.8%.

CMS

# New for 2009

- Based on both the recommendations contained in recent OIG audit reports and those of CMS' advisory medical staff, CMS modified the medical review process for the November 2009 improper payments report. CMS implemented three separate revisions to the review criteria to more strictly enforce Medicare policies.
  - Each application of new review criteria saw a corresponding increase in the error rate.

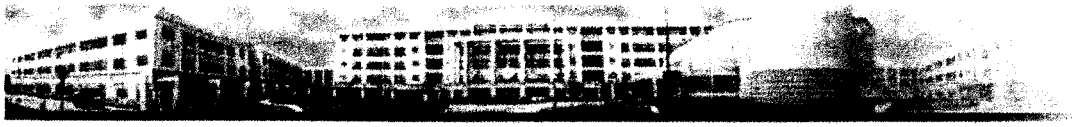
- In an effort to improve measurement accuracy, CMS changed the way it reviewed inpatient hospital claims for error rate measurement. In the past, inpatient hospital reviews were reviewed under a separate program than other Medicare FFS claims. CMS consolidated the programs and the review procedures for acute inpatient hospital claims are now consistent with the procedures used for review of all other Medicare FFS claims.

- **Because of the differences in approach, the 2009 error rates are not comparable to previous years' error rates.**

CMS

# OIG Audits

- The OIG auditors believed that CERT reviewers should have applied a strict interpretation of Medicare rules.
  - CERT considered available documentation and patient billing history and applied clinical judgment to make payment determinations
- CMS issued new CERT review guidance instructing CERT reviewers to review using a strict interpretation of Medicare rules.
  - Instructed that clinical judgment cannot override policy documentation requirements
  - Clarified medical necessity documentation requirements for DME
- CERT reviewers applied more stringent review criteria when reviewing claims selected for the November 2009 report after CMS issued the guidance. Due to time constraints, CERT was not able to apply the stricter criteria to claims reviewed prior to the date of the CMS guidance.

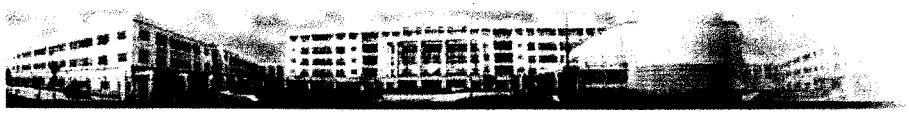


CMS

# Summary of 2009 Findings

- National Paid Claims Error Rate increased from 3.6% in Nov 08 to 7.8% in Nov 09
  - Improper payments increased from $10.4 B to $24.1 B
- The error rate increased for all service types

| Service Type | November 2008 | November 2009 | % of FFS Trust Fund $ |
|---|---|---|---|
| **Physician/Lab/Ambulance** | 4.4% | 9.9% | 27% |
| **DME** | 7.3% | 51.9% | 4% |
| **Non-inpatient hospital facilities** | 1.6% | 3.9% | 32% |
| **Inpatient hospitals** | 4.6% | 6.1% | 37% |



CMS

# Summary of 2009 Findings - cont

- Based on both the recommendations contained in recent OIG audit reports and those of CMS' advisory medical staff, CMS modified the medical review process for the November 2009 improper payments report.
  - CMS implemented three separate revisions to the CERT review criteria based on these recommendations.
- Due to these modifications, the CERT contractor was not able to meet the original goal of 120,000 reviewed claims.
  - Approximately 99,500 claims completed the review process. Of that number, approximately 19,000 claims were reviewed using the most stringent criteria.
- CMS consulted with the OIG concerning the limited time period covered by these claims and determined that reporting the error rate for this subset of claims only would not be in compliance with Improper Payment Information Act requirements.
- Because the modifications to the medical review criteria were made incrementally throughout the report period, CMS could not produce contractor-specific or service-specific error rates.

CMS

# Summary of 2009 Findings - cont.

- **For the claims reviewed under the most stringent criteria**, the national paid claims error rate is estimated at 12.4%
  - Estimated improper payments were $35.4 B

- The error rate increased for all service types

| Service Type | November 2008 | November 2009 | % of FFS Trust Fund $ |
|---|---|---|---|
| **Physician/Lab/Ambulance** | 4.4% | 18.9% | 27% |
| **DME** | 7.3% | 73.0% | 4% |
| **Non-inpatient hospital facilities** | 1.6% | 8.8% | 32% |
| **Inpatient hospitals** | 4.6% | 6.1% | 37% |

CMS

# Findings:
# Error Rates by Type of Error

| Type of Error | Nov 2004 Rpt | Nov 2005 Rpt | Nov 2006 Rpt | Nov 2007 Rpt | Nov 2008 Rpt | Nov 2009 Rpt |
|---|---|---|---|---|---|---|
| No Documentation | 3.1% | 0.7% | 0.6% | 0.6% | 0.2% | 0.1% |
| Insufficient Documentation | 4.1% | 1.1%* | 0.6%** | 0.4% | 0.6% | 1.9% |
| Medically Unnecessary | 1.6% | 1.6% | 1.4% | 1.3% | 1.4% | 4.0% |
| Incorrect Coding | 1.2% | 1.5% | 1.6% | 1.5% | 1.3% | 1.6% |
| Other | 0.2% | 0.2% | 0.2% | 0.2% | 0.1% | 0.1% |
| Total Error Rate | 10.1% | 5.2% | 4.4% | 3.9% | 3.6% | 7.8% |

NOTE: Columns may not sum correctly due to rounding

* This significant decline was due primarily to the CERT program now giving every provider a "second chance" to submit sufficient documentation

** The decline was due primarily to a new process which distributed reports of insufficient documentation errors to ACs who were encouraged to contact providers for final attempt to obtain missing documentation

CMS

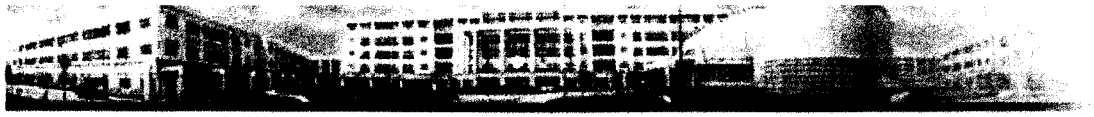
# Why the Increased Error Rate for Inpatient Hospital Claims?

- This is the first report where the reviews of inpatient hospital claims were conducted by CERT rather than HPMP.
  - Differences in error rate measurement methodology in the HPMP and CERT programs resulted in an increased error rate.
    - HPMP sampled claims 3 months after month of discharge which allowed time for adjustment bills. CERT samples claims as they are submitted for payment.
    - HPMP allowed more time for appeals to be submitted and adjudicated. In an effort to produce a more timely report, the CERT program counts fewer appeal overturns.
    - CERT applied all national and local policies when reviewing inpatient hospital claims

CMS

# Why the Increased Error Rates for Other Provider Types?

- Medical records from the treating physician not submitted or incomplete
  - Previously: CERT would review available documentation and patient billing history and apply clinical judgment
  - Now: CERT requires records from the treating physician.
- Medical records from the treating physician did not substantiate what was billed
  - Previously: CERT would review available documentation, including physician orders, supplier documentation, and patient billing history and apply clinical review judgment.
  - Now CERT can not use clinical review judgment to supersede documentation requirements in CMS statute, regulations, policies, or manuals
- Missing or illegible signatures on medical record documentation
  - Previously: CERT would apply clinical review judgment in considering medical record entries that contain missing or illegible signatures
  - Now: CERT is disallowing entries if a signature is missing or illegible
- Missing evidence of physician intent to order diagnostic tests
  - Previously: CERT would consider an unsigned requisition or physicians' initials on test results
  - Now: CERT requires evidence of the treating physician's intent to order tests, e.g., signed orders, progress notes



CMS

# Analysis of Errors

- Most of these new errors are due to a strict adherence to policy documentation requirements, signature legibility requirements, the removal of claims history as a valid source for review information, and the determination that medical record documentation received only from a supplier is, by definition, insufficient to substantiate a claim. As such, CMS will work closely with the healthcare industry to ensure that providers and suppliers understand and follow medical documentation requirements in the future.

CMS

# Challenges in Reducing Improper Payments

- In cases where the billing entity is not the ordering/referring physician, there is no requirement or incentive for the treating physician to submit medical records to support medical necessity
  - Example: A supplier submits a bill for an oxygen concentrator. The supplier documentation includes a Certificate of Medical Necessity (CMN) which lists the oxygen saturation at rest and during exercise as required by the local coverage determination (LCD). The LCD also requires that the information on the CMN be supported by the ordering/referring physician's medical records. If the physician's medical record documentation is not submitted to the review entity, the supplier claim is denied but there is no penalty to the ordering/referring physician.
- Signature and documentation requirements cannot be enforced by automated edits
  - CMS has limited resources to conduct complex medical review

CMS

# CMS Corrective Action Plan

- CMS will analyze the improper payment data to determine if there are geographical trends that can assist in identifying errors that highlight programmatic weaknesses. CMS will review trends by types of service to locate potential vulnerabilities that can assist in designing new innovative approaches to detecting emerging trends and vulnerabilities in high risk areas such as durable medical equipment and home health. As was previously stated, the error rate is not a measure of fraud. However, it may be an indication of a program weakness that requires more oversight and diligence by CMS.

CMS

# CMS Specific Corrective Actions

- CMS is conducting a review of its policies and manual instructions
  - Providing clarifications to promote consistent interpretation of policies
  - Updating policies where needed, e.g., signature requirements
- CMS has taken steps to improve the FFS error rate measurement program
  - Enhanced the Quality Assurance review process
  - Adding additional Medical Director oversight at CERT
- CMS requires claims processing contractors to develop error rate reduction plans to reduce errors in their jurisdiction
- DME MACs have established a DME Education Task Force to educate physicians and suppliers about coverage rules and documentation requirements

**STATEMENT OF**

**KATHLEEN SEBELIUS**

**SECRETARY**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**ON**

# THE PRESIDENT'S FISCAL YEAR 2011 BUDGET

**BEFORE THE**

**COMMITTEE ON FINANCE**

**UNITED STATES SENATE**

**FEBRUARY 3, 2010**

Chairman Baucus, Senator Grassley, and Members of the Committee, thank you for the invitation to discuss the President's FY 2011 Budget for the Department of Health and Human Services (HHS).

Last week, in his State of the Union, President Obama laid out an aggressive agenda to create jobs, strengthen opportunity for working families, and lay a foundation for long-term growth. His fiscal year (FY) 2011 budget is the blueprint for putting that vision into action.

At HHS, we are supporting that agenda by working to keep Americans healthy, ensure they get the health care they need, and provide children, families, and seniors with the essential human services they depend on.

Our budget will make sure that the critical health and human services our Department offers to the American people are of the highest quality and are directly helping families stay healthy, safe, and secure—especially as we continue to climb out of a recession.

It promotes projects that will rebuild our economy by investing in next generation research and the advanced development of technology that will help us find cures for diseases, innovative new treatments, and new ways to keep Americans safe, whether we are facing a pandemic or a potential terrorist attack.

But this budget isn't just about new programs or new priorities or new research. It is also about a new way of doing business with the taxpayers' money. Where there is waste and fraud, we must root it out. Where there are loopholes, we must close them. And where we have opportunities to increase transparency, accountability, and program integrity, we must take them. These are top priorities of the President. They are top priorities of mine. And our budget will make them top priorities for my department as well.

The President's FY 2011 Budget for HHS totals $911 billion in outlays, 90 percent of which is within the jurisdiction of the Committee on Finance.

***Reducing Health Care Fraud***

When American families are struggling to make every dollar count, we need to be just as vigilant about how their money is spent. That's why the Obama Administration is cracking down on criminals who steal from taxpayers, endanger patients, and jeopardize the future of our government health insurance programs.

Last May, President Obama instructed Attorney General Holder and me to create a new Health Care Fraud Prevention and Action Team, which we call HEAT for short. HEAT is an unprecedented partnership that brings together high-level leaders from both departments so that we can share information, spot trends, coordinate strategy, and develop new fraud prevention tools.

As part of this new partnership, we are developing tools that will allow us to identify criminal activity by analyzing suspicious patterns in claims data. Medicare claims data used to be scattered among several databases belonging to different contractors. If we wanted to find out how many claims had been made for a certain kind of wheelchair, we had to go look in several different places. But now, we are combining all Medicare paid claims data into a single, searchable database. Which means that for the first time ever, we'll have a complete picture of what kinds of claims are being filed across the country and where they're being filed from.

Our FY 2011 Budget includes $1.7 billion in funding to fight fraud, including $561 million in discretionary funds, to strengthen these Medicare and Medicaid program integrity activities, with a particular emphasis on fighting health care fraud in the field, increasing Medicare and Medicaid audits, and strengthening program oversight while reducing costs.

This investment, will better equip the Federal government to minimize inappropriate payments, pinpoint potential weaknesses in program integrity oversight, target emerging fraud schemes by provider and type of service, and establish safeguards to correct programmatic vulnerabilities. This multi-year discretionary investment will save $9.9 billion over ten years.

The Budget also includes a set of new administrative and legislative program integrity proposals that will give HHS the necessary tools to fight fraud by enhancing provider enrollment scrutiny, increasing claims oversight and improving Medicare's data analysis capabilities and will save approximately $14.7 billion over ten years.

***Improving Quality of and Access to Health Care***

At HHS, we continue to find ways to better serve the American public, especially those citizens least able to help themselves. We are working to improve the quality of and access to health care for all Americans by supporting programs intended to enhance the health care workforce and the quality of health care information and treatments through the advancement of health information technology (IT) and the modernization of the health care system.

As Congress continues its work to provide security and stability for Americans with health insurance and expand coverage to those Americans who do not have insurance, HHS maintains its efforts towards achieving those goals through activities with the Children's Health Insurance Program (CHIP), health IT, patient-centered health research, prevention and wellness, community health centers, and the health workforce.

Additional resources distributed to States and Territories after the enactment of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) resulted in 19 States expanding or improving child health coverage in FY 2009. Forty-seven States now cover children in families with incomes at or above 200 percent of the Federal poverty guidelines. In September of 2009, CMS awarded $40 million in grants to assist

in enrolling the over 5 million children who are uninsured but eligible for either Medicaid or CHIP.

The Budget includes $3.6 billion to strengthen the ability of the Centers for Medicare & Medicaid Services (CMS) to meet current administrative workload demands resulting from recent legislative requirements and continued beneficiary growth. The funding provides targeted investments to revamp IT systems and optimize staffing levels so that CMS can meet the future challenges of Medicare and Medicaid while being an active purchaser of high quality and efficient care.

For example, $110 million will support a comprehensive Health Care Data Improvement Initiative to transform CMS's data environment from one focused primarily on claims processing to one also focused on state-of-the art data analysis and information sharing. These changes are vital to modernizing the Medicare and Medicaid programs by making CMS a leader in value-based purchasing, improving systems security, and increasing analytic capabilities and data sharing with key stakeholders.

Everyone agrees that the scheduled Medicare physician payment cuts are not sustainable and would likely impact access to care for our Medicare beneficiaries. We look forward to working with Congress to reform Medicare's payment policy and give physicians incentives to improve quality and efficiency. The Budget assumes a zero percent update for physician payments. This is not a proposed policy but an honest and transparent budget display reflecting the Administration's best estimate of future Congressional action based on what Congress has done in recent years for physician payments.

The Budget includes $995 million for the Health Resources and Services Administration (HRSA) for a wide range of programs to strengthen and support our Nation's health care workforce. This funding will enhance the capacity of nursing schools, increase access to oral health care through dental workforce development grants, target minority and low income students, and place an increased emphasis on ensuring that America's senior population gets the care and treatment it needs.

The Budget includes an increase of $290 million to ensure better access to health centers through further expansions of health center services and integration of behavioral health into health centers' primary care system. This funding builds on investments made under the American Recovery and Reinvestment Act (Recovery Act) of 2009 and will enable health centers to serve more than 20 million patients in FY 2011, which is more than 3 million patients than were served in FY 2008.

The President is committed to improving health outcomes and reducing health disparities for American Indian and Alaska Native communities. The Budget includes nearly $5.4 billion in budget authority and collections, an increase of $354 million, enabling the Indian Health Service (IHS) to focus on reducing health disparities, supporting Tribal efforts to deliver high-quality care, ensuring that IHS services can be supplemented by care purchased outside the Indian health system where necessary, and funding health facility and medical equipment upgrades.

The Budget advances the President's health IT initiative by accelerating health IT adoption and electronic health records (EHRs) utilization – essential tools for modernizing the health care system. The Budget includes $78 million, an increase of $17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to continue its current efforts as the Federal health IT leader and coordinator. During FY 2011, HHS will also begin providing an estimated $25 billion over 10 years of Recovery Act Medicare and Medicaid incentive payments to physicians and hospitals who demonstrate meaningful use of certified EHRs, which will improve the reporting of clinical quality measures and promote health care quality, efficiency, and patient safety.

To continue to fulfill the President's commitment to ensuring access to health care for millions of Americans, the Budget includes a proposal to extend by an additional six months, through June 2011, the temporary Federal Medical Assistance Percentage (FMAP) increase provided by the Recovery Act. The extension will result in an additional $25.5 billion to States and Territories for maintaining support for children and families helped by Medicaid and promoting economic recovery by helping State budgets.

The Budget supports HHS-wide patient-centered health research, including $286 million within the Agency for Healthcare Research and Quality (AHRQ). HHS also continues to invest the $1.1 billion provided by the Recovery Act to improve health care quality by providing patients and physicians with state-of-the-art, evidence-based information to enhance medical decision-making.

***Promoting Public Health***

Whether responding to pandemic flu or preventing food-borne illness, HHS will continue its unwavering commitment to keeping Americans healthy and safe.

The President is committed to securing our Nation's food supply by transforming and improving our food safety system. The Budget includes $1.4 billion, an increase of $327 million, for food safety efforts that will strengthen the ability of the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to prioritize prevention, strengthen surveillance and enforcement, and improve response and recovery – key priorities of the Food Safety Working Group the President established in March 2009.

In June 2009, the President signed the Family Smoking Prevention and Control Act, providing FDA with new authorities and responsibilities for regulating tobacco use and establishing the FDA Center for Tobacco Products. The Budget includes $450 million from user fees to reduce tobacco use in minors by regulating marketing and distribution of tobacco products, promote public health understanding of harmful constituents of tobacco products, and reduce the toll of tobacco-related disease, disability, and mortality. In addition, $504 million in funding for CDC, the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) will further help reduce smoking among teens and adults and will support research on preventing tobacco use, understanding the basic science of the consequences of tobacco use, and improving treatments for tobacco-related illnesses.

The Budget includes over $3 billion, an increase of $70 million, for CDC and HRSA to enhance HIV/AIDS prevention, care, and treatment. This increase includes $31 million for CDC to integrate surveillance and monitoring systems, address high-risk populations, and support HIV/AIDS coordination and service integration with other infectious diseases. It also includes $40 million for HRSA's Ryan White program to expand access to care for underserved populations, provide life-saving drugs, and improve the quality of life for people living with HIV/AIDS.

Reducing the burden of chronic disease, collecting and using health data to inform decision-making and research, and building an interdisciplinary public health workforce are critical components to successful prevention efforts. The Budget includes $20 million for a CDC initiative to reduce the rates of morbidity and disability due to chronic disease in up to ten of the largest U.S. cities. These cities will be able to incorporate the lessons learned from implementing evidence-based prevention and wellness strategies of the Recovery Act's Communities Putting Prevention to Work Initiative.

The Budget also includes $10 million at CDC for a new Health Prevention Corps, which will recruit, train, and assign a cadre of public health professionals in State and local health departments. This program will target disciplines with known shortages, such as epidemiology, environmental health, and laboratory science.

To improve CDC's ability to collect data on the health of the Nation for use by policy-makers and Federal, State, and local leaders, the Budget provides $162 million for Health Statistics, an increase of $23 million above FY 2010. This increase will ensure data availability on key national health indicators by supporting electronic birth and death records in States and enhancing national surveys.

There is $222 million, an increase of $16 million, included in the Budget to address Autism Spectrum Disorders (ASD). NIH research will pursue comprehensive and innovative approaches to defining the genetic and environmental factors that contribute to ASD, investigate epigenetic changes in the brain, and accelerate clinical trials of novel pharmacological and behavioral interventions. CDC will expand autism monitoring and surveillance and support an autism awareness campaign. HRSA will increase resources to support children and families affected by ASD through screening programs and evidence-based interventions.

To support teen and unintended pregnancy prevention activities in the Office of Public Health and Science and CDC, the Budget provides $205 million in funds.

To invest in innovative approaches to prevent and treat substance abuse through evidence-based community prevention programs, a warning system to detect emerging drug threats, and the expansion of drug courts capacity, the Budget includes $93 million within SAMHSA.

The Budget includes $352 million, an increase of $16 million, for CDC Global Health Programs to build global public health capacity by strengthening the global public health workforce; integrating maternal, newborn, and child health programs; and improving global access to clean water, sanitation, and hygiene. Additionally, the Budget includes $6.4 million in the Office of Global Health Affairs to support global health policy leadership and coordination.

Finally, for FDA's medical product safety initiative to increase inspections and invest in tools that will enhance the safety of increasingly complex drugs, medical devices, and biological products, the Budget provides $1.4 billion, an increase of $101 million above the FY 2010 funding level.

***Protecting Americans from Public Health Threats and Terrorism***

Continued investments in countermeasure development and pandemic preparedness will help ensure HHS's preparedness to protect the American people in natural or man-made public health emergencies.

The Budget includes $476 million, an increase of $136 million, for the Biomedical Advanced Research and Development Authority to sustain the support of next generation countermeasure development in high priority areas by allowing the BioShield Special Reserve Fund to support both procurement activities and advanced research and development.

Reassortment of avian, swine, and human influenza viruses has led to the emergence of a new strain of H1N1 influenza A virus, 2009 H1N1 flu, that is transmissible among humans. On June 24, 2009, Congress appropriated $7.65 billion to HHS for pandemic influenza preparedness and response to 2009 H1N1 flu. HHS has used these resources to support H1N1 preparedness and response in States and hospitals, to invest in the H1N1 vaccine production, and to conduct domestic and international response activities. The Budget includes $302 million for ongoing pandemic influenza preparedness activities at CDC, NIH, FDA, and the Office of the Secretary for international activities, virus detection, communications, and research. In addition, the use of balances from the June 2009 funds, including approximately $330 million in FY 2011, will enable HHS to continue advanced development of cell-based and recombinant vaccines, antivirals, respirators, and other activities that will help ensure the Nation's preparedness for future pandemics.

***Improving the Wellbeing of Children, Seniors, and Households***

In addition to supporting efforts to increase our security in case of an emergency, the HHS Budget also seeks to increase economic security for families and open up doors of opportunity to those Americans who need it most.

The Budget provides critical support of the President's Zero to Five Plan to enhance quality early care and education for our Nation's children. The Budget lays the groundwork for a reauthorization of the Child Care and Development Block Grant and entitlement funding for child care, including a total of $6.6 billion for the Child Care and

Development Fund (discretionary and entitlement child care assistance), an increase of $1.6 billion. These resources will enable 1.6 million children to receive child care assistance in FY 2011, approximately 235,000 more than could be served in the absence of these additional funds.

The Administration's principles for reform of the Child Care and Development Fund include establishing a high standard of quality across child care settings, expanding professional development opportunities for the child care workforce, and promoting coordination across the spectrum of early childhood education programs. The Administration looks forward to working with Congress to begin crafting a reauthorization proposal that will make needed reforms to ensure that children receive high quality care that meets the diverse needs of families and fosters healthy child development.

To enable families to better care for their aging relatives and support seniors trying to remain independent in their communities, the Budget provides $102.5 million for a new Caregiver Initiative at the Administration on Aging. This funding includes $50 million for caregiver services, such as counseling, training, and respite care for the families of elderly individuals; $50 million for supportive services, such as transportation, homemaker assistance, adult day care, and personal care assistance for elderly individuals and their families; and $2.5 million for respite care for family members of people of all ages with special needs. This funding will support 755,000 caregivers with 12 million hours of respite care and more than 186,000 caregivers with counseling, peer support groups, and training.

The Head Start program, run by the Administration for Children and Families (ACF), will serve an estimated 971,000 children, an increase of approximately 66,500 children over FY 2008. Early Head Start will serve approximately 116,000 infants and toddlers, nearly twice as many as were served in FY 2008. The Budget includes an additional $989 million for Head Start to sustain and build on these historic increases enabled by Recovery Act investments. The increase includes $118 million in funds to improve program quality, and the Administration plans to implement key provisions of the 2007 Head Start Act reauthorization related to grantee recompetition, program performance standards, and technical assistance that will improve the quality of services provided to Head Start children and families.

To continue to fulfill the President's commitment to improving the development, safety, well-being, and permanency of children and youth in foster care, adoption assistance, and guardianship assistance, the Budget includes a proposal to extend by an additional six months, through June 2011, the temporary FMAP increase for foster care and adoption assistance provided by the Recovery Act. This extension will result in an additional $237 million to States for maintaining critical services to vulnerable children and youth.

The Budget includes an extension of the Temporary Assistance for Needy Families (TANF) block grant and related programs, including the Contingency Fund and

Supplemental Grants, through FY 2011. The Budget also incorporates the Healthy Marriage and Responsible Fatherhood grant funding into a new $500 million Fatherhood, Marriage, and Families Innovation Fund. The fund will provide competitive grants to States to conduct and rigorously evaluate comprehensive responsible fatherhood programs and new demonstrations geared towards improving child outcomes by improving outcomes for custodial parents with serious barriers to self-sufficiency. Because the TANF Emergency Fund helps States to create subsidized jobs for unemployed low-income individuals, the Budget also includes an additional $2.5 billion for the TANF Emergency Fund and makes several changes to facilitate State efforts to create jobs and provide work supports for needy families.

The Budget includes a one-year, $669 million extension of the Federal match to States' reinvestment of incentive payments into Child Support Enforcement programs. Without this critical extension of resources, it is estimated that States would reduce program expenditures by 10 percent. The Budget also includes two proposals focused on increasing child support collections and a proposal to expand resources for non-custodial parents' access to and visitation with their children.

The Budget proposes a new way to fund the Low Income Home Energy Assistance Program (LIHEAP) to help low-income households heat and cool their homes. Our request provides $3.3 billion in discretionary funding. The proposed new trigger would provide under our current estimates $2 billion in mandatory funding. Energy prices are volatile, making it difficult to match funding to the needs of low-income families, so under this proposal, mandatory funds will be automatically released in response to quarterly spikes in energy prices or annual changes in the number of people living in poverty. The $2 billion estimate is based on current projections of Supplemental Nutrition Assistance Program usage and energy prices.

***Investing in Scientific Research and Development***

The investments that HHS is proposing in our human services budget will expand economic opportunity but another critical way to grow and transform our economy is through a healthy investment in research that will not only save lives but also create jobs.

The Budget includes a program level of $32.2 billion for NIH, an increase of $1 billion, to support innovative projects from basic to clinical research. This effort will be guided by NIH's five areas of exceptional research opportunities: supporting genomics and other high-throughput technologies; translating basic science into new and better treatments; reinvigorating the biomedical research community; using science to enable health care reform; and focusing on global health. The Administration interest for the high-priority areas of cancer and autism fits well into these five NIH theme areas. In FY 2011, NIH estimates it will support a total of 37,001 research project grants, including 9,052 new and competing awards.

The additional $1 billion will enable NIH to capitalize upon recent successful investments in biomedical research, such as the Human Genome Project, that have provided a powerful foundation for a deeper level of understanding human biology and

have opened another window into the causes of disease. New partnerships between academia and industry are working to revitalize the drug development pipeline. An era of personalized medicine is emerging where prevention, diagnosis, and treatment of disease can be tailored to an individual rather than using the one-size-fits-all approach that all too often falls short, wasting health care resources and potentially subjecting patients to unnecessary and dangerous medical treatments and diagnostic procedures.

To advance regulatory science at FDA, the Budget provides $25 million. This initiative builds on the President's commitment to harness the power of science for America's benefit and includes $15 million for nanotechnology related research, which holds great promise for advances in medical products and cosmetics. The additional resources will also enable FDA to update review standards and provide regulatory pathways for new technologies, such as biosimilars.

***Recovery Act***

Since the Recovery Act was passed in February 2009, HHS has made great strides in improving access to health and social services, stimulating job creation, and investing in the future of health care reform through advances in health IT, prevention, and scientific research. HHS Recovery Act funds have had an immediate impact on the lives of individuals and communities across the country affected by the economic crisis and the loss of jobs.

As of September 30, 2009, the $31.5 billion in Federal Payments to States helped maintain State Medicaid services to a growing number of beneficiaries and provided fiscal relief to States. The National Institutes of Health awarded $5 billion for biomedical research in over 12,000 grants. Area agencies on aging provided more than 350,000 seniors with over 6 million meals delivered at home and in community settings. Health Centers provided primary health care services to over one million new patients.

These programs and activities will continue in FY 2010, as more come on line. For example, 64,000 additional children and their families will participate in a Head Start or Early Head Start experience. Approximately 30,000 American Indian and Alaska Natives' homes will have safe drinking water and adequate waste disposal facilities. HHS will be assisting States and communities to develop capacity, technical assistance and a trained workforce to support the rapid adoption of health IT by hospitals and clinicians. The CDC will support community efforts to reduce the incidence of obesity and tobacco use. New research grants will be awarded to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers about what interventions are most effective for patients under specific circumstances.

The Recovery Act provides HHS programs an estimated $141 billion for Fiscal Years 2009 – 2019. While most provisions in HHS programs involve rapid investments, the Recovery Act also includes longer term investments in health IT (primarily through Medicare and Medicaid). As a result, HHS plans to have outlays totaling $87 billion through FY 2010.

***Conclusion***

This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans. Under this budget, we will provide greater security for working families as we continue to recover from the worst recession in 70 years.
We will invest in research on breakthrough solutions for healthcare that will save money, improve the quality of care, and energize our economy. And we will push forward our goal of making government more open and accountable.

My department cannot accomplish any of these goals alone. It will require all of us to work together. And 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 answering your questions.

**United States Senate Committee on Finance**
**Public Hearing**
**"The President's Fiscal Year 2011 Health Care Proposals"**
**February 3, 2010**

**Question Submitted for the Record**

**Senator Baucus**

**Question for the Witness:**

**Health Care Reform and Deficit Reduction**

**The growth in health costs threatens the fiscal stability of businesses, families and federal and state governments. An increasing share of everyone's budget seems to be going toward health care due to runaway costs. Comprehensive health reform would address the cost problems that plague our health care system. According to CBO, the Senate health reform bill would reduce the budget deficit by more than $132 billion over the next ten years – and would reduce the deficit by $650 billion to $1.3 trillion in the following decade. And those figures include the cost of making sure that nearly every American has health coverage.**

1. **Secretary Sebelius, knowing you share a concern about the financial burden health care costs place on American families, businesses and government budgets, are there administrative actions you could take to reduce health costs in ways that would reduce the Federal deficit – in the absence of comprehensive health reform?**

   The Department has as part of its mission the goal of improving the affordability of health care. In the last year, we have taken significant steps to reduce the cost of Medicare and Medicaid by squeezing out excessive costs, fraud, and abuse with new provider enrollment standards and Strike Force enforcement activities. We've increased transparency and accountability with our Nursing Home rating system. We also have aggressively implemented the investments in the Recovery Act to advance health information technology and prevention. We continue to strive to be the best stewards of the health insurance programs as well as the taxpayer dollars that support them. I anticipate we will continue to use existing authority to reduce costs. But at the end of the day, we need legislation to get at the cost drivers in the U.S. health system. This is why the President made health insurance reform a top legislative priority.

2. **Or, is comprehensive reform the only real way to reduce the effect that health costs are projected to have on the Federal deficit?**

   Comprehensive health reform is the only true way to rein in spiraling health care costs. And the passage of health insurance reform legislation will help us to turn our health care system from one that rewards quantity to one that rewards quality; from one that has too many people falling through the cracks – generating high and avoidable emergency room and hospital bills, losing a hundred billion dollars in lost workplace productivity and leading to tens of thousands of avoidable deaths – to one that prevents illness and

manages disease more efficiently. This only happens when you align expanded health care coverage, improved insurance consumer protections, innovations to the delivery system, health care workforce initiatives, and prevention and wellness initiatives together.

Insurance Market Reforms

**The Senate health reform bill included several 'early deliverables.' Several of these were insurance market changes that would not increase premiums – like prohibiting rescissions, requiring minimum loss ratios, and prohibiting lifetime limits. We also proposed funds for a new high risk pool to provide premium subsidies for uninsured with pre-existing conditions. All of these policies were intended to help people immediately.**

3. **Secretary Sebelius, what impact would these early deliverables have on individuals and families struggling to keep up with rising health care costs?**

   The early deliverables will provide individuals and families with some protection from rising health care costs, by eliminating lifetime caps on benefits, providing affordable insurance options for those who cannot get insurance because of a pre-existing condition, and strengthening employer-based early retiree health insurance. However, comprehensive reform – including changing the insurance marketplace to end insurance discrimination and provide easy one-stop comparison shopping, reforming the delivery system to reward high-quality, efficient care, and providing premium assistance to make health insurance affordable – is needed if we want to truly protect Americans from rising health care costs and fix our broken health care system.

**Of course, many of the most important and meaningful insurance market reforms, like guarantee issue and rating reform can't be done immediately – otherwise premiums would spike upward for the entire system.**

4. **Would you agree that these reforms would need to be accompanied by a requirement for individuals to have health coverage?**

   Individuals, like employers, health insurers, and the government, must be part of the solution to our health system problems. All Americans should have affordable health insurance coverage. This spreads the risk of the high cost of illness across a wide population, making aggressive health insurance reforms possible. For example, insurance companies could be prohibited from pre-existing condition exclusions if healthy people are also in the system, not waiting until they get sick to purchase insurance. It prevents the "hidden tax" of cost shifting that results as the costs of uncompensated health care are passed on to the insured in the form of higher premiums. And it helps improve the productivity of our workers and prevent debilitating and costly diseases.

5. **And a requirement to have coverage would necessarily require subsidies to offset the cost of premiums for those who can't afford them. Wouldn't you agree?**

   Premium assistance is a vital part of making health insurance affordable to individuals

and families and ensuring that healthy people seek coverage, bringing down the cost of insurance generally. It is an essential element of fixing our broken health insurance system.

6. **Secretary Sebelius, do you see any other approach to achieving a fair and equitable health insurance system that what we have proposed? Are there other insurance market reforms we might be able to consider that would not raise premiums if not coupled with a requirement on individuals to have coverage?**

   The passage of health insurance reform will help us achieve a fair and equitable health insurance system by providing stability and security to those who have insurance, providing affordable options to those who do not currently have insurance, and reining in rising health care costs. The President and I have been and will continue to be open to all ideas about how best to achieve these ends.

**CHIP Implementation**

**CHIP is one of the greatest success stories of the past decade, and tomorrow marks the one-year anniversary of President Obama signing the CHIP Reauthorization Act of 2009. Members of this Committee worked hard to get CHIP done, and I am very proud of all that we've been able to do for kids.**

**Congress included funding in the CHIP legislation to encourage states to simplify enrollment practice and enhance outreach activities to ensure that more eligible children enroll in both Medicaid and CHIP.**

7. **Madame Secretary, what is the status of the implementation efforts of the outreach funding?**

   As you know, the Children's Health Insurance Program Reauthorization Act (CHIPRA) provided $100 million in Federal funding from FY 2009 to FY 2013 to support outreach and enrollment efforts targeting children who are eligible for Medicaid and CHIP, but are not enrolled. These funds are being used to support new and innovative outreach and enrollment strategies.

   On September 30, 2009, we awarded $40 million to 69 grantees in 42 States. Grantees include State Medicaid and CHIP agencies, community-based organizations and States partnered with the community-based organizations, and health centers, planning to develop and promote new enrollment strategies. These grant activities are underway across the country and we are looking forward to sharing lessons learned. Our approach to these grants has been very results oriented. As part of the grant awards, grantees are required to track, measure, and report the enrollment that results from their respective outreach efforts. This information will be reported to CMS on a regular basis. In April, we expect to announce another $10 million in grants to Indian Tribes and health care providers that work with Native American communities to find and enroll children in Medicaid and CHIP. An additional $40 million for outreach grants is anticipated to be awarded in September 2011.

The remaining $10 million is funding a national enrollment campaign that I helped launch at the National Children's Health Insurance Summit in Chicago in November 2009. The summit was attended by more than 500 representatives from the States, and members of the advocacy, policy and research communities who came together for two days of peer-to-peer learning and sharing of best practices. We have also updated and improved the "Insure Kids Now" website at www.insurekidsnow.gov to make it a more user-friendly focal point for families to obtain information about Medicaid and CHIP, as well a resource for States and other stakeholders to remain up-to-date on Federal and State activities. Finally, we are developing partnerships with stakeholders across the country and will be offering webinars and other activities to develop successful strategies to find and enroll eligible children.

8. **How have states changed or improved their programs since the new enrollment simplification incentives have been in place?**

We are working closely with States as they consider adopting the new options provided by CHIPRA to improve access to coverage, and States indeed made significant progress in 2009. More than half of the States have adopted children's coverage improvements since CHIPRA was enacted. These improvements include new efforts to simplify Medicaid and CHIP enrollment and renewal processes as well as expansions in coverage. At least 17 States formally submitted plans to simplify their application or renewal processes to promote enrollment and/or retention of eligible children who would otherwise be uninsured. This recent activity focuses on ways to cut through unnecessary paperwork by increasing reliance on technology to enroll and reenroll children. Three States have approved plans to enroll children through the new "Express Lane Eligibility" (ELE) option created by CHIPRA. ELE allows States to rely on findings from other programs or sources to determine or renew Medicaid and CHIP eligibility, rather than requiring families to resubmit information that the government already has on hand.

In addition to adopting new simplification measures, 15 States increased income eligibility for children in 2009. Today, all but two States provide coverage to children with incomes up to 200 percent of the FPL ($36,620 for a family of three in 2009); families at these income levels contribute to the cost of coverage (through premiums, cost-sharing or both) on a sliding scale basis.

9. **How many kids have been enrolled?**

States enrolled an additional 2.6 million children in Medicaid and CHIP between October 1, 2008 and September 30, 2009, boosting participation rates particularly among the lowest income children. Medicaid and CHIP served nearly 40 million children over the course of the year. The enactment of CHIPRA in combination with the Recovery Act played a significant role in enabling States to sustain and strengthen these critical coverage programs for children despite the economic crisis.

**Health IT Implementation**

**Last year's economic recovery act included a historic commitment to modernizing the health system through health information technology. The legislation called on HHS to set federal standards for interoperability and to eventually provide financial incentives to doctors and hospitals that adopt and "meaningfully use" qualified health IT systems.**

**Secretary Sebelius, this is a major undertaking for your department, and I applaud you for meeting the recent deadlines set forth in the recovery act.**

**10. The health IT implementation efforts are a "warm up" for comprehensive health reform, should it be enacted. After a year of health IT implementation, how is it going? What lessons has HHS learned that can be applied to health reform implementation?**

Health IT implementation lays a foundation for health reform, with the aim of improving quality, efficiency and safety in the health system while protecting patient privacy and reducing health costs. In the course of developing HIT rules this year, we have considered input from hundreds of technical experts, health care providers, and other key stakeholders. And, we are already administering grants that will help facilitate the implementation of a nationwide HIT infrastructure. We will continue to take and apply lessons learned from our experiences with health IT implementation to other reform initiatives. We look forward to continued partnership and broad engagement with all stakeholders, including providers, States, and the public to achieve a high-quality, affordable healthcare system.

**The Medicare and Medicaid incentives are the driving force of the health IT modernization effort. And the most important element of these incentives is the definition of "meaningful use" – that is, how will CMS determine whether a provider is meaningfully using health IT and therefore eligible for financial incentives.**

**11. How has CMS proposed to define "meaningful use"? How is CMS ensuring that providers are actually using their systems to improve quality and efficiency – but not setting the bar so high that few providers will actually qualify for bonuses?**

The Administration believes that widespread adoption of electronic health records (EHR) holds great promise for improving health care quality, efficiency, and patient safety. With the passage of the American Recovery and Reinvestment Act (Recovery Act), we now have the tools to begin a major transformation in American health care made possible through the creation of a secure, interoperable nationwide health information network, supported by an electronic health record infrastructure. The Administration realizes that simply digitizing paper records will not translate into improved quality and efficiency of the care being delivered. Connecting hardware with software is not sufficient without meaningful use of HIT. In establishing EHR incentive payments for eligible Medicare and Medicaid providers, the Recovery Act was explicit that providers must demonstrate "meaningful use" of such technology as a condition of receiving payment. On December 30, 2009, CMS published a Notice of Proposed Rule Making, with the goal of defining meaningful use consistent with applicable provisions of Medicare and Medicaid law while continually advancing the contributions certified EHR technology can make to improving health care quality, efficiency, and patient safety.

Cautious and cognizant that setting the bar for meeting "meaningful use" criteria too high would be an overall impediment to program participation, CMS partnered closely with the Office of the National Coordinator of Health Information Technology (ONC) and

collaborated with other Federal government agencies to ensure an adequate starting point for implementing the program. Along with an extensive public outreach campaign that involved subject matter experts, States, and other stakeholders, CMS was able to develop an initial set of reasonable criteria for providers to demonstrate meaningful use based on currently available technological capabilities and providers' practice experience. CMS' proposed rule would progressively phase in more robust criteria for demonstrating meaningful use over the course of three stages. CMS solicited public comment through a 60-day comment period on the proposed rule that ended on March 15th. We will give serious consideration to comments that improve our proposal while achieving the goals Congress established for the EHR incentive programs.

**Emphasizing the need for Improvements to the TANF program**

**Secretary Sebelius, the President's budget contains a new innovation fund for the TANF program. During the recession, TANF has been responsive in some states, but not in others.**

**12. What do you hope to learn from these innovations that could, in the future, help create a TANF program that is responsive in all states and helps states continue to focus on employment, even in periods of high unemployment?**

The Administration expects the Fatherhood, Marriage, and Families Innovation Fund to serve as a catalyst for innovative service models that integrate a variety of service streams to improve outcomes for children and families. The results from these demonstrations could form the basis for possible future TANF and Child Support Enforcement program changes at the Federal or State level.

The Fund will support state-initiated comprehensive fatherhood programs, including those with marriage components. The core elements of such programs typically include: co-parenting services and conflict resolution; connection to job training and other employment services; child support enforcement case management; financial incentives; earning supplements; employment preparation services; training subsidies; legal services; substance abuse and mental health treatment; linkages to domestic violence prevention programs; and linkages to public agencies and community-based providers offering housing assistance. We believe that ensuring both parents are involved in supporting their children emotionally and financially is part of an overall strategy to reduce poverty and improve outcomes for children.

The Families Innovation portion of the fund will support state efforts to implement and rigorously evaluate promising approaches that focus on improving child and family outcomes. Areas of interest include: (1) identifying families that have barriers to employment, including strategies that use mechanisms of ongoing assessment or focus on families at risk for involvement in the child welfare system; (2) implementing strategies to help families address these barriers and also prepare for employment; (3) promoting child well-being in highly disadvantaged families, including child-only cases; and (4) supporting those with barriers who find jobs so they can sustain employment.

**Highlighting the Impact of TANF Emergency Contingency Fund**

**The President's budget proposes to extend and improve the TANF Emergency Contingency Fund created by last year's economic recovery act. I'm particularly interested in the growing number of states using these funds to create subsidized jobs.**

**13. Can you give us examples of Emergency Contingency Fund programs and how they have contributed to the economic recovery?**

Funds for basic assistance and emergency needs have helped many struggling families make ends meet and, at the same time, have provided important economic stimulus as low-income families use the assistance to purchase food, school supplies, shoes, and other necessities in local stores throughout the country. These funds have played an important role in helping States maintain their level of benefits and services to vulnerable families despite the significant fiscal pressures States are facing.

Over the last year, we have also seen a growing number of States use these funds to develop innovative subsidized employment programs that are giving thousands of out of work parents what they most want and need – a job. The funds used for subsidized employment have enabled employers to hire individuals who otherwise would have remained unemployed. Indeed, some business owners have said that they would not have been able to remain in operation without these funds.

Some examples of programs are:

- Mississippi's The Steps Program focuses on private-sector jobs. Employers are reimbursed for each new worker's full salary for the first two months of work and then reimbursement is scaled back over the next four months. To increase small-business participation, Mississippi gives priority to employers with 25 employees or fewer.
- Los Angeles County, in collaboration with 7 Workforce Investment Boards and 35 WIA one- stop centers, has created 4,100 subsidized jobs as of December 2009, and is working on achieving its goal of placing up to 10,000 workers in subsidized jobs. They have created full-time jobs paying $10/hour in the public, private, and non-profit sectors for parents receiving TANF assistance, non-custodial parents, parents in the child welfare system, parents living in homeless and domestic violence shelters, and parents who are dislocated workers. In addition, in partnership with WIA Rapid Response teams, they are moving to avert mass layoffs and plant closures by subsidizing jobs of low-income parents that are slated for elimination.
- As of February 2010, Tennessee created 750 subsidized jobs for its residents to address the needs arising from the sharp increase in joblessness. The jobs are in the private sector and State agencies, for example, where individuals are working as highway maintenance workers and unemployment insurance interviewers.
- The Alabama Department of Human Resources implemented a transitional employment program across thirteen different counties, creating 112 subsidized jobs as of December 2009. The average wage for participants is $8.24/hour. The employers include: the Alabama Symphony Orchestra, the Humane Society, the

American Red Cross, grocery stores, hair salons, a law firm, day care centers, rehabilitation centers and janitorial services.

- Minnesota has contracted directly with State agencies to provide subsidized employment for individuals in its TANF program. For the quarter ending September 2009, 1,086 participants had subsidized wages recorded and were working as laborers, office helpers, nursing home assistants, in construction and in libraries.
- As of December 2009, Utah has created 120 subsidized jobs through two different programs. One program provides subsidized jobs to those with mental health issues. Jobs include transportation coordination, janitorial, secretarial, lawn care, and food prep. The other serves refugee families creating jobs at the Latter-day Saint Humanitarian Center in Salt Lake City.
- New York State permits each social services district to operate subsidized employment programs to help secure employment for public assistance recipients and other eligible low-income families. New York has funding available to districts for a Transitional Jobs program, and subsidized employment programs for health care sector jobs and green jobs. The New York Office of Temporary and Disability Assistance also directly contracts for subsidized employment services through the Wage Subsidy/Transitional Employment contracts. By January 2010, New York had placed 1,200 individuals in subsidized positions.

**14. How would the President's proposals affect the ability of states to expand subsidized jobs programs?**

The President's proposal will allow States to continue their subsidized employment programs after September 30, 2010, when the current funding under ARRA expires, expand existing programs, and create programs in instances where States would like to do so but are concerned about the lack of funding after September 30 under the current ARRA structure. They also will be reimbursed for these expenses at a higher rate (100%) than under current law (80%). Many States are beginning subsidized employment programs now, and without funding available in FY 2011 they would not be able to continue these programs beyond the end of this fiscal year. Allowing them to operate these programs past September 30 will result in more low-income families being placed in subsidized employment and support local job creation efforts.

**15. The fund expires in September -- what will happen if funding for this program is not extended?**

If the Fund is not extended, States will not be able to qualify for additional Emergency Funds through increased expenditures in one of the three Emergency Fund categories after September 30, 2010. For those States that have begun subsidized employment programs, experienced caseload increases, or provided short-term benefits, they will no longer receive Federal reimbursement for these increased expenditures, so will need to either cut back their efforts or seek to find another source of funding at a time when many States face significant budget shortfalls.

**Expired Medicare Provisions**

**A number of important Medicare provisions expired on December 31. Congress has consistently extended the majority of these laws. Most were included in the health reform proposals that passed the Senate or House. Without action, beneficiaries' access to quality care could be in jeopardy.**

**Of most concern to me are the Medicare therapy caps. Since 2006, Congress has authorized CMS to allow medically-necessary exceptions to the therapy caps.**

**16. How is CMS handling the implementation of the provisions that expired on January 1? How is CMS ensuring that beneficiary access to necessary services is not impaired?**

As you know, Congress enacted the Temporary Extension Act of 2010, extending the exception process for therapy claims that reach the annual cap through March 31$^{s}$. In addition, the health insurance reform legislation passed by Congress further extends the exceptions process for outpatient therapy caps. Under this new legislation, outpatient therapy service providers may continue to submit claims with the appropriate modifier indicating an exception is appropriate, for services furnished on or after January 1, 2010, through December 31, 2010.

CMS has been committed to maintaining open lines of communication with the provider and beneficiary communities on the expiration of the therapy caps exceptions process, and other expiring provisions, and CMS will be working with them to ensure accurate and timely payments now that these provisions have been extended by Congress. As appropriate, we have been reminding beneficiaries that there may be alternatives for accessing needed Medicare reimbursable services such as therapy services; when therapy services are furnished in a hospital outpatient setting, they are not subject to the therapy caps.

**17. With respect to therapy caps, is CMS finding that beneficiaries are already hitting the therapy cap? If so, how is CMS ensuring that access is not impaired?**

As we note above, Congress recently extended the exception process for therapy claims that reach the annual cap. Now that such legislation has been enacted, providers can submit claims requesting an exception to the cap for medically necessary services provided from January 1 through December 31$^{st}$.

As you know, Congress has repeatedly intervened to allow the exceptions process to continue and CMS does not want to begin denying claims which would be eligible for an exception to the therapy caps if Congressional action is forthcoming shortly. Accordingly, when legislation to extend the exceptions process is anticipated but not yet enacted, CMS directs contractors to temporarily hold affected therapy claims rather than deny them. Due to the nature of the therapy cap exception process and CMS's ability to easily identify these exceptions at the front-end of our claims processing system, CMS is able to hold therapy claims, which facilitates a smooth and timely implementation once there is a legislative extension. (The other alternative under the law would be to deny claims and then adjust them if future legislation retroactively incorporates the exceptions.) But, in both instances, delaying or denying the claims may eventually have

an adverse effect on beneficiary access to care. Finally, providers also have the option of holding their claims until the extent and timing of Congressional intervention becomes more clear.

**Extending the Medicare Trust Fund**

**Secretary Sebelius, as we all know, the Medicare Trust Fund is in trouble. The Medicare Trustees have indicated that it will be insolvent by 2017. And CBO projects that insolvency will come a year earlier – in 2016. The Trustees have recommended that we implement immediate reforms to shore up the Trust Fund.**

**18. What steps can Congress take to make Medicare more sustainable?**

**19. Can such steps be taken without shifting costs to seniors or harming seniors' access to care?**

**Answer to Baucus 18 & 19:** The President and I understand that in order to protect Medicare for current and future beneficiaries, we must act to assure its sustainability. Many provisions in the health insurance reform legislation passed by Congress go a long way toward aligning Medicare payment incentives and extending the life of Medicare, including health service delivery reforms, value-based purchasing initiatives, Center for Innovation, and the Independent Payment Advisory Board. Legislation passed by Congress is estimated to extend the solvency of Medicare for almost ten years.

**Senator Wyden**

**Question for the Witness:**

**In the Health and Human Services "Budget in Brief," a legislative proposal is described that "improves Medicaid integrity and beneficiary quality of care by requiring States to track and monitor prescription drug billing, prescribing, and utilization patterns that could be indicative of abuse or over-utilization."**

1. **What does the Secretary envision would be put into place under this proposed legislation in order to protect beneficiaries' privacy? How can the Secretary be sure that we are tracking beneficiaries that are truly overutilization drugs, instead of those who are justifiably high volume users?**

   The Administration is committed to eliminating fraud, waste and abuse in Federal health care programs. This budget proposal would complement and strengthen current State drug utilization review activities and encourage more effective monitoring of potential fraud and misuse in the Medicaid program. It is intended to help States obtain a better picture of program vulnerabilities in this area, measuring States' performance and results and improving the capability to address controlled substance misuse. However, Medicaid beneficiaries would continue to have access to necessary and appropriate pharmaceuticals under this policy.

   Protecting beneficiary privacy is already a key consideration of existing drug utilization review activities and we would continue to emphasize the importance of protecting beneficiary privacy as we enhance oversight. The Administration assures you that we are pursuing Medicaid program integrity efforts with commitment, but not to the detriment of access to needed services for eligible beneficiaries nor at the expense of current provisions to safeguard beneficiary privacy. Furthermore, CMS, in implementing this proposal, would provide the States with the proper guidance to ensure this proposal is implemented as intended.

**Senator Stabenow**

**Question for the Witness:**

**Madame Secretary, I appreciate your comments on the sustainable growth rate, improving mental health services, and graduate medical education.**

**I agree with the President that we must address the significant fiscal problems that face our nation. Nobody understands these problems better than our families in Michigan. And there is no doubt that we should and can reduce health care spending, both to help put our country on a more stable track, and to make care more affordable for families. This is why we need comprehensive health care reform, and why I hope we can enact legislation without delay.**

**We have learned a lot over the last year as we worked to pass health reform in the Senate. One of the good lessons learned is that there are things we can do to reform the way we deliver care in the Medicare program that will not only reduce costs and make the program sustainable over the long term, but will also help seniors get better care.**

**For example, we know we need to support better communication and coordination among health care providers, and between doctors and patients and families. We all know people who have experienced harmful drug interactions or who have gotten conflicting diagnoses. We all know people who have been subjected to duplicate tests and procedures. Better communication and coordination, with a focus on the patient, will go a long way to preventing these problems. The health care reform legislation passed by the Senate includes many new, innovative models of care that will help doctors communicate and patients receive better, more coordinated care.**

1. **Secretary Sebelius, do you agree that we need to change the way Medicare pays for care to encourage cooperation and integration? And that doing so can both lower costs, and improve the care our seniors receive?**

   Yes, this Administration is committed to advancing an agenda that will change the way Medicare pays for care to support better communication and coordination as well as promote innovative health care delivery models. These initiatives are vital to our efforts to improve the quality of care furnished to our beneficiaries and also to lower costs. A variety of demonstrations and pilot projects that are ongoing as well as many authorized in the health care reform bills will provide critical information on delivery system reforms that work, which can subsequently be adopted on a widespread basis to achieve these goals.

   There are a number of programs and demonstrations aimed at paying for quality services in the Medicare program. For example, hospitals and home health agencies are subject to pay-for reporting requirements under which these providers receive reduced payment updates if they do not report quality measures. Physicians are currently able to participate in voluntary pay-for-reporting initiatives, but in future years penalties will apply if physicians do not meet reporting requirements. CMS is also conducting a number of demonstrations to test value-based purchasing—meaning paying for

performance on quality measures rather than just reporting those measures—in the skilled nursing facility and home health settings. Further, we are implementing elements of a value-based purchasing agenda by integrating quality measures into Medicare payment systems such as that for dialysis facilities, and building on quality measures reported by physicians and hospitals.. CMS also continues to explore the development of quality measures for other provider types.

But much more needs to be done to improve the quality of care patients receive. Through health insurance reform legislation, we will have a more coordinated focus on quality, we will obtain better outcomes data to identify gaps in care and monitor progress, and we will have an additional focus on provider reporting and payment based on performance,.

I look forward to working with you as we transform our nation's healthcare system through these initiatives.

**Many hospitals in my state have been disadvantage by the way in which Medicare's hospital payment systems reimburse hospitals for their costs of labor. The wage index simply does not work for many of Michigan's hospitals. Congress included a temporary process in the Medicare Modernization Act to help hospitals that could not use the traditional Medicare appeals process to reclassify to a new region and obtain more accurate Medicare reimbursement. Called Section 508 because of the provision in the MMA, many Michigan hospitals have benefited from this provision. However, due to flaws in how we calculate average wage index and because of interactions in how 508 was implemented, there still are Michigan hospitals in need of assistance. Additionally, I have raised concerns about how 508 has been implemented.**

2. **Would you be willing to work with my staff on addressing these inequities? Congress did though give CMS a "special exemption" to help hospitals in dire straits that did not meet the 508 eligibility standards. Would you be willing to consider the special exemption process to help these hospitals?**

   I share your commitment to ensuring that Medicare pays appropriately for inpatient hospital services and look forward to working with you to mitigate any inequities that exist in the current hospital payment system. The Medicare statute requires that hospital payments be adjusted to reflect differences in area labor costs as compared to a national average of such costs. This adjustment factor, referred to as the wage index, is based on wage data that comes directly from hospitals themselves. However, in response to a mandate included in the Tax Relief and Health Care Act of 2006, the Medicare Payment Advisory Commission (MedPAC) identified major reforms regarding improvements to the hospital wage index system. Most of these proposals will require statutory changes so I look forward to working with you on such improvements. In addition, CMS regularly seeks public comment through rulemaking on ways to improve the wage index system.

   With regard to the "special exemption" authority you reference, CMS has used the "exceptions and adjustments" authority under section 1886(d)(5)(I) of the Social Security Act in a limited number of cases to address the circumstances of individual hospitals. However, in 2009, CMS publicly stated that, going forward, the Agency would only use

this authority to modify a general rule that affects all hospitals, not individual hospital situations. Such authority should only be exercised in accordance with substantive regulations that outline the clear criteria for when an exception or adjustment will be granted and should require the Agency to go through notice and comment rulemaking to do so.

3. **In some years, when Congress has extended these reclassifications after CMS has established the wage index for a given year, the agency has not recalculated the wage index as necessary, and thereby has deprived most of Michigan's hospitals of the benefit of their Section 508 reclassification. Presuming Congress again extends Section 508 reclassifications for fiscal year 2010, it will be after CMS has already established the wage index for that year. If we again extend these Section 508 reclassifications for fiscal year 2010, will you work with us to ensure that CMS recalculates the wage index as necessary so that all eligible hospitals benefit from Section 508 reclassification?**

   Section 508 of the MMA established a special one-time process to allow hospitals that were unable to qualify under the standard reclassification process to seek reclassification under a unique, one-time appeal process. Reclassifications under Section 508 have been statutorily extended on a number of occasions; most recently they were extended until September 30, 2010 in the health reform legislation passed by Congress.

   As you know, there are a number of complexities and costs associated with a retroactive extension of Section 508 – and these complexities have implications for all hospitals, not just those that benefit from Section 508. Given these complexities and the concerns that many have expressed about the current inequities in the hospital wage index system, we would be happy to work with you on this issue.

**My understanding is that CMS has requested a special rule in the last two extensions of 508 to clarify that it would not need to rerun the wage index. However, there are instances when CMS has rerun the wage index.**

**The criteria established by CMS for a hospital to qualify for wage index reclassification do not work for hospitals that are alone in their area. Specifically, a hospital that is the only hospital in its area cannot prove that its average hourly wage is greater than the average hourly wage of other hospitals in its area, because there are no other hospitals in its area to compare wages with. Even though these hospitals may satisfy all other criteria required to qualify for wage index reclassification, they cannot do so because they mathematically cannot satisfy this one comparison criterion.**

4. **Will you work with us to explore alternative criteria that might be suitable to evaluate whether these hospitals should qualify for reclassification such that they have genuine access to the reclassification opportunity?**

   I understand that CMS has sought public comment via rulemaking regarding this specific issue. Although CMS did not ultimately adopt any specific policy changes, the Agency did indicate that the out-commuting adjustment authorized under section 505 of the Medicare Modernization Act of 2003 (MMA) may help to address the concerns raised by

hospitals in single-hospital areas. More specifically, to the degree that hospitals in this situation experience disadvantages in competing for hospital workers with hospitals located in higher wage index areas, the counties in which these hospitals are located would likely exhibit rates of commuting that might meet the threshold for receiving an adjustment.

In addition, both MedPAC and CMS have been exploring ways to improve the hospital wage index system in response to the mandate included in the Tax Relief and Health Care Act of 2006. I look forward to working with you on moving forward with such improvements.

**I am proud of the President's continued fight against cancer as a budget priority. We know that we can defeat cancer once and for all if we have the right tools and resources available to our medical and research community.**

**An important initiative though would be to re-examine the process that certain cancer-only hospitals used to obtain an exemption from Medicare's prospective payment system. When this payment system was developed, Congress recognized that it would not work for all types of hospitals. Several cancer-only hospitals were exempted, and Congress has exempted additional hospitals over the years.**

5. **Would you be willing to work with our staff to address this inequity and improve cancer care in our communities?**

The President believes that there are scientific opportunities in FY2011 to combat cancer and other diseases. As such, the President's budget supports a range of bold and innovative cancer efforts.

I believe the issue you are addressing is the cancer hospital designation authorized under the Medicare statute (Section 1886 (d)(1)(B)(v) of the Social Security Act). Congress wanted to protect those few cancer hospitals whose primary focus was research and treatment for cancer patients. Consequently, the Congress exempted specific cancer hospitals from payment under the IPPS and has added to the list over time. Congressional action would be required to designate any additional hospitals as cancer hospitals and to exclude such hospitals from the IPPS.

Having said this, I am happy to work with you and your staff to further discuss this particular issue, or any other issue pertaining to cancer care.

**I have been contacted by both the Michigan Workers Compensation Agency (MWCA) and a coalition of legal professionals about a long-standing issue affecting Michigan and other states relating to the Workers' Compensation Medicare Set-Aside Arrangements (WCMSAs) under the Medicare Secondary Payer. I know that I and several of my colleagues off this Committee had contacted the prior Administration previously about this issue, but it was not resolved.**

**What I have heard is that the current process is delaying the settlement of workers' compensation cases, something that is a good policy goal. The Michigan workers'**

**compensation agency director also has noted there is a dispute between his agency's findings and CMS's findings about the number of open cases: the state of Michigan reports there are over 900 "pending" cases awaiting response, but CMS indicated there are less than 900 pending cases in the entire nation. In part, I have heard that there is no federal regulations on CMS's role in the settlement process, only agency guidance that has periodically changed and thus created confusion.**

6. **I am concerned that these delays not only prevent injured workers from getting their relief but also prevent them from getting finality in their cases. Will CMS work with the states, the legal community, employers, unions, and other interested stakeholders in a fair, transparent process such as rule-making that allows for public input and comment? Such a process would help ensure that workers in states such as mine receive their settlements in a timely, fair manner.**

   I understand and appreciate the need for timeliness in reviewing Workers' Compensation Medicare Set-aside Arrangements.

   Since the Medicare program pays secondary for work-related injuries and illnesses, all parties in a workers' compensation case have the responsibility to protect Medicare's interests when resolving workers' compensation cases that include future medical expenses. The recommended method to do so is a Workers' Compensation Medicare Set-aside Arrangement, which allocates a portion of the settlement for future medical expenses. In order to help ensure that Medicare's financial interests are taken into consideration, CMS created a voluntary review process for proposed set-aside amounts. This process is posted on the CMS website. Once the set-aside amount is exhausted, Medicare becomes the primary payer of any further health care services needed to treat the injury or illness.

   We have been working with and will continue to work with stakeholders on refining this process. Our goal is to make timely and fair decisions so that affected workers receive their settlements as soon as possible.

**I am very pleased with the progress that you have made on pushing the adoption of health information technology. I was very happy that many of the elements of the legislation Senator Snowe and I introduced in prior Congresses were included in the economic recovery package. CMS and the Office of the National Coordinator have done great work in putting forward a regulation under strict timetables that moves us forward on meaningful use.**

7. **I am concerned that the proposed regulation will leave out a significant portion of the physician community. I worked very closely with Chairman Baucus to ensure that physicians practicing in clinics affiliated with hospitals would still be eligible for Medicare incentives. Many clinics such as the Billings Clinic in Montana and the University of Michigan and Henry Ford in southeast Michigan have invested heavily in wiring their systems. These early adopters would not be eligible for assistance under the regulation as proposed. We specifically described what we meant by "hospital-based employee," and it was disappointing to me that some of the nation's**

**most respected early adopters will be excluded by the proposed regulation if unchanged.**

**I urge you to look again at the proposal and consider changes that will address my concern. Alternatively, I urge you to work with my staff and the Finance Committee to make whatever statutory changes are needed to make this work.**

The Department strives to follow the full intentions of the Recovery Act. We will continue to work with Congress during the implementation of the EHR incentive programs for eligible professionals and eligible hospitals participating in Medicare and Medicaid. Additionally, we strongly encouraged stakeholders to submit comments on the proposed rule during the public comment period, which ended on March 15, 2010. All comments received during this period will be taken into consideration in the development of the final rule, which we expect to publish later this year.

**Additionally, I want to make sure that we are helping our providers obtain the best and most helpful software packages that will really improve care coordination and patient safety. I note that Senator Grassley has sent inquiry letters to both hospitals and health IT vendors about safety, efficiency, and liability concerns. I think that we can all agree that we want to make sure that meaningful use of health IT is toward ensuring safety, promoting quality, and reducing costs.**

8. **Can you discuss what efforts HHS has made to ensure value for both health professionals and the patients they serve as you implement the HITECH act?**

Ensuring patient safety, promoting quality, and reducing costs are all important priorities that can be achieved through the meaningful use of health IT. In that regard, on Friday, February 12, 2010, HHS and the Department of Labor announced nearly $1 billion in awards in response to the HITECH Act to help health care providers advance the adoption and meaningful use of health IT and to train workers for the health care jobs of the future. The awards will help make health IT available to over 100,000 hospitals and primary care physicians by 2014 and train thousands of people for careers in health care and information technology. Of the approximately $750 million announced by HHS on February 12, 2010, $386 million will go to 40 States and qualified State Designated Entities (SDEs) to facilitate electronic health information exchange (HIE) at the State level, while $375 million will go to an initial 32 non-profit organizations to support the development of regional extension centers (RECs) that will aid health professionals as they work to implement and use health IT. After all awards are made, the approximately 70 RECs will provide outreach and support services to at least 100,000 primary care providers and hospitals within two years. We expect to announce additional REC awards in the near future.

Additionally, on March 15, 2010, HHS awarded $162 million to 16 States and qualified SDEs to establish HIEs. In turn, a total of nearly $548 million has been awarded to every State and qualified SDE to establish HIEs, which are critical to enabling care coordination and improving the quality and efficiency of health care.

We believe that these two major initiatives, the $118 million in Recovery Act funding that ONC is investing in develop the health IT workforce, and the nearly $225 million invested by the Department of Labor in health IT workforce training, will help make it possible for health professionals to be more efficient at what they do and keep their patients safe.

The use of EHRs by providers will increase efficiency and lower administrative costs. It will also help patients and reduce waste by reducing the occurrence of duplicative health services. These services might include imaging tests or laboratory tests that may not be needed. Also, EHRs will help reduce avoidable medical errors, administrative burden and costs on providers, and paperwork.

**I am pleased that the President's budget calls for some key improvements in the Temporary Aid to Needy Family program, or TANF. TANF can be a building block for state job training programs and lift families out of poverty and into work. But TANF needs some adjustments, and I hope that we are able to revisit some of the changes made in the 2006 reconciliation law. I would add that those changes were never considered by this Committee or by the Senate.**

**In Michigan, we're experiencing some of the highest unemployment rates in the county. My state has made great use of the "Emergency TANF Fund" to provide subsidized employment and an important child care credit. Without an extension of the Emergency TANF Fund and additional resources, these jobs will be lost and the state child care credit will be in jeopardy.**

9. **Can you discuss in greater detail the Administration's proposal on the Emergency TANF Fund, and any new guidelines the Administration might propose on its use for things such as subsidized employment?**

   The Administration supports providing an additional $2.5 billion to the TANF Emergency Fund for use through FY 2011. This funding would be used to reimburse States, Tribes and Territories for increased expenditures in several TANF categories. Increased expenditures for subsidized employment would be eligible for 100 percent reimbursement, and employment services would be eligible for 80 percent reimbursement, in addition to the 80 percent reimbursement currently provided for non-recurrent short-term benefits and cash assistance. These changes would make it easier for States to create jobs for parents who need them and help more parents prepare for and find unsubsidized employment.

**As a member of both the Finance and Agriculture Committees, I'd like to applaud the Administration for including a proposal to establish a joint partnership between HHS, USDA, and Treasury to improve food access. The $50 million proposal would help food entrepreneurs establish or expand markets and grocery stores through loans, grants, and promotion, to make healthy foods available to underserved Americans. This is a critical issue in many urban and rural communities in my state, who lack the access to healthy and fresh foods. We know that by addressing this problem, we can promote health and nutrition in communities that lack it.**

**10. I'd like to work with you and your fellow cabinet secretaries in the future to continue promoting this important initiative. How do you envision the role of HHS?**

I appreciate your support for the Administration's food deserts initiative and look forward to working with you and our partners at USDA and Treasury to improve food access in underserved communities. The Community Economic Development program within the Administration for Children and Families is the focal point of HHS' role in this key initiative. With a proposed funding level of $36,000,000 in FY 2011, the Administration would dedicate up to $20,000,000 to the Healthy Food Financing Initiative, to address the lack of affordable healthy food in many urban and rural communities. HHS will award competitive grants to Community Development Corporations to support projects that finance grocery stores, farmers markets, and other sources of fresh nutritious food. These projects will serve the dual purposes of providing employment and business development opportunities in low-income communities while at the same time facilitating access to healthy food options. In addition, grocery stores oftentimes serve as anchor institutions in commercial centers, which may further employment and business development opportunities in these communities.

**Demographic shifts, advances in technology, rising hospital costs and lifestyle changes have made demand soar for long-term care services. In a recent report, the U.S. Bureau of Labor Statistics noted personal home care aides and home health aides are the nation's second- and third-fastest-growing occupations. "Employment of personal and home health aides is projected to grow by 51 percent between 2006 and 2016, which is much faster than the average for all occupations. The occupation will be among the occupations adding the most jobs, growing by about 389,000 jobs."**

**11. With the increased need for long-term care expected as our health care system continues its transition from a focus on acute illness to chronic care management, will this Administration support efforts to ensure an adequate workforce for providing long-term care services? What is the Administration's position on the availability of home and community-based care for the elderly and people with disabilities?**

The Administration shares your support for efforts to improve the availability of home and community-based care for the elderly and people with disabilities. Last June, on the 10th anniversary of the landmark Supreme Court decision in the case of Olmstead v. L.C., President Barack Obama launched "The Year of Community Living," a new effort to assist Americans with disabilities. He directed HHS to collaborate with the Department of Housing and Urban Development to identify ways to improve access to housing, community supports, and independent living arrangements. In support of this initiative, we made $10 million in grant funds available to States to strengthen and expand Aging and Disability Resource Center Programs (ADRCs), which are visible and trusted sources of information about long-term supports and services. We formed a Coordinating Council, led by the Office on Disability, with the Administration on Aging, CMS, the Office of Civil Rights, the Office of the Assistant Secretary for Planning and Evaluation, and the Substance Abuse and Mental Health Services Administration, who

are working together to put in place solutions that address barriers to community living for individuals with disabilities and to give people more control over their lives and the supports they need.

We also have solicited input about possible ways to improve current regulations by removing Federal barriers that stand in the way of States' ability to design needs-based, person-centered Medicaid home and community-based waiver programs. Finally, the FY2011 HHS Budget requests $2.5 million for Real Choice Systems Change grants to continue assisting States in designing and implementing improvements to community-based support systems that enable people with disabilities and long-term illnesses to live and participate in the community. Helping States to ensure adequate workforce capacity to provide community-based long-term care services and supports will be integral to our success.

**I know one area that has great bipartisan support is investing in our nation's community health centers. Each year, Senator Bond and I have championed a letter in support of funding for our nation's health centers that has the overwhelming support of Senators on both sides of the aisle.**

**Community health centers and other safety-net providers such as rural health clinics, community mental health centers, and school-based health centers though are in desperate need of capital improvements. As more people lose their insurance, we are seeing more and more people turn to community health centers and other safety-net providers to get their primary care.**

**While we have provided construction grants for health centers in both the economic recovery act and again in the Senate health reform bill, these aren't enough to meet our centers' long-term needs. For example, the recovery act included $1.5 billion for construction, but according to a study commissioned in 2008 by the National Association of Community Health Centers, overall health center capital needs are in excess of $10.5 billion between now and 2015. I have centers in Detroit and other parts of Michigan that have not been able to access these construction dollars, and their needs continue to grow.**

**And in the current credit crisis, there are few places for safety-net providers to look in the private market for capital. To paraphrase what the President himself said when he announced grant funding last December, finding a creative solution would not only create new job opportunities in construction and health care but also help provide care for additional patients in underserved communities.**

**In fact, the noted journal Health Affairs is releasing a report on the day of this hearing about how successful the construction dollars were and that more public-private investment truly pays off. The study authors found that these and other public dollars helped increase virtually all services, especially mental health treatment and counseling. The authors predict that an additional $500,000 in federal grants to federally qualified health clinics would help provide $135,000 worth of free or discounted care and could translate into 540 more uninsured patients who receive treatment. If federally qualified health centers leveraged their federal grant support to gain additional state, local, and private grant**

**dollars, this could lead to higher levels of service and more care for the uninsured, the researchers conclude.**

12. **Would you be willing to work with me and my staff look at creative ways that the federal government can help leverage private capital to renovate and modernize our nation's safety-net providers? For example, I note that the Treasury Department's "Green Book" includes expanding the Build America Bonds, and the Department of Housing and Urban Development has unused loan guarantee programs that could be modified for community health centers and other safety-net providers. By coordinating these different programs, we could not only create infrastructure jobs but also improve access to care for millions of Americans.**

    The Health Resources and Services Administration (HRSA), which administers the Health Center Program, would be happy to work with you and your staff to examine strategies health centers can use to leverage private capital for construction and renovation. HRSA recognizes health centers' need for funds to address significant and pressing capital improvement needs.

    In addition to the capital improvement funds awarded under ARRA, HRSA provides health centers with information on other sources of funding and administers a loan guarantee program for construction financing. HRSA's Loan Guarantee Program for Health Center facility projects assists health centers with obtaining a loan guarantee for the financing of medical facility construction, renovation, and modernization. This Loan Guarantee Program is designed to significantly lower capital project barriers and allow for the provision of low cost capital for the facility projects of the health centers—particularly for health centers that have had difficulty in finding affordable lending rates, and have experienced delays in finding any available financing. HRSA also maintains a cooperative agreement with Capital Link, a non-profit organization that has provided planning and capital funding strategies for hundreds of health center building projects. Capital Link provides extensive technical assistance on capital development to health centers.

**Thank you for the decision to rescind the August 2007 proposed rule on Medicaid coverage for rehabilitative services. Doing so recognizes the need to strengthen and improve Medicaid so that it works better for the millions of Americans who rely on Medicaid and our partners in state government.**

**As you know, I introduced the Medicaid Services Restoration Act in response to the proposed changes to Medicaid's rehabilitative services and targeted case management. One of the provisions is to modernize how Medicaid's "rehab option" can be used to provide therapeutic foster care. As part of the Finance markup, I worked closely with Chairman Baucus to include a federal definition of therapeutic foster care in the committee's mark. Representative Tammy Baldwin secured similar language in the House.**

13. **Although the 2007 regulation has been rescinded thankfully, it is critical that we continue to work to strengthen Medicaid. Providing a clear definition of therapeutic foster care is an important part of that goal. Would you be willing to work with me on strengthening this important service for some of our nation's most vulnerable children?**

Senator Stabenow, I appreciate your longstanding interest in promoting therapeutic foster care, which provides medically necessary, evidence-based, intensive services to children with severe mental and behavioral health needs in a community setting. In December 2009, HHS took action to withdraw a proposed CMS regulation that might have had the effect of restricting coverage of Medicaid rehabilitative services, including therapeutic foster care. We decided on this course of action in large part because of concerns expressed by the Congress and the public in comments we received on the proposed rule. Withdrawing the rule enables us to examine this issue more carefully with input from States, Members of Congress, and advocacy organizations. Out of similar concerns, HHS also has rescinded certain provisions of an interim final regulation that restricted Medicaid payment for the case management services from certain types of providers and thus limited state flexibility in determining efficient and effective delivery systems for covering such services. I am committed to assuring the health and safety of our nation's most vulnerable children and to strengthening all of the programs that serve them.

**Senator Grassley**

**Questions for the Witness:**

**FDA review of class III medical devices under the Safe Medical Devices Act**

**During your confirmation hearing in April 2009, I submitted questions for the record asking you to respond to questions regarding FDA's premarket review of class III medical devices, in particular the requirement under the Safe Medical Devices Act that FDA issue regulations for the submission of premarket approval (PMA) applications for class III device types not reclassified as class I or II. In your response, you stated that "Under the Federal Food, Drug, and Cosmetic Act, the first step in this process is for FDA to order manufacturers of preamendment class III devices for which no final regulation has been issued requiring the submission of PMAs to submit to the agency a summary of any information known or otherwise available to them about those devices. If confirmed, I would ask for a status update on this important first step."**

1. **Have you requested a status update? If so, please describe the status of submission of safety and effectiveness information that the FDA required from 25 manufacturers for their class III devices marketed in the U.S. prior to the Medical Device Amendments of 1976 and any steps the FDA has taken to complete the review of these class III devices.**

2. **If you have not requested a status update, please explain why not.**

**Answer to Grassley 1& 2:** FDA remains committed to requiring PMAs for, or reclassifying, each remaining preamendment class III device that is currently being marketed through 510(k)s. Of 140 original preamendment class III devices, 113 final regulations have been issued and 27 remain subject to 510(k). At least four of these devices have fallen into disuse.

On April 9, 2009, FDA issued a 515(i) notice requiring manufacturers of the remaining preamendment class III devices to submit to FDA a summary of, and citation to, any information known or otherwise available to them respecting such devices. FDA is requiring this information in order to determine, for each device, whether the device should remain in class III, whether FDA should initiate rulemaking to require submission of a PMA, or whether the device should be reclassified into class I or II. This is the first step toward addressing the remaining 27 preamendment class III devices.

FDA is currently reviewing comments received in response to the aforementioned notices and plans to publish a minimum of five proposed regulations in FY 2010 while actively working to complete the remainder in FY 2011.

**FDA and Suppression of Scientific Dissent**

**Secretary Sebelius, I continue to receive allegations that some FDA employees are being pressured by their managers to change their reviews of the safety and/or effectiveness of FDA-regulated products and retaliated against if they fail to make those changes. I am sure you would agree that retaliation against employees who report concerns to their managers and suppression of scientific dissent are unacceptable and need to be addressed once and for all.**

3. **Please describe what HHS is doing to ensure that the employees at FDA are not being pressured to suppress or revise their findings and conclusions.**

4. **Please also describe what HHS is doing to ensure that FDA employees can report safety and/or efficacy problems without fear of retaliation.**

**Answer to Grassley 3 & 4:** I support the Commissioner's commitment to creating a culture that enables all voices to be heard.

With regard to employee scientific dissent in the Center of Devices and Radiological Health (CDRH), a number of steps have been taken. In September 2009, FDA Commissioner Hamburg named Dr. Jeff Shuren as Director of the Center and he held an all hands meeting at which he identified six priorities for the Center. One of these was "fostering a work environment in which all Center staff can freely express differing views about scientific and regulatory matters without fear of retaliation." On October 1, 2009, at a subsequent all hands meeting, Dr. Shuren announced CDRH's new Standard Operating Procedure (SOP): "Resolution of Internal Differences of Opinion in Regulatory Decision-Making." The SOP is the work product of many and represents a diversity of input. It is about respect for the opinions of the individual as well as protecting the integrity of the Center's decision-making. It is a fair, transparent and legally and scientifically rigorous process that allows staff members to share and discuss their views with each other and with managers. It provides clear expectations for documentation, specifies that decisions be supported by appropriate evidence, and sets time limits on each stage in the process. The new SOP makes clear that it is unacceptable to retaliate in any form against staff members or managers who express differing views. The new SOP will provide assurance to all involved in the decision-making process that they have had an opportunity to be heard, that their opinions have been considered, and that the basis for the decision reached will be documented in the administrative record along with a description of any unresolved differences of opinion.

Staff training on the SOP for resolving internal differences of opinion is ongoing, and a draft guidance on resolving differences of opinion between CDRH and external parties will be completed in 2010. Further, a contractor will be conducting an assessment of the interpersonal workplace environment and will make recommendations for improvements. These recommendations are expected this summer.

The new SOP and supporting documents are posted on FDA's Web site. http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOmbudsman/ucm113713.htm

FDA's Center for Drug Evaluation and Research (CDER) has also developed several policies and procedures describing the process for consultative review of drugs regulated within the Office of New Drugs (OND) and interactions between offices within CDER. These manuals of policies and procedures (MaPPs) are posted on the FDA website at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/default.htm; 4151.1 (PDF-17 KB) Resolution of Disputes: Roles of Reviewers, Supervisors, and Management: Documenting Views and Findings and Resolving Differences; 4151.2 (PDF-142 KB) Documenting Differing Professional Opinions and Dispute Resolution – Pilot Program (Posted 11/5/2004); 6025.3 Good Review Practice: Consultative Review of Drugs Regulated Within OND. (Issued 1/12/2007; Posted 1/16/2007)

These MaPPs are intended to ensure quality and consistency in review processes. They describe the sign-off policies and procedures for investigational new drug applications, new drug applications, therapeutic biologic license applications, and supplements for drugs regulated in OND. In addition, OND and the Office of Surveillance and Epidemiology (OSE) Directors have signed a Memorandum of Agreement (MOA) between OND and OSE on the management of significant safety issues associated with pending drug applications and approved drug products. This MOA sets out the management framework for drug safety issues. It clarifies the roles of OSE and its authority over regulatory actions and provides for accountability throughout the administrative process. One of the items identified in the MOA under accountability is that every member of the team is provided an opportunity to express his or her view on the appropriate resolution of the issue.

A copy of the MOA is posted on FDA's website at: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111520.pdf

**Off-labe promotion of drugs and devices**

**In questions I submitted for the record during your confirmation hearing, I expressed serious concerns about FDA's guidance on the dissemination of scientific literature on off-label uses of drugs and devices to physicians by drug and device sales representatives in light of studies and editorials on "ghostwriting" and manipulation of data by the drug industry and my own findings regarding the lack of or limited transparency in the financial relationships between the drug and device industries and physicians.**

5. **I asked you what your position is on the FDA guidance and you stated that if confirmed, you would closely examine the new guidance and work with the FDA Commissioner to determine how best to proceed. Have you examined the guidance and/or discussed it with Commissioner Hamburg? If so, what is your position on the guidance and what was the outcome of the discussion(s) with the FDA Commissioner?**

6. **I also asked you how you would ensure appropriate oversight by the FDA, especially with no requirement that manufacturers submit copies of the literature being disseminated. You stated that you would instruct FDA to provide appropriate oversight or to advise you if new authorities are needed to provide that oversight. Has Commissioner Hamburg advised you if new authorities are needed? If so, please describe what additional authorities FDA believes the agency needs in order to ensure appropriate oversight.**

   **Answer to Grassley 5 & 6:** It is my understanding that the Commissioner has been briefed on the guidance and that the Agency is in the process of evaluating the various options for moving forward.

   Under the current guidance, FDA relies on various means of obtaining information on dissemination of information on off-label uses. FDA learns about such dissemination from health care providers, attendance of FDA staff at medical conferences, training sessions, and other professional events, and from FDA-initiated investigations. In addition, competitors will often report what they perceive as promotional violations. Upon receipt of information of potential violations, FDA will investigate and take appropriate regulatory action.

   At this time the Administration does not have proposals for additional authorities in this area, but we would be pleased to discuss any options with you for strengthening oversight of drug promotion.

**Medicaid**

**Last fall, I received information regarding felons who were convicted of illegal possession or sale of prescription drugs, in particular narcotics or other controlled substances, continuing to obtain and sell such drugs illegally using their Medicaid beneficiary cards.**

7. **What is your position on requiring prior review of Medicaid prescriptions for such drugs for such convicted felons to prevent them from defrauding the Medicaid program by filling multiple prescriptions for the same drug(s)? Prior review would be required during the individual's prison term and entire sentence, from conviction until the conclusion of the individual's supervised release or probation.**

   The President's budget includes new tools to improve the integrity of the Medicaid program by tracking, monitoring, and identifying potential prescription drug overutilization in the Medicaid program. I am supportive of controls that States can use to deter fraudulent behavior and contribute to patient safety, such as prior authorization and drug utilization review programs. Like you, we are concerned about incidences in which individuals convicted of illegal possession or sale of prescription drugs continue to obtain or sell drugs illegally using their Medicaid beneficiary cards. However, I do want to clarify that Medicaid does not pay for health care coverage for individuals who are incarcerated.

   Several States currently use a system of prior authorization to control abuse and misuse of controlled substances at the point of sale. Program edits in state automated claims

processing systems are designed to identify possible misuse such as duplicate therapy, exceeding normal quantity limits, and exceeding normal daily dosage limits. When a recipient shows a pattern of substance misuse, their access to services can be restricted in a manner to mitigate the potential for system misuse, while still allowing the individual to access needed services to allay concerns about restricting necessary care. States have also adopted the restricted recipient program or "lock-in" program as a tool to limit "doctor shopping" by assigning Medicaid beneficiaries to one primary care prescriber and one pharmacy. This has been successful at minimizing program misuse. I would welcome the opportunity to work with you and other Senators to examine what the effects on State Medicaid programs would be of mandating this policy for convicted felons.

**Inside CMS reported that as of January 1, 2010, Medicare is no longer paying for drugs with drug codes on the "non-matched national drug code" list that is posted on CMS's website in an effort to identify unapproved drugs that are ineligible for reimbursement.**

8. **Why is this restriction on reimbursement limited to the Medicare program when CMS officials had informed my staff that this is an even bigger problem in the Medicaid program?**

   The reimbursement restriction you refer to was extended to the Medicare program starting on January 1, 2010 to better identify unapproved drugs that are ineligible for reimbursement. At this time, we are exploring whether this same approach can be applied to the Medicaid program and our experience with the Medicare program will inform our policy for Medicaid going forward.

9. **Please describe any efforts under way to expedite the identification of unapproved drugs that should be ineligible for Medicaid reimbursement.**

   I appreciate this question as we certainly recognize the importance of identifying unapproved drugs that should be ineligible for Medicaid reimbursement. CMS and FDA continue to work together to identify and remove unapproved, ineligible drugs from the Medicaid drug rebate program. Both agencies are also working toward reconciling their systems so that CMS can more easily identify those unapproved, ineligible drugs that manufacturers erroneously submit for coverage under the Medicaid drug rebate program.

   Please be assured that the Department will continue to diligently monitor, and remove when appropriate, prescription drugs that do not meet the requirements for inclusion in the Medicaid drug rebate program set forth in the statute.

**Health Information Technology**

**In questions submitted for the record during your confirmation hearing last April, I asked you who regulates computer physician order entry (CPOE) devices. I also asked if there were any monitoring of adverse outcomes of care that may be linked to the use of such devices. You responded that "FDA can regulate products, including software, when they meet the definition of a medical device, and some CPOE systems may be medical devices. The increasing complexity of more recent CPOE versions and their use by physicians to**

**make clinical decision may require additional oversight by the agency. If confirmed, I look forward to looking into this important issue in detail to ensure that patient safety and provider confidence in these products are assured."**

10. **Your response did not address whether or not there is adverse event monitoring for CPOE devices. Is HHS planning to establish a system for health care providers, HIT vendors, and others to report adverse events, product defects, or any other problems linked to the use of CPOE devices and other HIT products being adopted in hospitals across this country? If so, please describe the Department's plans and specify what agency would be responsible for maintaining, monitoring and reviewing these reports. If not, please explain why there should not be monitoring similar to the post-marketing surveillance that occurs with devices approved or cleared for marketing by the FDA.**

11. **With over $20 billion in taxpayer money at stake and with increasing complexity in the technologies being used in our hospitals, do you believe it is time to revisit FDA's responsibilities in regulating HIT products being used in clinical care? If not, how is HHS making sure that the health information technologies being developed and implemented are safe and effective? Who is or should be responsible for ensuring that the HIT vendors are meeting quality manufacturing processes?**

**Answer to Grassley 10 & 11:** Since you submitted these questions for the record, I received a subsequent letter from you inquiring about these issues. Accordingly, I will provide a comprehensive response to your questions on this issue in my reply to your letter in the near future.

**David Blumenthal, the National Coordinator for Health Information Technology at HHS, stated last fall that "Broad use of health information technology has the potential to improve health care quality, prevent medical errors, and increase the efficiency of care provision." While I strongly agree that HIT has the potential to prevent medical errors and increase the efficiency of health care delivery, thereby improving the safety and quality of care, I am surprised by the lack of discussion about patient safety concerns when HIT products are not functioning properly or when they are being used incorrectly.**

12. **Just as we see the potential of HIT for improving patient safety and health care quality, we should also recognize the potential adverse effects of HIT. What is HHS doing to identify and limit the potential adverse effects?**

We are actively following instances where HIT may cause adverse events or patient safety concerns. In that regard, we have begun a process to more fully examine what the most prominent HIT and patient safety concerns are and what strategies can be employed to assuage these concerns. As part of this process we have asked the HIT Policy Committee to make recommendations to the National Coordinator on HIT safety. The HIT Policy Committee's Certification and Adoption Workgroup held an all day hearing on HIT safety on February 25, 2010. At this hearing the Workgroup identified issues related to HIT safety, heard testimony from stakeholders, and discussed possible approaches with subject matter experts from FDA, AHRQ, and the private sector.

We are also continuing to work with our colleagues in other HHS agencies to better understand the scope and prevalence of certain concerns and to discuss possible approaches as well as which agency may be best equipped to address the concerns. We anticipate receiving recommendations from the HIT Policy Committee in the near future on HIT safety and will carefully consider these recommendations as we formulate what will most likely be a multi-faceted approach to better identify and limit adverse events and patient safety issues.

**The Health Information Technology for Economic and Clinical Health Act provides incentive payments to hospitals and physicians that make "meaningful use" of "certified" electronic health records (EHR). One of HHS's responsibilities is to issue regulations on the certification process for EHR technology. The Certification Commission for Health Information Technology (CCHIT), a nonprofit organization, has been certifying EHRs since 2006. Its certification program examines EHRs for functionality, interoperability and security. It also recently added a requirement of full compliance with HHS criteria and standards for certified EHR technology.**

13. **Will HHS's certification process include a safety evaluation of the technologies?**
The certification programs we have proposed would require certification bodies authorized by the National Coordinator to certify Complete EHRs and EHR Modules in accordance with the standards and certification criteria adopted by the Secretary. Adopted certification criteria specify the capabilities that Certified EHR Technology needs to include in order to support an eligible professional or eligible hospital's achievement of meaningful use. Several of the adopted certification criteria have the potential to provide patient safety benefits. These certification criteria include, but are not limited to, computerized provider order entry (CPOE), clinical decision support (CDS), and drug-drug interaction checks. Finally, we have included in the definition of the term "standard" the potential for "performance standards" to be established for Certified EHR Technology and cite the following as an example: "a performance standard could specify certain operational requirements for HIT such as being able to properly identify a drug-allergy contraindication 99.99% of the time for patient safety purposes." We believe that performance standards could be used to improve patient safety.

**The Fiscal Year 2011 Budget in Brief states that the Recovery Act provides an estimated $20.6 billion in incentives from FY 2009 to FY 2019 to encourage eligible professionals and hospitals to adopt certified electronic health records. Yet your testimony before the Committee on Finance states that "during FY 2011, HHS will also begin providing an estimated $25 billion over 10 years of Recovery Act Medicare and Medicaid incentive payments to physicians and hospitals who demonstrate meaningful use of certified EHRs."**

14. **Which is the correct estimate -- $20.6 billion or $25 billion? Please explain the discrepancy.**

We apologize for the discrepancy between the numbers provided in the FY 2011 Budget in Brief and in my testimony to the Senate Finance Committee on February 3, 2010. To clarify, the $25 billion figure represents the total *gross* incentive payments to Medicare and Medicaid eligible professionals and hospitals for FYs 2011 - 2020. The $20.6 billion figure represents the total *net* incentive payments to Medicare and Medicaid eligible professionals and hospitals for FYs 2009 - 2019; this total net incentive payment figure reflects penalty adjustments (payment reductions) for Medicare providers made during the course of the incentive payment program.

**15. What is the total amount being provided for incentive payments for eligible professionals and hospitals?**

We estimate the total amount of authorized EHR incentive payments under the Health Information Technology for Economic and Clinical Health (HITECH) Act will be $25 billion over the course of the program.

**16. How much of the appropriated dollars from Congress have been obligated or awarded for HIT grants, loans, CONTRACTS and demonstration programs, and how much remains for fiscal year 2010? Have all funds from the American Recovery and Reinvestment Act been expended?**

In February 2009, the American Recovery and Reinvestment Act appropriated $2 billion, to be available until expended, to the Office of the National Coordinator for Health Information Technology (ONC). As of March 15, 2010, ONC has announced awards totaling $930 million of the $2 billion for the Health Information Technology Extension Program, Health Information Exchange State Grant Program, and privacy and security activities. ONC plans to award nearly $940 million over the remainder of FY 2010 for the Health Information Technology Extension Program, Health IT Workforce Program, and Beacon Communities. ONC will also use these funds to advance the goal of supporting the care of all Americans with electronic health records by 2014 through additional activities such as addressing existing barriers to the adoption and meaningful use of health information technology, harmonizing standards, establishing a health IT standards testing infrastructure, and ensuring privacy and security. In FY 2011, ONC will award $2 million to continue harmonizing standards and establishing a health IT standards testing infrastructure, and in FY 2012, ONC plans to award the last $45 million to continue the Health Information Technology Extension Program begun in FY 2010. In addition, ONC transferred $20 million of the discretionary appropriation to the National Institute of Standards and Technology at the Department of Commerce as instructed by the American Recovery and Reinvestment Act.

**HHS Responses to Management Implication Reports**

**I wrote to HHS late last year about the Department's handling of alerts from the Office of Inspector General regarding possible programmatic flaws that contributed to health care fraud. I wrote to you after my office received information indicating that the Department – and the Program Integrity Group specifically – either ignored or failed to follow up on these alerts. You responded by saying that CMS would be putting in place a new process to track and respond to these critical reports.**

**17. What processes and procedures has the Department put in place to ensure that these alerts are not only responded to, but also responded to in a timely manner?**

Significant changes have been implemented to both the process the Office of the Inspector General (OIG) uses in developing and submitting Management Implication Reports (MIR) to CMS and to the tracking of MIRs and responses by CMS. These process changes will ensure that the alerts regarding possible programmatic flaws are not redundant, are recommending policy changes that are consistent with existing legal authorities, and are responded to in a timely manner.

The OIG has recently revised its MIR development and approval process. Prior to submitting final MIRs to CMS or other operating divisions for formal comment and plan of action, OIG's legal, evaluation, and audit staff will conduct a thorough review, and all reports will be signed by the Inspector General and issued directly to the program head. CMS has also revised its process regarding MIRs. Once received by the CMS Administrator, the agency's Office of Strategic Operations and Regulatory Affairs (OSORA) in the Office of the Administrator will oversee the process so that all incoming MIRs and corresponding responses are formally coordinated in the agency. CMS will continue to work to ensure that all MIRs receive a formal and timely response to the OIG. This change will also facilitate the process by which CMS tracks all MIRs.

**FMAP Extension**

**In ARRA, Congress provided additional FMAP funds for states on the condition they not reduce Medicaid or CHIP eligibility. This means that states trying to balance their budgets can cut services or provider reimbursements in Medicaid and CHIP but not eligibility.**

**18. Is the Department aware of any cases where states have chosen to cut services or reimbursements in Medicaid or CHIP since ARRA was passed?**

The Administration is committed to sustaining the Medicaid program during the current economic downturn. As of March 2010, States and the Territories were awarded more than $53 billion in increased Federal Medicaid matching funds. This funding has helped secure existing Medicaid coverage during difficult financial times where States otherwise would have cut back.

Under the Recovery Act, a State must meet five criteria in order to be able to draw down the increased FMAP funding. For example, States must attest that they have not modified or eliminated services that impact an individual's ability to maintain Medicaid eligibility. None of these attestations require that the State maintain a certain level of services or benefits, nor is there a prohibition against reducing reimbursement rates. However, given the significant increases in Federal funding provided to States under the Recovery Act, we expect States to carefully consider the impacts on Medicaid beneficiaries and Medicaid providers of any benefit or rate reductions.

With that said, we are aware that many States continue to struggle with fiscal challenges of varying magnitudes. Amidst these challenges, CMS is providing technical assistance

to States to ensure that any reductions in services or reimbursement meet both the Recovery Act, and Medicaid requirements.

**19. By preventing states from reducing Medicaid and CHIP eligibility, states are forced to consider other budgetary tools like raising taxes or cutting other state spending to balance their budgets. Do you have evidence to suggest that the maintenance of effort requirement in Medicaid remains necessary?**

The Administration is committed to helping to promote economic recovery and we are working with States to ensure that the Recovery Act is implemented effectively. To ensure that eligibility is not rolled back, we believe the maintenance of effort requirement does remain necessary. The Act authorizes an estimated $85.4 billion in additional Federal funding for States, in the form of a temporary increase in the funds that the Federal government contributes toward Medicaid and Title IV-E programs. This investment will protect people whose eligibility for Medicaid might otherwise be at risk if State budget shortfalls resulted in Medicaid reductions.

**20. Please explain why Medicaid eligibility and ONLY Medicaid eligibility is a higher priority than protecting post-secondary education, special education programs, taxes on small business or lower income individuals, law enforcement, or transportation?**

The increased FMAP has been an important tool in protecting Medicaid beneficiaries and providing additional fiscal relief to States. The increased FMAP means that States pay a reduced portion of their share of Medicaid expenditures. This, in turn, frees up otherwise obligated State-only funds for use on education, taxes, law enforcement, or transportation. Because of the unique Medicaid State-Federal financing partnership, providing an increased FMAP is an effective way to deliver fiscal relief to States.

**21. The FMAP provision in ARRA provided states additional funds based on a specific formula. Please explain why that formula is still appropriate.**

Section 5001 of the Recovery Act specifies that FMAP rates shall be temporarily increased for the following: 1) a hold harmless provision where there is a maintenance of FMAP rates for FY 2009, FY 2010, and first quarter of FY 2011, so that the FMAP rate will not decrease from the prior year; 2) in addition to any maintenance increase, the application of an increase in each State's FMAP of 6.2 percentage points; and 3) an additional percentage point increase based on the State's increase in unemployment during the recession adjustment period. The resulting increased FMAP cannot exceed 100 percent.

The President's FY 2011 Budget proposes to extend the Recovery Act FMAP increase using the same criteria described above. The formula has been an effective way to deliver relief to States. The Administration fully expects that the Recovery Act and subsequent measures will lead to an economic recovery. Nonetheless, in light of projected high levels of unemployment in FY 2010 and FY 2011 States would still qualify for unemployment-related FMAP increases under the original formula and, therefore, we do not believe the Recovery Act FMAP formula should be altered.

**Outstanding Regulations**

**Congress passed amendments to the Social Security Act in the Deficit Reduction Act of 2005 increasing state flexibility in Medicaid by providing states the ability to use additional cost-sharing for higher income Medicaid recipients (Section 1916A) and providing states the ability to use benchmark benefit plans for specific populations (Section 1937). In 2009, the Administration suspended regulations implementing those provisions seeking further comments.**

**22. Given that those provisions are statutory and that states could use those provisions to modernize their Medicaid programs in difficult economic times, can you provide the Committee any assurance that those regulations will be reissued soon and consistent with the statute and Congressional intent?**

Last year, we temporarily delayed the effective date of the final rules implementing the benchmark benefit package and the premium and cost-sharing provisions of the DRA. The delay was necessitated by provisions in CHIPRA and the Recovery Act that required us to revise a substantial portion of both regulations. These revisions required us to solicit public comment, which is a time-consuming but important process. CHIPRA included several technical corrections to the benchmark benefit provisions that were included in the DRA. The Recovery Act included a provision that directly affects the premiums and cost-sharing regulation by prohibiting Medicaid and CHIP from imposing enrollment fees, premiums, or similar charges on American Indians and Alaska Natives for services provided directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization.

The effective date for both rules has been delayed until July 2010 to allow time to incorporate public comments and revise the regulations to conform to the recently enacted legislation.

**In 2005, Congress moved to create a new methodology for reimbursing for prescription drugs in the Medicaid program by requiring reimbursement to be based on the average manufacturer price (AMP) of the drugs. The initial regulation implementing the regulation was halted by a federal court. As of today, the AMP methodology has yet to be implemented.**

**23. Does the Department have any plans to implement AMP?**

As you know, the Administration is limited in its ability to implement certain provisions of the current AMP regulation due to a preliminary court injunction. Despite this, we are committed to transforming and modernizing America's health care system. HHS will continue to work with you and other members of Congress to promote the cost-effective purchase and delivery of prescription drugs for Medicaid beneficiaries.

**24. Would you consider correcting the initial AMP regulation or do you think further clarifying legislation by Congress would be useful before the acting?**

As you know, the Administration is limited in its ability to implement certain provisions of the current AMP regulation due to a preliminary court injunction. Though we cannot

specifically comment on pending litigation, we agree that AMP policy should lead to more equitable and appropriate reimbursement for prescription drugs. However, we believe that if a change is not made with respect to Medicaid payment for prescription drugs, the Federal government and States will not realize the cost savings that are intended by some of the policies in the AMP regulation.

Recent health reform legislation passed by Congress would directly address this issue; we would be happy to discuss the effects of these provisions on Medicaid upper payment limits for prescription drugs.

**Childcare / Child Welfare**

**The President's budget for FY 2011 includes a $1.6 billion increase in child care funding. In your testimony you stated that an additional 235,000 children who otherwise would not have received child care assistance would receive it. Can you please provide a detailed summary of the analysis used to arrive at this number?**

The estimate of 235,000 additional children is a projection which compares a baseline estimate of the number of children who would be served under current funding levels in FY 2011 versus the number of children that could be served with an additional $1.6 billion in funding. The estimate takes into account a number of factors including spending rates, TANF transfer to the Child Care and Development Fund (which includes discretionary and mandatory child care funds), TANF direct spending on child care and SSBG spending on child care, 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.

25. **In providing this increase, does the Administration contemplate targeting these resources to families at greatest need, such as families making the transition from welfare to work?**

    The child care program provides a critical support for those families with the greatest need. The block grant statute requires that States give priority for child care services to children from very low-income families and children with special needs. In FY 2009, 38 States reported having a guaranteed child care subsidy for families receiving TANF or transitioning from TANF. In addition, the Administration proposes that half of the total increase to the child care block grant ($800 million) be provided through the mandatory funding stream which requires that States spend at least 70% of the total amount of those funds, including required State match, to meet the child care needs of families who are receiving TANF assistance, attempting through work activities to transition off TANF assistance, and those families at risk of becoming dependent on TANF.

26. **During previous debates on welfare reform and increasing child care funding, some Members of Congress have proposed conditioning increased child funding on increased requirements for recipients of cash assistance. Would the Administration support policies that conditioned state receipt of additional child care funds to a state's ability to improve engagement of individuals receiving cash assistance?**

Additional funding for child care is important to support States' ability to promote self-sufficiency for low income families, including the ability to increase the number of individuals receiving cash assistance who engage in TANF activities. The child care program continues to be a critical support for families on TANF, but one of the hallmarks of its success is the support that it provides to low-income families to help them work and avoid the need for cash assistance. Currently, only 16 percent of the families who receive CCDF are receiving TANF cash assistance. However, there are many more families that have successfully transitioned off TANF or who have been able to avoid receiving TANF assistance because they received child care subsidies to support their work. In FY 2008, 83% of families receiving child care subsidies reported employment as a reason for needing care and nearly 80% of families receiving CCDBG had incomes below 150% of poverty. Limiting a State's access to additional child care funding could put these families in jeopardy and negatively impact employment among parents and TANF caseloads. In addition, the child care program plays an important role in supporting school readiness for children in these low-income families. The Administration's proposed budget increase includes a strong focus on improving the quality of child care to meet the dual goals of the program - parental employment and child well-being.

**The Budget in Brief document provided to Congressional offices from the Department of Health and Human Services, correctly notes that the proposed reduction in the Foster Care program is, "partially due to a reduction in the foster care children funded under the federal program because the income eligibility criteria required by statute is tied to the old Aid to Families with Dependent Children (AFDC) which has resulted in the payment's value eroding over time due to inflation."**

**27. Does the Administration believe that continuing to base eligibility for foster care on the AFDC standard serves the best interest of vulnerable children and families?**

The link between foster care and AFDC eligibility poses a very difficult budgetary issue that both branches of government have struggled with over the years. As you know, in the *Fostering Connections to Success Act of 2008*, Congress established a phasing out of the link between the 1996 AFDC standard and the title IV-E Adoption Assistance Program. We look forward to continued discussions with you on this issue as it relates to foster care.

**28. Is the Administration going to propose improvements to the child welfare system, including the financing structure? If so, could you highlight the form those improvements might take?**

An important priority for the Administration is ensuring the safety, well-being and permanency of children who are involved with the foster care system. We are working to continue implementation of key provisions in the *Fostering Connections to Success Act of 2008.* In addition, we will continue strong focus on monitoring. We look forward to sharing information on these efforts and continuing discussions with members of this committee on improving the child welfare system in a variety of manners.

**Healthy Marriage and Families Initiatives**

**29. The President's budget eliminated funding for Healthy Marriage initiatives included in the Deficit Reduction Act. Can you detail the rational for the elimination of these programs?**

The FY 2011 request includes a proposal to establish a $500 million Fatherhood, Marriage, and Families Innovation Fund. The Administration proposes to redirect the existing Healthy Marriage and Responsible Fatherhood program funding ($150 million) toward a more comprehensive effort to encourage States' implementation of proven and promising strategies that focus on responsible fatherhood initiatives, including those with marriage components, and the improvement of child and family outcomes by addressing parents' employment and self-sufficiency needs. The goal is to build a stronger evidence base about what service intervention models work to remove barriers to employment and increase family functioning and parenting capacity that could be replicated within the TANF, Child Support Enforcement, and other State and community-based programs.

Half of the funds will support comprehensive fatherhood programs, including those with marriage components. The core elements of these programs typically include: co-parenting services and conflict resolution; connection to job training and other employment services; child support enforcement case management; financial incentives; earning supplements; employment preparation services; training subsidies; legal services; substance abuse and mental health treatment; linkages to domestic violence prevention programs; and linkages to public agencies and community-based providers offering housing assistance.

**30. The President's budget also includes funding for a "Families Innovation Fund." Can you describe what the Administration contemplates the types of programs this fund would support?**

The Families Innovation portion of the fund will support state implementation and evaluation of promising approaches that focus on improving child and family outcomes. Areas of interest include: (1) identifying families that have serious barriers to employment, including strategies that use mechanisms of ongoing assessment or focus on families at risk for involvement in the child welfare system; (2) implementing strategies to help families address these barriers and also prepare for employment; (3) promoting child well-being in highly disadvantaged families, including child-only cases; and (4) supporting those with barriers who find jobs so they can sustain employment.

All initiatives will be required to establish meaningful performance goals, such as higher family earnings and improvements in factors that relate to child outcomes, and to measure progress toward those goals. States may propose to target their initiative to support families facing a broad range of barriers or to target specific subgroups. In either case, however, the Administration anticipates that the innovations tested will be multi-dimensional given the complex and varied needs of families facing these kinds of challenges. Thus, programs may include both services designed to promote employment as well as services designed to improve family functioning and parenting skills. Grantees will be required to agree to participate in a rigorous evaluation as a condition of funding.

Temporary Assistance for Needy Families (TANF)

**The Deficit Reduction Act included a provision that required states operating separate state programs for cash assistance to meet the same requirements that federally supported programs had to meet. This had the effect of requiring separate state programs for two parent families receiving cash assistance to meet a 90% participation standard. In the past, some Members have supported eliminating this provision. The President's budget does not include a proposal to eliminate this provision.**

**31. Can you detail the reasons why this provision was not included in the TANF Legislative Proposal section of the Budget in Brief?**

The Administration chose to focus primarily on the immediate need of supporting State efforts to innovate, and ensuring that States have continued access to the TANF Emergency Fund to support subsidized jobs, provide short-term benefits, increase work-related expenditures, and respond to the need for assistance. As the economy recovers and States are better prepared to engage in a more comprehensive updating of the TANF program, the Administration is prepared to work with Congress and the States on a comprehensive TANF reauthorization.

**32. Should Members of Congress assume that the proposal included in the TANF Legislative Proposals represent the sum of the Administration's changes for the TANF program?**

In the FY 2011 budget, the Administration proposes a one year extension of most TANF related programs along with a few targeted initiatives highlighted earlier in these responses. As the economy recovers and States are better prepared to engage in a more comprehensive updating of the TANF program, the Administration is prepared to work with Congress and the States on a comprehensive TANF reauthorization.

**The President's budget includes $2.5 billion for the TANF Emergency Fund.**

**33. Why did the Administration choose to direct additional funds to this fund, rather than seek to improve the existing contingency fund?**

Extending the Emergency Fund provides an immediate response to States still struggling in the economic downturn. The amount of funding a State may receive and eligibility criteria in the Emergency Fund are more apparent to the States. Further, the Emergency Fund is specifically targeted to expenditure increases in categories that help States provide basic assistance, non-recurrent short-term benefits, or subsidized employment. While the Contingency Fund was created to help States during an economic downturn, it is not targeted in this way. The Administration is requesting to fully fund the Contingency Fund but also envisions working with Congress to revise this fund when a full reauthorization is considered.

**34. How does the Administration respond to continued concerns that, as drafted, the TANF Emergency Fund undermines key principles of welfare reform by providing for a financial incentive to raise the welfare role and exempts new families on welfare from any meaningful work requirement?**

The Administration does not believe the Emergency Fund undermines the principles of welfare reform. It leaves in place the existing work participation requirements and time limits, and does not exempt newly served families from work requirements. If States use the Emergency Fund to provide increased basic assistance, they will have a larger number of families to engage in work related activities to meet the TANF work requirements. Moreover, the Emergency Fund, even if extended through FY 2011, is temporary. While it may help support increased caseloads in the short-run, States are cognizant of the fact that when the Fund expires, they will be responsible for serving the added families with regular TANF funds. This serves as a fiscal restraint. In addition, the Emergency Fund does not reimburse 100 percent of increased assistance costs, so states with rising caseloads must find the resources from other sources to fund the remaining 20 percent of increased expenditures.

The Emergency Fund also supports expenditures for non-recurrent short-term benefits and subsidized employment expenditures that directly support welfare-to-work efforts. In addition, the Administration's proposal to add the category of work-related expenses puts additional emphasis on employment.

**35. As described in the Budget in Brief, the ARRA "temporarily allow(s) certain adjustments to the caseload reduction credit." Can you detail these adjustments, provide a justification for them, describe what effect they had on a state's ability to meet their federal performance standard and whether or not the Department intends to continue to allow these "adjustments" and if so, for how long?**

The caseload reduction credit reduces a State's required work participation rate for a fiscal year (FY) by the number of percentage points its caseload declined between FY 2005 and the year prior to the current fiscal year, called the comparison year. Under the Recovery Act, in FYs 2009, 2010, and 2011, a State may either use the prior fiscal year as its comparison year or may use the caseload reduction credit it qualified to receive when the comparison year was FY 2007 or FY 2008, whichever had the lower caseload. This means that if a State serves more TANF families in the normal comparison year than it did in FYs 2007 or 2008, this provision holds the State harmless in the caseload reduction credit calculation. As a result, the State's required work participation *rate* will not increase simply because the State assisted more families during this period of increased need.

This provision recognizes that during an economic downturn, caseloads may rise. This provision helps ensure that a State's work participation rate targets are not increased as a result of economic downturn. However, while the target *rates* may not change, States with higher caseloads will have to engage a larger absolute number of work-eligible individuals to meet the participation rate targets.

During future reauthorization discussions, the Administration is prepared to reexamine the caseload reduction credit and other aspects of the TANF program.

**HHS Website**

**I have written to you in October and November of last year about the "State Your Support" link on the HHS and Health Reform websites. I am concerned that this may constitute a misuse of appropriated funds. I appreciate the responses you have provided so far to both of my letters. My staff continues to review your responses, and I will have a number of follow-up questions. But there are still incomplete responses. This includes an actual list of all communications sent to the people who signed the letter, a definitive response on the source of funding for this initiative, and an up-to-date figure on the number of people that have signed the letters.**

**36. When can I expect these important pieces of information that directly bear on whether violations of criminal and appropriations laws have taken place?**

My staff has been in communication with your staff to discuss the responses in question, as well as additional questions they have subsequently submitted to us. We look forward to continuing to work with you and your staff to resolve this issue, and to be as responsive as possible to your requests for information.

**Senator Hatch**

**Questions for the Witness:**

**Health IT**

**Health care providers have told me that the CMS proposed rule on health information technology (the "meaningful use" rule) is very problematic. This proposed rule sets up a structure where hospitals have to meet a "meaningful use" standard in order to qualify for the incentive payments and basically most hospitals can't meet it in the time frame set up. Even the "most wired" hospitals won't meet the standards in time. I realize that public comment on the proposed rule is currently being solicited but I wanted to put this issue on your radar screen.**

1. **Would you and your staff at CMS be willing to work with me on this issue?**

   The Administration is willing to work with you and your colleagues in achieving high participation in the incentive programs. In addition, the Administration realizes that building a nationwide health information technology infrastructure will require a close partnership with medical providers and hospitals. To achieve high participation rates and make this program a success in transforming the health care system, the Administration has and will continue to work with stakeholders in attaining the goals of this program specified by the Congress in the Recovery Act.

   CMS has been working to engage partners and stakeholders in implementing the health IT (HIT) provisions of the Recovery Act. The proposed definition of "meaningful use" of certified EHR technology is based primarily on recommendations from the National Committee on Vital Health Statistics (NCVHS), the HIT Policy Committee, and the HIT Standards Committee, which are Federal Advisory Committees consisting of representatives from the public and private sectors. Last summer, the HIT Policy Committee, whose membership includes health policy experts, providers, and public health officials, submitted its recommendations on meaningful use (available electronically at http://healthit.hhs.gov) to ONC. More than 700 public comments on these recommendations were received. In addition, ONC and CMS hosted 21 teleconference listening sessions with rural providers, small practices, small hospitals, CAHs, and urban safety net providers that typically have below average adoption rates of HIT, to hear their perspectives and obtain their input on the definition of meaningful use. More than 200 representatives from these target audiences participated on the calls. CMS reviewed input from these and additional sources to help inform the definition of "meaningful use".

   In addition, ONC administers programs to provide assistance and technical support to providers and enable coordination and alignment within and among states in building the necessary infrastructure. The Health Information Technology Extension Program offers grants to establish regional extension centers that offer technical assistance, guidance and information on best practices to support and accelerate health care providers' efforts to

become meaningful users of EHRs. State Health Information Exchange Cooperative Agreement Program support States or State Designated Entities (SDEs) in establishing health information exchange (HIE) capability among healthcare providers and hospitals in their jurisdictions.

**Abstinence Only Education**

**During the Finance Committee's health reform mark-up, I offered an amendment (that was accepted by the Committee) that restores $50 million for abstinence education programs. The President's FY2011 budget includes a pregnancy prevention initiative that will only fund programs that have been proven, scientifically, to work.**

**A recent study appearing in the Archives of Pediatric & Adolescent Medicine found that abstinence only education programs made a significant difference in delaying sexual activities. The Washington Post recently ran a front page article about these findings.**

2. **In light of that study, would abstinence only programs be included in the President's pregnancy prevention initiative? Essentially, this study states that abstinence only education programs work and there is scientific evidence to back it up.**

   As you know, the President's FY2011 Budget provides resources to support evidence-based teen pregnancy prevention approaches that are medically accurate and age appropriate; to carry out evaluations; and to provide comprehensive services to pregnant and parenting adolescents. Funding of $129 million will support:
   - Community evidence-based programs that have been proven effective through rigorous evaluation to reduce teenage pregnancy, behavioral risk factors underlying teenage pregnancy, or other associated risk factors;
   - Research and demonstration projects to develop, replicate, refine, and test additional models and innovative strategies for preventing teenage pregnancy; and
   - Training and technical assistance, evaluation, outreach, and additional program support activities.

   The findings of the recent study appearing in the Archives of Pediatric & Adolescent Medicine suggest that this kind of abstinence education program would be competitive for grant funding through HHS's new teen pregnancy prevention program.

**Medicare Physician Fee Schedule**

**The President's budget also addresses fixing the Medicare physician fee schedule. I am a strong supporter of physicians participating in Medicare and want to make sure that they are being paid appropriately so beneficiaries will continue to receive high quality health care.**

3. **Could you walk us through the details of how the President's budget would restore payment for physicians participating in Medicare? How would it be financed? Do**

The Administration supports comprehensive but fiscally responsible reforms to the payment formula. The Administration believes Medicare and the country need to move toward a system in which doctors face better incentives for providing high-quality care rather than simply more care.

To promote more honest and transparent budgeting, the FY 2011 Budget includes an adjustment totaling $371 billion over ten years (FY 2011–FY 2020) to reflect the Administration's best estimate of future Congressional action, based on Congress' repeated interventions on scheduled physician payments in recent years. However, this adjustment does not signal a specific Administration policy. I look forward to working with you and members of Congress to reform Medicare's payment methodology for physicians' services.

**Senator Snowe**

**Questions for the Witness:**

**Last year, when this Committee considered an FMAP increase as part of the stimulus package, it was included because states were struggling to serve even their current Medicaid enrollees, never mind facing the growing demand for Medicaid for those that were now eligible. Today, states continue to struggle. The National Association of State Budget Officers reports that "General fund revenues dropped from $670 billion in fiscal 2008 to $609 billion in fiscal 2009, illustrating the severity of the economic downturn." So it should come as no surprise that according to the Rockefeller Institute, state tax collections could take five years or more from when the recession began in December 2007 to recover to prerecession levels. The President's budget contains a six month extension of the increase in FMAP funding from the stimulus package. Yet under CBO's projections, unemployment is projected to remain high for several years.**

1. **What economic assumptions are you making in recommending a six-month extension? Is this a strict time limit or do you envision asking for another extension? And if so, what conditions would warrant that extension before you would recommend that the FMAP increases contained in the stimulus truly sunset? In responding to the economic crisis, how much of the FMAP increase have states spent thus far on the growth in Medicaid enrollment versus filling in state program shortfalls, such as preservation of optional health care services for beneficiaries or averting provider cuts?**

   To protect Medicaid beneficiaries and provide additional fiscal relief to States, the President's FY 2011 Budget proposes to extend, through June 2011, the temporary FMAP increase first provided by the Recovery Act. As of March 12, 2010, the cumulative Recovery Act Medicaid FMAP awards totaled $53.7billion. All increased FMAP funds are used to match eligible Medicaid expenditures.

   The FY 2011 Budget assumes unemployment levels of 10.1% in FY 2010 and 9.5% in FY 2011. Therefore, we believe a six-month extension of the FMAP increase, which includes an additional increase for States with high unemployment, is necessary.

   The Administration is committed to sustaining the Medicaid program through this tough economic period. I welcome the opportunity to work with you, other Senators, and the States to examine whether an extension beyond the six-month period we propose may be needed.

**I note that the President's budget strives to strengthen the health care workforce in our country, particularly in medically underserved areas through programs such as the National Health Service Corps. Maine is one of the most rural states in the nation with much of the state designated as "medically underserved." Today, there are approximately 200 openings for primary care physicians in Maine. While these programs are vital, another critical piece to the health care workforce problem is graduate medical education.**

**As you know, medical students tend to set up practice where they complete their residency. Sadly, the relationship between CMS and residency programs in Maine has been fraught with contention, first with the issue of training at non-hospital sites and now with what is being called a "clarification" of CMS's "redistribution of cost" rule.**

**Following the 1997 Balanced Budget Act, CMS initially allowed hospitals to qualify for new residency slots under a cap when the hospital created "new programs," which CMS defined as programs that received "initial accreditation" by the American College for Graduate Medical Education (ACGME) or other appropriate accrediting body such as the American Osteopathic Association (AOA). Now, more than ten years later, CMS has reversed its prior interpretation and defined "new" program with many criteria in addition to accreditation. And CMS is applying this new policy retrospectively to justify disallowances to hospitals that had relied on the prior interpretation.**

2. **Why has CMS issued these regulations when they are counter to the intent of the Balanced Budget Act of 1997 that created new community-based primary care training programs in underserved areas of this country?**

   This Administration recognizes the importance of primary care within the health care delivery system and acknowledges the value of providing more training for medical residents in the community. It is our intent to make sure Medicare rules encourage and facilitate this kind of activity within the parameters of current law.

   Under Medicare, hospitals are able to receive medical education payments for residents' training outside of the hospital if the hospital incurs "all or substantially all of the costs" of the training. CMS recently provided additional guidance to hospitals and nonhospital sites as to what meets this standard. This issue surfaced during the health reform discussions, and I am happy to work with you to identify new and innovative ways to encourage this type of training.

   With respect to the "new program" requirement, it is important to ensure that cap adjustments are not made for programs that are not actually new programs, that is, programs that existed previously at other hospitals. We believe this policy is consistent with the concern that the Congress articulated in the Conference Report to the Balanced Budget Act of 1997 when establishing the caps on resident positions.

3. **Secondly, in Maine, the threat of CMS's unanticipated actions and retroactive audits posed too great a financial risk for the integrated training program of the University of New England and Southern Maine Medical Center to continue. How can CMS and its contractors work more cooperatively with primary care training programs in the future to minimize confusion and identify problems early on?**

   The Administration is committed to maintaining open lines of communication with the provider and beneficiary communities. In this way, I would encourage providers in your State to contact CMS and its contractors early when they have questions or concerns. Establishing a cooperative relationship and maintaining open lines of communication are the best ways to ensure that CMS, its contractors, and its provider partners can all successfully carry out our shared mission of providing high-quality care to Medicare beneficiaries.

**Senator Bunning**

**Questions for the Witness:**

**In the 2010 Medicare Physician Fee Schedule (MPFS) Final Rule, the Center for Medicare and Medicaid Services (CMS) implemented a variety of changes in payment for physician services, including the use of the results of the American Medical Association's Physician Practice Information Survey (PPIS) into its formula for calculating practice expense relative value units (RVUs).**

1. **Does the formula for determining practice expense RVUs provide payments that are equitable across different types of services? That is, do practice expense payments cover a similar percentage of direct costs for different types of services (for example, office based vs. hospital based, surgery vs. diagnostic tests)? Has this changed with the implementation of the PPIS data?**

   Based on the data available to CMS, the methodology for determining practice expense payments is equitable across different types of services. Recently, the AMA conducted a new Physician Practice Information Survey (PPIS). The PPIS data indicated that the indirect costs of running a physician practice, such as rent and non-clinical labor costs, have increased faster than the direct costs, such as clinical labor and medical equipment. The incorporation of the new PPIS data ensures that the practice expense RVUs reflect the best and most current data available. With that said, CMS is aware of concerns with the impact of using the new PPIS data and established a 4-year transition to the use of the new data beginning in CY 2010.

**Senator Cornyn**

**Question for the Witness:**

**The Administration's FY2011 Budget laid out some broad estimates assuming the health care reform bills passed by the House and Senate become law, but the Budget did not include specific line items indicating the total amount of new outlays or the total amount of Medicare savings associated with health care reform. The Budget does include a $590 billion line item labeled "allowance for health reform" under the "outlays" table on page 151 of the Budget of the U.S. Government for fiscal year 2011.**

1. **Is that $590 billion number a net outlays number for health care reform, which reflects both new mandatory spending under health care reform and health reform's Medicare cuts? If this $590 billion is not a net outlays number, what does it represent and what assumptions were used to calculate it?**

   This calculation is based on an average of the CBO estimates of the House and Senate bills, trended forward to 2020. Specifically, the $590 billion in outlays for health reform are the on-budget net outlays from 2011-2020. They are consistent with our technical budgeting requirements and transparency standards. The important line to focus on, however, is the net deficit reduction effects of health reform of $150 billion over 10 years.

**Please explain the $743 billion line item for "health insurance allowance" on page 170 of the Budget of the U.S. Government, which falls under the table footnoted as "receipt effects."**

2. **Does that $743 billion line item represent total federal receipts from the health care reform proposals? (This seems consistent with receipts table on page 151, which notes receipts of $712 billion from the line item "allowance for health reform" and is slightly lower than $743 billion as it is an on-budget number.) If $743 billion does not represent total receipts from proposed health care reform legislation, what does it represent and what assumptions were used to calculate it?**

   This budget number is derived from the average of the receipt provisions in the House and Senate bills. The number is then trended forward from 2011 to 2020 to provide a 10-year window from FY2011. Overall, likely costs, savings, and revenues from health reform are estimated to reduce the deficit by $150 billion over 10 years while expanding coverage, strengthening Medicare by reducing waste and fraud and extending the life of the trust fund, reducing the Part D coverage gap, improving quality, and reforming insurance practices. It is essential that we lower the rising cost of health care. Rising health care costs are putting an unsustainable burden on families, businesses, the economy and our government. As the numbers indicate, the passage of health insurance reform legislation will reduce this burden and lay the foundation for greater prosperity.

3. **What assumptions led to this number being significantly higher than the Joint Committee on Taxation's revenue estimates of both the House ($574 billion) and Senate ($518 billion) health reform bills?**

   This number is derived from an average of the receipts from the House and Senate bills, trended forward to 2020. Along with reforms that make our healthcare system more efficient and responsive, these changes will lead to deficit reduction of $150 billion over 10 years and ease the burden of rising health care costs on government and the private sector.

**We all know that the Medicare program is in serious fiscal condition. The Administration's Budget predicts that Medicare will spend nearly $7 trillion over the next 10 years. The Medicare Trustees estimate that Medicare has an unfunded liability of nearly $38 trillion. Director Elmendorf of the Congressional Budget Office said that Medicare savings from the health reform legislation cannot be used to "pay for" health reform and simultaneously be used to make Medicare more solvent: "The key point is that the savings to the HI trust fund under the 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."**

4. **What are your plans to ensure the solvency of the Medicare program? Have these plans been scored by CBO or OMB or the Medicare Trustees, and if so, what estimates were provided that demonstrate they will make a measurable impact to extend the solvency of the Medicare Trust Fund?**

   The President and I understand that in order to protect Medicare for current and future beneficiaries, we must act to assure its sustainability. Many of the provisions in the health insurance reform legislation, including the health service delivery reforms, value-based purchasing initiatives, and the Center for Innovation, will go a long way toward aligning Medicare payment incentives and extending the life of Medicare. They provide the underlying structural basis for reforming Medicare's health service delivery system and providing higher quality care at a lower cost. The Office of the Actuary in CMS estimated that the changes in H.R. 3590 would achieve Medicare savings of about $541 billion over 10 years and extend the Hospital Insurance trust fund until 2027, almost an additional 10 years.

**Last year, the President's Budget proposed requiring wealthy Medicare beneficiaries to pay minimally more for the Medicare prescription drug benefit. This is a common-sense change in health care that has bipartisan support.**

5. **Why wasn't this proposal included in the Administration's FY2011 Budget?**

   Currently, higher-income beneficiaries enrolled in Medicare Part B already pay higher Part B premiums, based on a sliding scale according to income. Aligning Part D premiums with Part B premiums makes the Medicare program more consistent, while also easing budgetary pressure posed by the growing costs of the Medicare drug benefit.

The Administration continues to support this concept, but did not include a separate legislative proposal to do so because the policy was already being pursued in the context of Health Insurance Reform legislation.

**The Senate health care reform bill proposes to cut nearly $500 billion from the Medicare program, and then sets up a Payment Advisory Board to make further cuts to the Medicare program.**

6. **What areas of waste and abuse do you see in the Medicare program where those further cuts could come from without hurting beneficiary access to care?**

We must do everything we can do ensure that Medicare spends its resources as wisely as possible. Through careful analysis, the Independent Payment Advisory Board, included in the health insurance reform legislation passed by Congress, will make recommendations to target Medicare spending reductions to areas of excess cost growth, as well as make recommendations to improve the efficiency of health care delivery systems. Existing demonstrations and pilot projects, as well as those authorized in health insurance reform legislation passed by Congress, will provide critical information on delivery system reforms that will allow Medicare to provide higher quality, but less costly care.

In addition, I am committed to making every effort to root out wasteful and fraudulent spending. Part of this effort will be to ensure that the CMS and the HHS Inspector General's office have sufficient resources to identify and take measures to stop fraudulent activities. The President's Budget proposes a historical level of program integrity resources to combat Medicare and Medicaid fraud and abuse. We will also continue working on the HEAT initiative, which brings together HHS and the Department of Justice to collaborate on anti-fraud activities.

While the vast majority of health care providers and beneficiaries are honest, we need to make sure that appropriate controls are in place to stop those with the intent to defraud the Medicare program.

**The Administration's Budget proposes a "Bridge" from the Budget Enforcement Act Baseline to a new "Baseline Projection of Current Policy" outlined on page 158 in Table S-7. Specifically for the Medicare sustainable growth rate (SGR), that bridge uses what it calls an "adjustment" of $371 billion. Under the Budget Enforcement Act, which is federal law, the Congressional Budget Office will say the Administration's SGR policy adds $371 billion to the deficit.**

7. **What recommendations do you have for Congress on this issue since, under the Budget Enforcement Act, this policy will add $371 billion to the deficit?**

The Administration is not proposing any specific policy to fix the Medicare physician payment system. To promote more honest and transparent budgeting, the FY 2011 Budget includes an adjustment totaling $371 billion over ten years (FY 2011–FY 2020) to reflect the Administration's best estimate of the impact of future Congressional action,

based on Congress' repeated interventions to prevent scheduled reductions in physician payments in recent years. We believe this approach allows for honest budgeting to reflect the expected cost of truly addressing this policy. I look forward to working with you and other members of Congress to reform Medicare's payment methodology for physicians' services.

**The FY2011 Budget includes 6-months of additional Medicaid funding for the states, but fails to specify what "strings" will be attached to that funding.**

8. **Under the Administration's Budget, what requirements will be on the states to get a portion of that $26 billion in new Medicaid spending?**

   The President's Budget policy extends the current Recovery Act provision. As such, it would extend the Recovery Act's FMAP requirements. The increased FMAP has been critical in protecting Medicaid beneficiaries and providing additional fiscal relief to States. Medicaid is, by definition, a countercyclical program -- more people become eligible for Medicaid during a recession but the same economic conditions that give rise to more need also result lower State revenues. Although the economy is beginning to improve, States are continuing to experience significant budget problems. The President's FY 2011 Budget proposes to extend, through June 2011, the temporary FMAP increase first provided by the Recovery Act.

9. **Secretary Sebelius, you have been a Governor that has had to run a Medicaid program. Now as Secretary of Health and Human Services, what are your plans to assist states in achieving sustainable long-term budgeting? What tools do you plan to give the states to better manage their programs?**

   As a former Governor, I understand the challenge states face with long-term budgeting. Despite this challenge, we are developing a number of tools to help states better manage their programs.

   First, we are committed to deploying evidence-based tools that States can use to combat waste, fraud and abuse in Medicaid. CMS is currently working with States to assess their activities in the area of program integrity and how successful those activities have been. We have made great headway in this area by conducting routine State Program integrity reviews and, more recently, with the collection and release of the State Program Integrity Assessment (SPIA). SPIA is the first national data collection of State Medicaid program integrity (PI) activities. One of our next steps will be to use the data from SPIA to develop descriptive reports on each State's program integrity activities, and identify target areas needing technical assistance as well as "best practices." We believe SPIA is a tool that will reap long-term benefits for the Medicaid program in terms of administrative and program efficiencies.

   Second, we are also dedicated to ensuring Medicaid beneficiaries have access to economic and efficient quality health care. The Department is in the process of implementing a number of initiatives and reforms that will help bend the cost curve by

improving the quality and efficiency of care being delivered in the Medicaid program. One important initiative is facilitating the widespread adoption of EHRs, which holds great promise for improving health care quality, efficiency, and patient safety. With the passage of the Recovery Act, an estimated $25 billion was authorized to implement Medicare and Medicaid incentive payments for eligible professionals and hospitals to adopt EHR technology. The Recovery Act also provides approximately $2 billion in grant funds in addition to the Medicare and Medicaid incentive payments, to help facilitate the use of EHRs by ensuring the interoperability and exchange of health information and other health information technology initiatives. Combined, these efforts are transforming the Medicaid program and the U.S. health system into a seamless digital environment while seeking to improve the quality and efficiency of care. States have been and will continue to be a close partner as we implement this program together to build a national EHR infrastructure. States will surely benefit from these initiatives and be able to effectively manage their health care programs to reap long-term cost savings.

We appreciate your interest in this area. I would be happy to work with you and your colleagues in the Senate to provide more tools to which States may achieve program efficiencies and higher quality care.

**The Budget included $286 million for comparative effectiveness research, but does not specify what policy will govern the use of those funds.**

**10. What parameters do you believe should guide the use of that funding? Should funds be allowed for research about comparative cost effectiveness?**

Also called Patient-Centered Health Research, this funding continues to build on previous investments to support research that compares the clinical effectiveness of different medical treatments and procedures. The research will never be used to ration care or dictate medical decisions – it simply provides medical research to inform clinical decisions by doctors and patients. Patient-centered research gives doctors and patients the best medical information to help them make the best decisions by comparing treatments and strategies intended to improve health outcomes.

**I appreciate Commissioner Hamburg's February 2, 2010 letter in response to my letter from May 2009, but I believe she failed to answer some important and detailed questions about the emergency contraceptive product, Plan B (levonorgestrel) so I am following up with you directly to get an answer to my questions. Please provide a summary analysis of the impact of over-the-counter (OTC) Plan B approval on help-seeking behaviors.**

**11. What process did the FDA use to consider the potential impact that OTC availability of Plan B might have on help-seeking behavior, including the potential for patients to lose the opportunity to receive counseling about safe sexual practices and the consequences this might have?**

**12. What conclusions did the FDA reach, and more specifically, does the Agency believe that OTC availability of Plan B might have a different impact on the help-seeking**

**13. What data did FDA rely on to inform its views of the impact that OTC availability would have on help-seeking behavior for woman under the age of 18? Please provide details on the manner in which this data was collected, including the actual process used to provide this product to girls under the age of 18 and to collect information about how they used the product.**

**Answer to Cornyn 11, 12 & 13:** As you know, the FDA's policy change regarding 17 year olds was ordered by a court and backed by sound science going back to 2005. The judge in the case, *Tummino v. Torti*, No. 05-CV-366 (E.D.N.Y.), ordered FDA to permit the drug sponsor to make Plan B available to 17 year olds without a prescription. He issued his ruling after finding that FDA's decision-making was marred by improper political interference and that FDA's justification for denying non-prescription access to 17 year olds was "implausible" and "untenable." FDA's Center for Drug Evaluation and Research had previously concluded in August 2005 that the available scientific data were sufficient to support the safe use of Plan B as a non-prescription product for women who are 17 years or older. FDA announced that finding after a rigorous review of the data and information on the product that had been submitted to the agency. The judge did not consider that finding to be tainted by political influence, and, in fact, relied on that finding in explaining his order.

Generally, when considering whether to switch a product from prescription to nonprescription status, FDA evaluates whether the supervision of a licensed practitioner is necessary, including whether the drug is safe and effective for use in self-medication as directed in the proposed labeling. See 21 C.F.R. 310.200(b). Switch of a drug to nonprescription status may require label comprehension studies to assess how well consumers understand the information on the label and actual use studies to assess how well they can actually use the product based upon the label information. FDA is not required to consider the impact of non-prescription availability on help-seeking behavior when deciding whether to switch a product from prescription to nonprescription status. Under the Federal Food, Drug, and Cosmetic Act, drugs are prescription because their toxicity or other potentiality for harmful effect means that they are not safe for use except under the supervision of a licensed practitioner. See 21 U.S.C. 353(b). In contrast, nonprescription drugs do not require the supervision of a licensed practitioner for safe and effective use.

In the case of Plan B, FDA approved the switch of Plan B to nonprescription status for women age 17 and over after determining that the label comprehension and actual use studies supported the safe and effective use of the product without the supervision of a learned intermediary.

FDA does not believe that nonprescription drug availability restricts the ability of a consumer to see his or her physician, pharmacist or other healthcare provider, and obtain

counseling about health conditions. Such counseling is available regardless of the availability of nonprescription products. The availability of nonprescription products gives consumers additional options for safely and effectively managing their health, and complements the options available through health care professionals.

FDA takes its responsibility as a science-based agency very seriously, and as HHS and FDA are faced with additional issues on the complex topic of access to Plan B, we intend to base our decisions on best available science, as well as applicable statutory and regulatory standards.