THE FISCAL YEAR 2013 HHS BUDGET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

MARCH 1, 2012

Serial No. 112–121

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

77–557 PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON ENERGY AND COMMERCE

FRED UPTON, Michigan
Chairman

JOE BARTON, Texas
Chairman Emeritus
CLIFF STEARNS, Florida
ED WHITFIELD, Kentucky
JOHN SHIMKUS, Illinois
JOSEPH R. PITTS, Pennsylvania
MARY BONO MACK, California
GREG WALDEN, Oregon
LEE TERRY, Nebraska
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
Vice Chairman
JOHN SULLIVAN, Oklahoma
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
BRIAN P. BILBRAY, California
CHARLES F. BASS, New Hampshire
PHIL GINGREY, Georgia
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY McMORRIS RODGERS, Washington
GREGG HARPER, Mississippi
LEONARD LANCE, New Jersey
BILL CASSIDY, Louisiana
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. McKINLEY, West Virginia
CORY GARDNER, Colorado
MIKE POMPEO, Kansas
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia

HENRY A. WAXMAN, California
Ranking Member
JOHN D. DINGELL, Michigan
Chairman Emeritus
EDWARD J. MARKEY, Massachusetts
EDOLPHUS TOWNS, New York
FRANK PALLONE, JR., New Jersey
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
GENE GREEN, Texas
DIANA DEGETTE, Colorado
LOIS CAPPS, California
MICHAEL F. DOYLE, Pennsylvania
JANICE D. SCHAKOWSKY, Illinois
CHARLES A. GONZALEZ, Texas
JAY INSLEE, Washington
TAMMY BALDWIN, Wisconsin
MIKE ROSS, Arkansas
JIM MATHESON, Utah
G.K. BUTTERFIELD, North Carolina
JOHN BARROW, Georgia
DORIS O. MATSUI, California
DONNA M. CHRISTENSEN, Virgin Islands
KATHY CASTOR, Florida

SUBCOMMITTEE ON HEALTH

JOSEPH R. PITTS, Pennsylvania
Chairman

MICHAEL C. BURGESS, Texas
Vice Chairman
ED WHITFIELD, Kentucky
JOHN SHIMKUS, Illinois
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
TIM MURPHY, Pennsylvania
MARSHA BLACKBURN, Tennessee
PHIL GINGREY, Georgia
ROBERT E. LATTA, Ohio
CATHY McMORRIS RODGERS, Washington
LEONARD LANCE, New Jersey
BILL CASSIDY, Louisiana
BRETT GUTHRIE, Kentucky
JOE BARTON, Texas
FRED UPTON, Michigan *(ex officio)*

FRANK PALLONE, JR., New Jersey
Ranking Member
JOHN D. DINGELL, Michigan
EDOLPHUS TOWNS, New York
ELIOT L. ENGEL, New York
LOIS CAPPS, California
JANICE D. SCHAKOWSKY, Illinois
CHARLES A. GONZALEZ, Texas
TAMMY BALDWIN, Wisconsin
MIKE ROSS, Arkansas
JIM MATHESON, Utah
HENRY A. WAXMAN, California *(ex officio)*

C O N T E N T S

THE FISCAL YEAR 2013 HHS BUDGET

THURSDAY, MARCH 1, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Whitfield, Rogers, Myrick, Murphy, Blackburn, Gingrey, Latta, McMorris Rodgers, Lance, Cassidy, Guthrie, Barton, Upton (ex officio), Pallone, Engel, Capps, Schakowsky, Christensen, Markey, and Waxman (ex officio).

Staff present: Clay Alspach, Counsel, Health; Gary Andres, Staff Director; Mike Bloomquist, General Counsel; Howard Cohen, Chief Health Counsel; Brenda Destro, Professional Staff Member, Health; Nancy Dunlap, Health Fellow; Paul Edattel, Professional Staff Member, Health; Julie Goon, Health Policy Advisor; Debbee Keller, Press Secretary; Ryan Long, Chief Counsel, Health; Carly McWilliams, Legislative Clerk; Nika Nour, NewMedia Specialist; John O'Shea, Professional Staff Member, Health; Monica Popp, Professional Staff Member, Health; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Phil Barnett, Democratic Staff Director; Alli Corr, Democratic Policy Analyst; Eric Flamm, FDA Detailee; Amy Hall, Democratic Senior Professional Staff Member; Ruth Katz, Democratic Chief Public Health Counsel; Purvee Kempf, Democratic Senior Counsel; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Nelson, Democratic Deputy Committee Staff Director for Health; and Anne Morris Reid, Democratic Professional Staff Member.

Mr. PITTS. This subcommittee will come to order.

As agreed earlier with the Democrat side of the aisle, each side will be recognized for 1 minute for opening statements. Then we can move straight to Secretary Sebelius's testimony and questions. The Chair reminds the members that pursuant to the committee rules, all members' opening statements will be made part of the record. The Chair recognizes himself for 1 minute for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

First, I would like to thank Secretary Sebelius for being here with us today to discuss the fiscal year 2013 budget. One of the most striking features of this year's budget is just how much of it is not dependent upon Congress.

For example, the phrase "ACA Mandatory Funding" appears throughout the budget tables, and this designation means, of course, that the Affordable Care Act requires automatic appropriations for certain items. The phrase "Prevention Fund" also appears numerous times, referencing the Prevention and Public Health Fund, a multibillion-dollar fund over which the Secretary has sole discretion.

Beyond the absence of Congressional authority over these funds, I am deeply troubled by the lack of accountability and transparency practiced by the department, and I hope the Secretary will be able to explain why her department is so late on so many of the rules required by PPACA.

[The prepared statement of Mr. Pitts follows:]

Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health
Hearing on "The FY 2013 HHS Budget"
March 1, 2012

I would like to thank Secretary Sebelius for being here with us today to discuss the FY2013 budget.

One of the most striking features of this year's budget is just how much of it is not dependent upon Congress.

For example, the phrase "ACA Mandatory Funding," appears throughout the budget tables. This designation means, of course, that the Affordable Care Act requires automatic appropriations for certain items.

The phrase "Prevention Fund" also appears numerous times, referencing the Prevention and Public Health Fund – a multi-billion dollar fund over which the Secretary has sole discretion.

Beyond the absence of Congressional authority over these funds, I am deeply troubled by the lack of accountability and transparency practiced by the Department.

Regarding the rule-making process for PPACA, HHS has repeatedly missed deadlines for issuing rules, has issued interim final rules that do not require public comment with no apparent intention to move toward a final rule, and has issued "bulletins" instead of final rules.

One controversial rule that HHS issued as an interim final rule and has caused considerable backlash is the so-called Preventive Services rule.

This illegal and unconstitutional rule mandates that abortion drugs be provided in all health insurance plans with only a very narrow exemption for some churches.

Such a requirement violates a number of legal protections for religious exercise and expression and violates the rights of conscience long protected in our country and enshrined in our Constitution.

Perhaps recognizing the controversy, President Obama announced on February 10, his *intent* to make changes to the interim final rule and referenced an "accommodation."

According to a White House "fact sheet," some religious employers will no longer be required to provide insurance coverage for abortion-inducing drugs, sterilizations and contraception, but insurance companies will be required to do so.

Of course, insurance companies will pay for this "free" benefit with the premiums they collect from the very same organizations who opposed paying for abortion-inducing drugs in the first place.

Ultimately, this is not an argument about contraception or any particular service.

This is about religious liberty and whether people with deeply held moral and religious beliefs should be put in a situation where they have only two choices: comply with the law, thus violating their consciences OR not comply with the law and face ruinous fines, forcing them to close their doors.

I hope the Secretary will be able to explain why her Department is so late on so many of the rules required by PPACA.

And, I hope she has some better answers for us on the Preventive Services rule than what we've heard so far.

Mr. PITTS. The Chair now recognizes the ranking member of the subcommittee, Mr. Pallone, for 1 minute for an opening statement.

OPENING STATEMENT OF FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts, and Secretary Sebelius for being here today.

I know I have to limit my remarks so I just want to say with regard to the Affordable Care Act, I think we are making a lot of progress and I certainly urge the President and the Secretary to continue taking the steps necessary under the ACA to improve our health care system.

But I am also a strong believer in the importance of government investment in advancing science and research. That is why I was also pleased to see the President's continued support towards innovative biomedical and behavioral advancements through investments in the NIH and the FDA.

I was also pleased to see that the administration has proposed an expansion of the Small Business Health Care Tax Credit that could benefit almost 3 billion workers this year. My state of New Jersey has a high cost of living and a high wage base, which has made it tougher for New Jersey small employers to access this tax. I would like to see the wage base in each State included in the calculation for eligibility of the tax credit, and therefore I am planning on introducing legislation that would remedy this issue, and I hope I can work with HHS on this.

So thank you, Madam Secretary, for being here.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

Our witness today will be the Secretary of the Department of Health and Human Services, the Honorable Kathleen Sebelius. Secretary Sebelius, we are delighted to have you back with us today, and you are recognized for 5 minutes for an opening statement.

STATEMENT OF KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. SEBELIUS. Thank you so much, Chairman Pitts and Ranking Members Pallone and Waxman and members of the committee. I am pleased to be with you today to discuss the President's 2013 budget for the Department of Health and Human Services.

Our budget helps to create an American economy built to last by strengthening our Nation's health care, supporting research that will lead to tomorrow's cures and promoting opportunities for American children and families so everyone has a fair shot to reach his or her own potential.

It makes investments that we need right now while reducing the deficit in the long run to make sure that the programs that millions of Americans rely on will be there for generations to come, and I look forward to answering your questions, Mr. Chairman, about the budget, but I want to just take a few minutes to share some of the highlights.

Over the last 2 years, we have worked to deliver the benefits of the Affordable Care Act to the American people. Thanks to the law, we now have 2.5 million additional young millions already getting coverage through their parents' health plans. More than 25 million seniors have already taken advantage of the free recommended preventive services under Medicare, and small business owners are getting tax breaks on their health care bills that allow them to hire more employees. This year we will build on that progress by continuing to support States as they work to establish affordable insurance exchanges by 2014. Once these competitive marketplaces are in place, they will ensure that all Americans have access to quality, affordable health coverage.

But we know that a lack of insurance isn't the only obstacle to care, so our budget also invests in our health care workforce. The budget supports training more than 7,100 primary care providers and placing them where they are needed most. It also invests in America's network of community health centers. Our budget helps health centers provide access to quality care for 21 million Americans, 300,000 more than were served last year.

This budget also continues the administration's commitment to improving the quality and safety of care by spending health dollars more wisely, and that means in health information technology. It means funding the first-of-its-kind CMS Innovation Center, which is partnering with physicians, nurses, private payers, hospitals and others who have accepted the challenge to develop new, sustainable methods for the health care system. In addition, the budget ensures that a 21st century America will continue to lead the world in biomedical research by maintaining funding for the National Institutes of Health.

At the same time, we recognize the need to set priorities, make difficult tradeoffs and ensure we use every dollar wisely. That starts with continuing support for President Obama's historic push to stamp out waste, fraud and abuse in the health care system. Now, over the last 3 years, every dollar we have put into health care fraud has returned more than $7. That is a pretty good investment. Last year alone, those efforts recovered more than $4 billion, which are both in the Medicare and Medicaid trust funds around the country. And this week, our administration arrested the alleged head of the largest individual Medicare and Medicaid fraud operation in history. Our budget builds on those efforts, giving law enforcement the technology and data to spot perpetrators early and prevent payments based on fraud from going out in the first place. The budget also contains more than $360 billion in health savings over the next 10 years, most of which comes from reforms to Medicare and Medicaid. These are significant but they are carefully crafted to protect beneficiaries.

For example, we proposed significant savings in Medicare by reducing drug costs, a plan that not only reduces the costs of pharmaceuticals but puts money back in the pockets of Medicare beneficiaries. The budget makes smart investments where they will have the greatest impact, and it puts us all on a path to build a stronger, healthier and more prosperous America for the future.

Again, thank you, Mr. Chairman, for this invitation,k and I look forward to our conversation.

[The prepared statement of Ms. Sebelius follows:]

STATEMENT OF

KATHLEEN SEBELIUS

SECRETARY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

THE PRESIDENT'S FISCAL YEAR 2013 BUDGET

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 1, 2012

Testimony of
Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
before the
United States House of Representatives
Committee on Energy and Commerce
March 1, 2012

Chairman Pitts, Ranking Member Pallone, Chairman Upton, Ranking Member Waxman, and Members of the Committee, thank you for the invitation to discuss the President's FY 2013 Budget for the Department of Health and Human Services (HHS).

The Budget for the Department of Health and Human Services (HHS) invests in health care, disease prevention, social services, and scientific research. HHS makes investments where they will have the greatest impact, build on the efforts of our partners, and lead to meaningful gains in health and opportunity for the American people.

The President's fiscal year (FY) 2013 Budget for HHS includes a reduction in discretionary funding for ongoing activities, and legislative proposals that would save an estimated $350.2 billion over ten years. The Budget totals $940.9 billion in outlays and proposes $76.7 billion in discretionary budget authority. This funding will enable HHS to: Strengthen Health Care; Support American Families; Advance Scientific Knowledge and Innovation; Strengthen the Nation's Health and Human Service Infrastructure and Workforce; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Complete the Implementation of the Recovery Act.

STRENGTHEN HEALTH CARE

Delivering Benefits of the Affordable Care Act to the American People: The Affordable Care Act expands access to affordable health coverage to millions of Americans, increases consumer protections to ensure individuals have coverage when they need it most, and slows increases in health costs. Effective implementation of the Affordable Care Act is central to the improved fiscal outlook and well-being of the Nation. The Centers for Medicare & Medicaid Services (CMS) is requesting an additional $1 billion in discretionary funding and 136 full-time equivalents to continue implementing the Affordable Care Act, including Affordable Insurance Exchanges, and to help keep up with the growth in the Medicare population.

Expand and Improve Health Insurance Coverage: Beginning in 2014, Affordable Insurance Exchanges will provide improved access to insurance coverage for millions of Americans. Exchanges will make purchasing private health insurance easier by providing eligible individuals and small businesses with one-stop shopping where they can compare benefit plans. New premium tax credits and reductions in cost-sharing will help ensure that eligible individuals can afford to pay for the cost of private coverage through Exchanges. FY 2013 will be a critical year for building the infrastructure and initiating the many business operations critical to enabling Exchanges to begin operation on January 1, 2014. The expansion of health insurance coverage for millions of low-income individuals who were previously not eligible for coverage also begins in 2014. CMS has worked closely with states to ensure they are prepared to meet the 2014 deadline and will continue this outreach in FY 2013.

Many important private market reforms have already gone into effect, providing new rights and benefits to consumers that are designed to put them in charge of their own health care. The Affordable Care Act's Patient's Bill of Rights allows young adults to stay on their parents' plans until age 26 and ensures that

consumers receive the care they need when they get sick and need it most by prohibiting rescissions and lifetime dollar limits on coverage for care, and beginning to phase out annual dollar limits. The new market reforms also guarantee independent reviews of coverage disputes. Temporary programs like the Early Retiree Reinsurance Plan (ERRP) and the Pre-Existing Condition Insurance Plan (PCIP) are supporting affordable coverage for individuals who often face difficulties obtaining private insurance in the current marketplace. Additionally, rate review and medical loss ratio (MLR) provisions helps ensure that health care premiums are kept reasonable and affordable year after year. The already operational rate review provision gives states additional resources to determine if a proposed health care premium increase is unreasonable and, in many cases, help enable state authorities to deny an unreasonable rate increase. HHS reviews large proposed increases in states that do not have effective rate review programs. The MLR provisions guarantee that, starting in 2011, insurance companies use at least 80 percent or 85 percent of premium revenue, depending on the market, to provide or improve health care for their customers or give them a rebate.

Strengthen the Delivery System: The Affordable Care Act established a Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center is tasked with developing, testing, and—for those that prove successful—expanding innovative payment and delivery system models to improve quality of care and reduce costs in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Since the Innovation Center began operations it has undertaken an ambitious agenda encompassing patient safety, coordination of care among multiple providers, and enhanced primary care. These projects can serve as crucial stepping stones towards a higher-quality, more efficient health care system.

HHS is also working to ensure that the most vulnerable in our Nation have full access to seamless, high-quality health care. The Affordable Care Act established a new office to more effectively integrate benefits and improve coordination between states and the Federal Government for those who are eligible for both Medicare and Medicaid. While Medicare-Medicaid beneficiaries make up a relatively small portion of enrollment in the two programs, they represent a significant portion of expenditures. HHS is currently supporting 15 states as they design models of care that better integrate Medicare and Medicaid services and is designing additional demonstrations to continue to improve care.

CMS is currently offering three initiatives that will help spur the development of Accountable Care Organizations (ACOs) for Medicare beneficiaries. ACOs are groups of health providers who join together to give high-quality, coordinated care to the patients they serve. If an ACO meets quality standards, it will be eligible to share in savings it achieves for the Medicare program, and may be subject to losses, offering a powerful incentive to restructure care to better serve patients.

Ensuring Access to Quality Care for Vulnerable Populations: Health Centers are a key component of the Nation's health care safety net. The President's Budget includes a total of $3 billion, including an increase of $300 million from mandatory funds under the Affordable Care Act, to the Health Centers program. This investment will provide Americans in underserved areas, both rural and urban, with access to comprehensive primary and preventive health care services. This funding will create 25 new health center sites in areas of the country where they do not currently exist and provide access to quality care for 21 million people, an increase of 300,000 additional patients over FY 2012. The Budget also promotes a policy of steady and sustainable health center growth by distributing Affordable Care Act resources over the long-term. This policy safeguards resources for new and existing health centers to continue services and ensures a smooth transition as health centers increase their capacity to provide care as access to insurance coverage expands.

Improving Healthcare Quality and Patient Safety: The Affordable Care Act directed HHS to develop a national strategy to improve health care services delivery, patient health outcomes, and population health.

In FY 2011, HHS released the National Strategy for Quality Improvement in Health Care, which highlights three broad aims: Better Care, Healthy People and Communities, and Affordable Care. Since publishing the Strategy, HHS has focused on gathering additional input from private partners and aligning new and existing HHS activities with the Strategy. HHS will enhance the Strategy by incorporating input from stakeholders and developing metrics to measure progress toward achieving the Strategy's aims and priorities. Already, the Strategy is serving as a blueprint for quality improvement activities across the country.

CMS will continue funding for the Partnership for Patients, an initiative launched in April 2011 that sets aggressive targets for improving the quality of healthcare: reducing preventable hospital-acquired conditions by 40 percent and preventable readmissions by 20 percent by the end of 2013, as compared to 2010.

Investing in Innovation: HHS is committed to advancing the use of health information technology (health IT). The Budget includes $66 million, an increase of $5 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate the adoption of health IT and promote electronic health records (EHRs) as tools to improve both the health of individuals and the health care system as a whole. The increase will allow ONC to provide more assistance to health care providers as they become meaningful users of health IT. Furthermore, through the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act, CMS is providing hospitals and medical professionals who participate in Medicare and Medicaid with substantial incentive payments for the adoption and meaningful use of EHRs. As of the end of 2011, CMS had made incentive payments to 15,859 providers who have met the objectives for meaningful use in the Medicare EHR Incentive Program and 15,132 providers who have adopted, implemented, or upgraded EHRs in the Medicaid EHR Incentive Program. By encouraging providers to modernize their systems, this investment will improve the quality of care and protect patient safety.

SUPPORT AMERICAN FAMILIES

Healthy Development of Children and Families: HHS oversees many programs that support children and families, including Head Start, Child Care, Child Support, and Temporary Assistance for Needy Families (TANF). The FY 2013 Budget request invests in early education, recognizing the role high-quality early education programs can play in preparing children for school success. The request also supports TANF and proposes to restore funding for the Supplemental Grants without increasing overall TANF funding.

Investing in Education by Supporting an Early Learning Reform Agenda: The FY 2013 Budget supports critical reforms in Head Start and a Child Care quality initiative that, when taken together with the Race to the Top Early Learning Challenge, are key elements of the Administration's broader education reform agenda designed to improve our Nation's competitiveness by helping every child enter school ready for success.

On November 8, 2011 the President announced important new steps to improve the quality of services and accountability at Head Start centers across the country. The Budget requests over $8 billion for Head Start programs, an increase of $85 million over FY 2012, to maintain services for the 962,000 children currently participating in the program. This investment will also provide resources to effectively implement new regulations that require grantees that do not meet high quality benchmarks to compete for continued funding, introducing an unprecedented level of accountability into the Head Start program. By directing taxpayer dollars to programs that offer high-quality Head Start services, this robust, open competition for Head Start funding will help to ensure that Head Start programs provide the best available early education services to our most vulnerable children.

The Budget provides $6 billion for child care, an increase of $825 million over FY 2012. This funding level will provide child care assistance to 70,000 more children than could otherwise receive services without this increased investment; 1.5 million children in total. In addition to providing funding for direct assistance to more children, the Budget includes $300 million for a new child care quality initiative that states would use to invest directly in programs and teachers so that individual child care programs can do a better job of meeting the early learning and care needs of children and families. The funds would also support efforts to measure the quality of individual child care programs through a rating system or another system of quality indicators, and to clearly communicate program-specific information to parents so they can make informed choices for their families. These investments are consistent with the broader reauthorization principles outlined in the Budget, which encompass a reform agenda that would help transform the Nation's child care system to one that is focused on continuous quality improvement and provides more low-income children access to high-quality early education settings that support children's learning, development, and success in school.

Keeping America Healthy: The President's Budget includes resources necessary to enhance clinical and community prevention, support research, develop the public health workforce, control infectious diseases, and invest in prevention and management of chronic diseases and conditions.

Million Hearts Initiative: The Million Hearts Initiative is a national public-private initiative aimed at preventing 1 million heart attacks and strokes over 5 years, from 2012 to 2017. It seeks to reduce the number of people who need treatment and improve the quality of treatment that is available. It focuses on increasing the number of Americans who have their high blood pressure and high cholesterol under control, reducing the number of people who smoke, and reducing the average intake of sodium and trans fats. To achieve this overall goal, the Initiative will promote medication management and support a network of electronic health record registries to track blood pressure and cholesterol control, along with many other public-private collaborations. In FY 2013, the Budget requests $5 million for CDC to achieve measurable outcomes in these areas.

Preventing Teen Pregnancy: The Budget includes $105 million in the Prevention and Public Health Fund for the Office of the Assistant Secretary for Health for teen pregnancy prevention programs. These programs will support community-based efforts to reduce teen pregnancy using evidence-based models as well as promising programs and innovative strategies. The Budget also includes $15 million in funding for CDC teen pregnancy prevention activities to reduce the number of unintended pregnancies through science-based prevention approaches.

Protect Vulnerable Populations: HHS is committed to ensuring that vulnerable populations continue to receive critical services during this period of economic uncertainty.

Reduce Foodborne Illness: The Budget reflects the Administration's commitment to transforming our Nation's food safety system into one that is stronger and that reduces foodborne illness. To reach this goal, the Budget includes $1.5 billion, an increase of $271 million over FY 2012, for FDA and CDC food safety activities. HHS will continue to modernize and implement a prevention-focused domestic and import safety system. Collaboratively, FDA and CDC are working to decrease the rate of Salmonella Enteritidis illness in the population from 2.6 cases per 100,000 to 2.1 cases per 100,000 by December 2013. In FY 2013, CDC will enhance surveillance systems and designate five Integrated Food Safety Centers of Excellence at state health departments. In addition to working with manufacturers to implement preventive controls, the Budget proposes an FDA food inspection and food facility registration user fee that will aid in providing resources to FDA to ensure the safety and security of the Nation's food supply.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

Biomedical and Behavioral Research: The FY 2013 Budget maintains funding for the NIH at the FY 2012 level of $30.9 billion, reflecting the Administration's priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing medical science to improve health. NIH is generating discoveries that are opening new avenues for disease treatment and prevention and revolutionizing patient care. In FY 2013, NIH will seek to take advantage of such discoveries by investing in basic research on the fundamental causes and mechanisms of disease, accelerating discovery through new technologies, advancing translational sciences, and encouraging new investigators and new ideas.

National Center for Advancing Translational Sciences: In FY 2013, NIH will continue to implement the new National Center for Advancing Translational Sciences (NCATS), established in FY 2012, in order to re-engineer the process of translating scientific discoveries into new medical products. Working closely with partners in the regulatory, academic, nonprofit, and private sectors while not duplicating work going on in the private sector, NCATS will strive to identify innovative solutions to overcome hurdles that slow the development of effective treatments and cures. A total of $639 million is proposed for NCATS in FY 2013, including $50 million for the Cures Acceleration Network.

Medical Countermeasure Development: The HHS Medical Countermeasure Enterprise includes initiatives across the Department covering the spectrum of medical countermeasure development, from early biological research to stockpiling of approved products. The FY 2013 Budget includes $547 million for the Biomedical Advanced Research and Development Authority, an increase of $132 million over FY 2012, to develop and improve next-generation medical countermeasures (MCM) in response to potential chemical, biological, radiological, and nuclear threats. The Budget also provides $50 million to establish a strategic investment corporation that would function as a public-private venture capital fund providing companies developing MCMs with the necessary financial capital and business acumen to improve the chances of successful development of new MCM technologies and products. Together, these investments will provide HHS with new tools to enhance the success of medical countermeasure development.

Enhancing Health Care Decision-Making: The HHS Budget includes $599 million for research that compares the risk, benefits, and effectiveness of different medical treatments and strategies, including health care delivery, medical devices, and drugs, including $78 million from the Patient-Centered Outcomes Research Trust Fund established by the Affordable Care Act. Evidence generated through this research is intended to help patients make informed health care decisions that best meet their needs. This level of funding will primarily support research conducted by NIH, core research activities within the Agency for Healthcare Research and Quality (AHRQ), and data capacity activities within the Office of the Secretary. Resources from the Trust Fund will support comparative clinical effectiveness research dissemination, improved research infrastructure, and training of patient-centered outcomes researchers. HHS core research will be coordinated to complement projects supported through the Trust Fund and through the independent Patient-Centered Outcomes Research Institute.

STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORK FORCE

Investing in Infrastructure: A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The Budget includes $677 million, an increase of $49 million over FY 2012, within HRSA to expand the capacity and improve the training and distribution of primary care, dental, and pediatric health providers. The Budget will support the placement of more than 7,100 primary care providers in underserved areas and begin investments that expand the capacity of institutions to train 2,800 additional primary care providers over 5 years.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILIY OF HHS PROGRAMS

Living Within our Means: HHS is committed to improving the Nation's health and well-being while simultaneously contributing to deficit reduction. The FY 2013 discretionary request demonstrates this commitment by maintaining ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the FY 2013 request includes over $2.1 billion in terminations and reductions to fund initiatives while achieving savings in a constrained fiscal environment. Many of these reductions, such as the $177 million cut to the Children's Hospital Graduate Medical Education Payment Program, the $327 million cut to Community Services Block Grants, and the $452 million cut to the Low Income Home Energy Assistance Program (LIHEAP), were very difficult to make, but are necessitated by the current fiscal environment.

Regarding LIHEAP, the Administration proposes to adjust funding for expected winter fuel costs and to target funds to those most in need. The request is $3 billion, $452 million below the FY 2012 level and $450 million above both FY 2008 and the 2012 request. With constrained resources, the Budget targets assistance where it is needed most. The request targets $2.8 billion in base grants using the state allocation Congress enacted for FY 2012. The request also includes $200 million in contingency funds, which will be used to address the needs of households reliant on home delivered fuels (heating oil and propane) should expected price trends be realized, as well as other energy-related emergencies.

In September 2011, the Administration detailed a plan for economic growth and deficit reduction. The FY 2013 Budget follows this blueprint in its legislative proposals, presenting a package of health savings proposals that would save more than $360 billion over 10 years, with almost all of these savings coming from Medicare and Medicaid. Medicare proposals would encourage high-quality, efficient care, increase the availability of generic drugs and biologics, and implement structural reforms to encourage beneficiaries to seek value in their health care choices. The Budget also seeks to make Medicaid more flexible, efficient, and accountable while strengthening Medicaid program integrity. Together, the FY 2013 discretionary budget request and these legislative proposals allow HHS to support the Administration's challenging yet complementary goals of investing in the future and establishing a sustainable fiscal outlook.

Program Integrity and Oversight: The FY 2013 Budget continues to make program integrity a top priority. The Budget includes $610 million in discretionary funding for Health Care Fraud and Abuse Control (HCFAC), the full amount authorized under the Budget Control Act of 2011 (BCA). The Budget also proposes to fully fund discretionary program integrity initiatives at $581 million in FY 2012, consistent with the BCA. The discretionary investment supports the continued reduction of the Medicare fee-for-service improper payment rate; investments in prevention-focused, data-driven initiatives like predictive modeling; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiatives, including Medicare Strike Force teams and fighting pharmaceutical fraud.

From 1997 to 2011, HCFAC programs have returned over $20.6 billion to the Medicare Trust Funds, and the current three-year return-on-investment of 7.2 to 1 is the highest in the history of the HCFAC program. The Budget proposes a 10-year discretionary investment yielding a conservative estimate of $11.3 billion in Medicare and Medicaid savings and 16 program integrity proposals to build on the Affordable Care Act's comprehensive fraud fighting authorities for savings of an additional $3.6 billion over 10 years.

Additionally, the Budget includes funding increases for significant oversight activities. The request includes $84 million for the Office of Medicare Hearings and Appeals, an increase of $12 million, to continue to process the increasing number of administrative law judge appeals within the statutory 90-day timeframe while maintaining the quality and accuracy of its decisions. The Budget also includes $370 million in discretionary and mandatory funding for the Office of Inspector General (OIG), a 4 percent increase from FY 2012. This increase will enable OIG to expand CMS Program Integrity efforts in areas such as HEAT, improper payments, and focus on investigative efforts on civil fraud, oversight of grants, and the operation of new Affordable Care Act programs.

Additionally, Durable Medical Equipment (DME) Competitive Bidding is providing competitive pricing, while continuing to ensure access to quality medical equipment from accredited suppliers, which will save Medicare $25.7 billion over 10 years and help millions of Medicare beneficiaries save $17.1 billion in out-of-pocket costs over 10 years. The Budget proposes to extend some of the efficiencies of DME Competitive Bidding to Medicaid by limiting Federal reimbursement on certain DME services to what Medicare would have paid in the same state for the same services. This proposal is expected to save Medicaid $3.0 billion over 10 years.

COMPLETING IMPLEMENTATION OF THE RECOVERY ACT

The American Recovery and Reinvestment Act provided $140 billion to HHS programs, of which $110 billion had been spent by grant and contract recipients by the end of FY 2011. The vast majority of these funds helped state and local communities cope with the effects of the economic recession.

Thousands of jobs were also created or saved, including subsidized employment and training for over 260,000 people through the Temporary Assistance for Needy Families (TANF) program Emergency Contingency Fund.

The Recovery Act provided states fiscal relief through a temporary increase in Federal matching payments of $84 billion for Medicaid and foster care and adoption assistance.

HHS Recovery Act funds are also making long-term investments in the health of the American people and the health care system itself. Beginning in FY 2011 and continuing for the next few years, HHS will be investing more than $20 billion to support implementation of health information technology in the health care industry on a mass scale. This effort is expected to significantly improve the quality and efficiency of the U.S. health care system. In addition, $10 billion in Recovery Act funds were invested in biomedical research programs around the country, including a major effort to document genomic changes in 20 of the most common cancers and to build research laboratory capacity. Of more immediate impact, $1 billion has been supporting prevention and wellness programs, including projects in 44 communities with a total combined population of over 50 million aimed at reducing tobacco use and the chronic diseases associated with obesity.

HHS has also met the challenges of transparency and accountability in the management of its Recovery Act funds. More than 23,000 grantees and contractors with Recovery Act funding from HHS discretionary programs have submitted reports on the status of their projects over the last 10 quarters. More than 99 percent of the required recipient reports have been submitted on time and are available to the public on Recovery.gov; non-filers have been sanctioned. Finally, HHS Recovery Act program managers are working hand-in-hand with the Secretary's Council on Program Integrity to ensure that risks for fraud, abuse, and waste are identified and steps are taken to mitigate those risks.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

Mr. PITTS. The Chair thanks the gentlelady and we will now begin questioning, and I will recognize myself for 5 minutes for that purpose.

Regardless of one's opinion of the health care law, I think everyone can agree there is a lot of regulatory uncertainty regarding the rules of the road moving ahead. States, health providers, small businesses and patients have been asking HHS for final or even just proposed Federal rules as they relate to PPACA's exchanges. The stakes are high since taxpayers are on the hook for a new $1 trillion entitlement. With that in mind, I would like to ask you about the status of PPACA rules required by the statute, and given my limited amount, I would respectfully ask that you answer yes or no. I have a series of questions.

First, has HHS released a final rule as it relates to the individual market exchange?

Ms. SEBELIUS. The State-based market exchange, a final rule? No, sir.

Mr. PITTS. Has HHS released a final rule detailing what States must do to receive Federal approval for their exchange?

Ms. SEBELIUS. We have not issued a final rule, sir, but we have certainly put out bulletins and guidance. We are preparing an interim final rule. We want feedback at every point along the way and we are actively working with States around the country——

Mr. PITTS. But a bulletin has no real guidance for the State. You have not proposed a final rule?

Ms. SEBELIUS. We have not proposed a final rule, sir, but they have a lot of guidance and are very actively engaged in the process of helping us shape the final rule.

Mr. PITTS. Thank you. Has HHS released a final rule related to the establishment and operation of a Federal exchange?

Ms. SEBELIUS. Again, no, Mr. Chairman, but we are in the process. I don't think you would want us to do that without actively engaging stakeholders along the way, and that is exactly what we are doing including the last weekend when the governors were in town and we spent hours with state officials talking about——

Mr. PITTS. So the answer is no. Has HHS released a final rule related to Federal accreditation requirements for health plans?

Ms. SEBELIUS. Regarding? I am sorry.

Mr. PITTS. Federal accreditation of health plans.

Ms. SEBELIUS. No, sir.

Mr. PITTS. Has HHS released a final rule related to guaranteed issue and community rating bands?

Ms. SEBELIUS. We do not have the final rules released at this point.

Mr. PITTS. Has HHS released even a proposed rule for cost sharing or federally mandated benefits, otherwise known as essential health benefits?

Ms. SEBELIUS. We have released guidance. Most recently we are talking to States about the interim final rule. We have given them a strategy with a——

Mr. PITTS. But not a final rule?

Ms. SEBELIUS [continuing]. Benchmark plan, and we are preparing the rules as we speak, Mr. Chairman.

Mr. PITTS. No final rule. The Federal requirements on benefit coverage and cost sharing are two of the most basic and critical pieces of information needed for States to implement an exchange. We are less than 18 months from when plans are supposed to enroll customers in exchange plans yet HHS has not even issued a proposed rule on these fundamental pieces of law. Is that correct?

Ms. SEBELIUS. Mr. Chairman, again, we are actively engaged in benchmark plans. We have released guidance. We are getting input on that. We are trying to make sure that when we release an interim rule and when we move to final rules that these are workable arrangements with States, with markets around the country. So that guidance is very much underway. We are engaged in dialog and——

Mr. PITTS. I understand.

Ms. SEBELIUS [continuing]. They are beginning to frame their plans but——

Mr. PITTS. My time is limited.

Ms. SEBELIUS [continuing]. We would agree that we need rules to monitor them.

Mr. PITTS. Let me continue. I would submit this is symbolic with the state of regulation in Washington. States, small businesses and individuals are shoved aside and told that a Federal agency is needed to meddle around in their lives and then we pass a law giving Washington almost universal control over one-sixth of the economy and then Washington writes some vague rules for some parts of the law and delays rules for other parts of the law. Deadlines are not met. States, health care providers and consumers are left in the dark and Washington thinks it can just dump a thousand requirements on States and the private sector at the last minute with no consequences for patient health.

I have just 35 seconds left. Yesterday, I was contacted by Catholic Charities, and I was asked if I would read into the record their actual position on this so-called accommodation because they believe some have mischaracterized where they stand, and upon the announcement of the so-called accommodation, Reverend Larry Snyder, President and CEO of Catholic Charities USA, stated "Catholic Charities USA welcomes the administration's attempt to meet the concerns of the religious community and we look forward to reviewing the final language. We are hopeful that this is a step in the right direction. We are committed to continuing our work to ensure that our religious institutions will continue to be granted the freedom to remain faithful to our beliefs while also being committed to providing access to quality health care for our 70,000 employees and their families across the country." However, upon actually seeing what was proposed and having their position mischaracterized as if they believed the accommodation was sufficient to protect religious liberty, they posted the following clarification: "In response to a great number of mischaracterizations in the media, Catholic Charities USA wants to make two things very clear: One, we have not endorsed the accommodation to the HHS mandate that was announced by the administration on February 10. Two, we unequivocally share the goal of the U.S. Catholic Bishops to uphold religious liberty and will continue to work with

the USCCB towards that goal. Any representation to the contrary is false."

[The information follows:]

"In response to a great number of mischaracterizations in the media, Catholic Charities USA wants to make two things very clear:

1. We have not endorsed the accommodation to the HHS mandate that was announced by the Administration on February 10.

2. We unequivocally share the goal of the US Catholic bishops to uphold religious liberty and will continue to work with the USCCB towards that goal.

Any representation to the contrary is ***false***."

Catholic Charities USA.
Working to Reduce Poverty in America.

-http://www.catholiccharitiesusa.org/
Emphasis Added
http://www.catholiccharitiesusa.org/page.aspx?pid=1174

Mr. PITTS. Now the Chair recognizes the ranking member, Mr. Pallone, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

Madam Secretary, I apologize but I have to try to get in two questions, one on Children's Graduate Medical Education and the other is on cosmetic user fees, so if I cut you short on the first one, it is only because I want to get to the second one.

I want to say I am pleased that the administration has come to its senses and included funding for the Children's Graduate Medical Education, or CHGME, in this year's budget. However, I am dismayed that the White House only proposes $88 million, approximately one-third the amount which Congress appropriated for the program last year. As you know, there are serious national shortages in many pediatric specialties, shortages which the CHGME program has been crucial in helping to address. Children's Specialized Hospital in New Jersey has told me that significant reductions to the program would exacerbate these shortages and create additional barriers to access to specialty care for children.

So I wanted to ask you, if the CHGME is not adequately funded, which obviously I don't think it is, how do you expect to train these providers, not only for the shortage in primary care pediatrics but also in the specialties with this level of funding essentially?

Ms. SEBELIUS. Well, Mr. Pallone, we have had this discussion before, and I know we share your interest in training of primary care providers and particularly pediatric providers. There are other streams of funding available. We are trying to use what are relatively limited resources to focus on a broad array of primary care training programs, and in a better budget time, we clearly would have proposed additional resources but this reflects tough decisions made at a very difficult time.

Mr. PALLONE. No, and I appreciate that. I just wanted to stress that I just don't think the investments in the pediatric specialty loan repayment program alone will be enough to compensate for the cuts, and I know that the budget eliminates the IME costs and only funds the direct medical expenses for pediatric GME, but the problem is, and again, I am very conscious of this and I am not saying this to you personally, but I always think that we worry about adults, particularly senior citizens, and then at the same time we were not doing what we should for kids. And so the administration has not proposed to completely cut the IME funding for adults in the Medicare population but eliminates this funding that directly benefits the health of kids, and it just seems like the kids are always taking the back seat. It is not just here, it is in so many other aspects of the budget, and I just think the consequence of that is that, you know, we are really going to threaten the already vulnerable pediatric health care workforce.

But let me get to my second question on cosmetic user fees. The President's budget for the FDA includes a proposed new user fee that would address cosmetic safety, and that fee would cover activities relating to the establishment of registration fees, cosmetic standards and refine inspections and sampling of imported and domestic products. You know that myself, Mr. Dingell and Mr. Waxman have been working on a proposal that would require registration of cosmetic facilities and listing of products requiring substan-

tiation of the safety of cosmetic products, requiring adverse-event reporting and giving FDA the authority to recall cosmetic products. It is obvious the administration agrees that the cosmetics program is in need of resources because your budget includes fees for activities like registration and standard setting, but if we were to adopt my proposal and add on more responsibilities in the cosmetic area, do you agree that there would be an even greater need for additional fees? That is my question.

Ms. SEBELIUS. Mr. Pallone, we do share your interest in this important area. I think that the fees in the budget would support, according to the FDA, a cosmetic registration program. We would be very eager to work with you looking at other areas that might be appropriate but are reluctant to do that without additional resources, giving the FDA lots of assignments without the resources to carry them out effectively. But this is an area that I think needs attention, which is why the President has proposed the cosmetic registration program and it would allow us to implement and standardize and collect information that just isn't available right now for consumer safety.

Mr. PALLONE. And I appreciate that. I mean, we all want the FDA to do a good job ensuring the safety of cosmetic products, and I think it is critical that we ensure that they have the resources to do it, and I appreciate your——

Ms. SEBELIUS. And we would be eager to work with you to do that.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the chairman of the full committee, Mr. Upton, for 5 minutes for questions.

Mr. UPTON. Thank you, Mr. Chairman.

Welcome, Madam Secretary. A couple things that I would like to ask this morning. I am seeing different numbers in the 2013 budget than the spending levels that you provided to the committee a year ago, and I don't know if you want to respond by letter in response back, but let me just walk you through a couple things. Last year, you stated that HHS was estimated to spend $400 million on State exchange grants in fiscal year 2012 but according to your latest budget, your department will have spent $900 million plus on these very same grants in fiscal year 2012, more than double your estimate from a year ago. Is that correct?

Ms. SEBELIUS. Mr. Chairman, we have spent so far out of the allocation 2 years of a billion dollars about $475 million, and 261 of that was spent by HHS.

Mr. UPTON. No, this is specifically the State exchange grants.

Ms. SEBELIUS. Oh, the State exchange grants.

Mr. UPTON. You might want to come back to us.

Ms. SEBELIUS. And I would be happy to get back. I want to make sure we get all these details.

Mr. UPTON. As a former budget official, we look forward to a written response.

Now, Congress in the President's health care law appropriated a billion dollars for the implementation yet in this year's budget you estimated that the fund will be exhausted by the end of 2012 and

you have asked for another billion to implement the law. Is that correct?

Ms. SEBELIUS. Yes, Mr. Chairman, and that is the question I was answering. I apologize. We had an original $1 billion in the Affordable Care Act when it was passed.

Mr. UPTON. Now it is two.

Ms. SEBELIUS. Pardon me?

Mr. CHAIRMAN. And now it is two.

Ms. SEBELIUS. Well, the CBO estimate in March of 2010 was that it would cost about a billion dollars a year to implement. We have actually well underspent that estimate so we are now in fiscal year 2012. We have spent at HHS about $261 million, total with our other agency partners of $475 million but we think by the end of 2012 that original billion dollars will be spent and 2–1/2 years will have expired. So we are significantly underspending what the estimates were.

Mr. UPTON. Let me put this then in writing and let me point some of these out. I want to get to a question as it relates to my State and my district.

This committee, we received a memo from CRS, Congressional Research Service, outlining possible penalties for religious employers if they failed to comply with the HHS mandate to cover drugs and services that they have religious or moral objections toward, and according to CRS, those penalties of $100 per day per affected individual could be levied against the institution for following their conscience. In my State and in my district, I have a hospital, Borgess Hospital, a pretty large institution. It is part of the Ascension Hospital System in Michigan. They employ throughout the State 31,000 people. So according to this CRS memo, Ascension is likely to be subject to fines of over a billion dollars—that is B as in big—because of that mandate. So my question, Ascension, like many religious-affiliated organizations in fact is self-insured, so the so-called accommodation announced by the White House on February 10th doesn't attempt, as I understand, to address the violation of conscience against self-insured employers. So what are your plans for accommodating self-insured employers with conscience issues like Borgess Hospital?

Ms. SEBELIUS. Mr. Chairman, the accommodation that the President talked about on the 10th of February would apply to the nonexempted employers who currently do not offer contraception because of religious objections. As you know, churches, church auxiliaries, we think many parochial and Catholic elementary schools and high schools are likely to already be totally exempted. Grandfathered plans are totally exempted. The accommodation——

Mr. UPTON. So schools are totally exempted?

Ms. SEBELIUS. If a parochial school meets the definition that is in the IRS where they have a majority of Catholic employees, serve a majority of—or religious employees, serve a majority of——

Mr. UPTON. So how would this impact an institution like Borgess Hospital?

Ms. SEBELIUS. Well, I am getting to that, Mr. Chairman. So that the rule that we intend to propose, we will propose a rule in the near future after reaching out and having dialog with folks. It would require insurance companies in a directly insured plan to

provide contraceptive coverage so that a religious employer who had objections would not have to either pay for or provide or refer people for contraception. We are confident that similar arrangements can be made with self-insured institutions who work with third-party administrators. There is an independent body outside the board. There are a variety of arrangements already in place in the 28 States that have this already in place, and we intend to be informed by that when we propose the rules. So whether it is through a third-party administrator, which would not be the employer group, or a side-by-side plan as operates in Georgetown or many other hospital arrangements, we will offer a variety of strategies to make sure that religious liberties are respected at the same time that millions of women who work in these institutions and spouses of employees and daughters of employees have access to these important health——

Mr. UPTON. I know my time is expired but I am not sure that that is going to work, but I yield back.

Mr. PITTS. The Chair thanks the gentleman. We are voting. We are going to go one more 5-minute break and come back immediately after the vote. The Chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for questions.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Madam Secretary, welcome to the committee.

Ms. SEBELIUS. Thank you.

Mr. WAXMAN. I must say, in the decades that I have been in the Congress, you are one of the finest Secretaries we have had for Health and Human Services, and I am somewhat amused at the questions you are going to get and have already gotten today because you almost can't win. If you came in with rules and regulations that spelled them out, you would be criticized for dumping a lot of regulations on the table without consulting, and now that you are consulting, you are being criticized for not having the rules already in place

I know there is a lot of work to be done leading up to 2014 to create a transparent and competitive marketplace where consumers will be offered quality insurance products that cover their health care needs. Insurers, consumer groups, States and others have been encouraging the administration to share their thoughts early to allow for maximum planning and preparation. I recognize the need to share information early. I also recognize the need to work through issues thoroughly. That is why I was pleased with the issuance of subregulatory guidance on the formation of the essential health benefits package and on the actuarial value and cost sharing and qualified health plans. This starts the conversation early. It allows for input before more formal and lengthy rulemaking is released. You have been criticized for this position, wrongly, in my view. Can you tell us what you see as the advantage of this approach and confirm whether you intend to continue towards formal notice and comment rulemaking process?

Ms. SEBELIUS. Mr. Waxman, I think you have spelled out what has been part of the strategy, which is to actually put in place around framework issues where States need to know, so we do have proposed rules, in answer to the chairman's questions earlier, around the exchange setup. We have proposed rules for Medicaid

expansion, both of which were informed by active conversations from the States. We have now put out lengthy guidance on a strategy toward the essential health benefits and are having many conversations trying to reach the balance between affordable coverage and comprehensive coverage, making sure that we are mindful of the law but know that having a product priced and able to be operated in a State is also an essential piece of the puzzle. So we fully intend to put out interim rules and final rules. You can't enforce without final rules in place. But we want to be informed by State insurance commissioners, employers on the ground, our colleagues in governors' offices across this country, and that dialog is very——

Mr. WAXMAN. Well, that sounds like to me a very reasonable approach.

This hearing is about the budget, although you are going to be asked about the budget, although you are going to be asked about everything, but the budget includes important funding to ensure effective administration of Medicare, Medicaid, child health program, continued implementation of the health care law. The budget request includes an increase of a billion dollars over the fiscal year 2012 level. That includes a request for $864 million for establishing insurance exchanges in the States.

Now, it is essential that Congress meet the President's budget request. Some of my colleagues may wish to deny your agency this funding in an effort to halt the progress of the health reform law. I think this political approach would jeopardize all the progress we made. More than 2.5 million young adults under the age of 26 now have health insurance under their parents' plan. More than 85 million people including those in Medicare and private health insurance plans have access to free preventive coverage. More than 30 States have begun to plan health exchanges, helping make good on the promise of affordable coverage for all, and more premium dollars going to health benefits, not corporate overhead. So this will help consumers get the value for their dollar.

Can you address the critics that are claiming that your budget request for implementation money for the Affordable Care Act is a wasteful overspending by the government? Can you describe the kinds of initiatives that money will be used for?

Ms. SEBELIUS. Well, Mr. Waxman, the additional billion dollars in Medicare and Medicaid is for really two categories. One is about $800 million that actually is for the one-time build-out of the federally operated exchange program—IT, consumer outreach, the variety of services that will be needed for those areas in the country where the State has chosen not to set up a State-based exchange or wants a State-based exchange in partnership with the Federal government, and we will be picking up the other pieces. So part of the dollars are for that. Part of the dollars actually about $200 million are directed toward increases and enhancements in the Medicare and Medicaid programs themselves. So the overall administration of these two efforts where we have about 118 million people currently enrolled in either Medicare or Medicare and needs to continue to update. I will tell you, Mr. Chairman, even with that additional request, our overall administrative costs for the largest insurance programs in the world are running just under 3 percent, even with that billion-dollar increase.

Mr. WAXMAN. That is very impressive. Thank you.

Mr. PITTS. The Chair thanks the gentleman. The committee will stand in recess until the end of the last vote, and we will reconvene immediately. The committee stands in recess.

[Recess.]

Mr. PITTS. The committee is reconvened, and the Chair recognizes the vice chairman of the subcommittee, Dr. Burgess, for 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman, and Secretary, welcome back to our committee.

I have a lot of stuff to ask today. I know we have 5 minutes, so I will of necessity be having to submit a lot of questions for the record and I really would appreciate a thoughtful yet timely response to those questions, but let me follow up on where Chairman Upton was going a few moments ago. We have got the 2013 budget from the President on the Refundable Premium Assistance Tax Credits, and the line items between the fiscal year 2012 budget as submitted and the fiscal year 2013 budget as submitted are different year by year, and in fact, the total increase in this year's President's budget is $111 billion. So what has happened that accounts for this change? Are you having to reassess the number of people that perhaps might be driven out of employer-sponsored insurance onto an exchange?

Ms. SEBELIUS. Mr. Burgess, the one issue that I think has changed definitively is that there was a legislative change dealing with the adjusted gross income for people in Medicaid versus the exchange, which we feel will actually have an impact on fewer people eligible for Medicaid and more people eligible for the exchange. Much of the changes in those numbers are also again in the Treasury Department budget, not in our budget. I would be glad to get you a very specific answer in writing but I am not as familiar with some of the Treasury issues, but I can tell you that legislative change has impacted the estimates of how many people will be eligible for the exchange, the MAGI rule.

Mr. BURGESS. Fair enough, but this is a budget hearing and that is a 30 percent increase and——

Ms. SEBELIUS. I just——

Mr. BURGESS. We would like——

Mr. SEBELIUS. There is a legislative change. I would be delighted to get additional details from the Department of Treasury.

Mr. BURGESS. From the standpoint of the oversight function of this committee, I think we have to have that.

Now, speaking of the Treasury, can you give us a line item on how much money has been transferred to the Internal Revenue Service for their role in the Affordable Care Act?

Ms. SEBELIUS. Mr. Chairman, let me see if I can get the Treasury number up. I know that of the $474 million, $261 million has been spent by our department, and the rest is our partners. Treasury dollars, we have transferred $210 million to the Treasury Department. In terms of how they have allocated those funds, I cannot answer that question.

Mr. BURGESS. And that was my next question. Do you require for them to provide you with the allocation numbers?

Ms. SEBELIUS. Yes, we do.

Mr. BURGESS. And when do you expect to receive those from Treasury?

Ms. SEBELIUS. Again, I would be happy to get you that answer in writing. I know that is $210 million, and I will give you the detailed report of what we have so far.

Mr. BURGESS. I think it is important.

Ms. SEBELIUS. We get a quarterly report from them in terms of how they are expending and what dollars, and I would be happy to answer that for you.

Mr. BURGESS. Well, they are your partners on this. After all, they are the enforcers who are going to enforce the individual mandate, so I think it is important that you share that information with the committee.

Now, last year, you were asked whether Section 1311(h) of the Patient Protection and Affordable Care Act provided you the authority to exclude doctors and other health professionals from participating in exchange plans. Are you prepared to answer that question today?

Ms. SEBELIUS. Sir, what is the question?

Mr. BURGESS. Section 1311(h) of the Patient Protection and Affordable Care Act that deals with exchanges, (h) starts out, "Beginning January 1, 2015, a qualified health plan may contract with—it goes through A, which is hospitals. Paragraph B is "may contract with a health care provider only if such provider implements such mechanisms to improve health quality as the Secretary may by regulation require." So are you prepared to exclude providers from the exchange? Are you developing that set of criteria? Are providers to see the day soon where they would be prohibited from participating in an exchange if they don't comply with all the things that you set forth?

Ms. SEBELIUS. Mr. Burgess, we see that issue as one that at the State level will be decided between the board of the exchange and the issuers who——

Mr. BURGESS. How about a State that doesn't do an exchange? My State is not right now, as you know, and there will be a Federal exchange.

Ms. SEBELIUS. Pardon me?

Mr. BURGESS. And there may be a Federal exchange if we can get through the problems with the tax code.

Ms. SEBELIUS. We will again make decisions at the Federal exchange level about which issuers who have networks of their own to include based on their quality performance, based on their——

Mr. BURGESS. But the Congress in its wisdom said that you would decide, not that the State would decide.

Ms. SEBELIUS. I am telling you, for the Federal exchange, we will be making decisions about issuers. We do not intend to reach into a State exchange. They will be making the determinations at the State level.

Mr. BURGESS. Well, are you asking us for a change in legislative language in the Affordable Care Act to allow you the freedom to do that?

Ms. SEBELIUS. I am not, Mr. Burgess.

Mr. BURGESS. But it says in statute that you will make that decision, correct?

Ms. SEBELIUS. Well, I am just telling you how I will make the decision. We will be working with the State-based exchanges so they will make determinations based on their issuers. If for some reason there was an outlier, we could have a conversation, but we intend to work with the States as the law intends so the State will set up a State-based exchange. We will at the same time be establishing a program for a Federal exchange.

Mr. BURGESS. And will you exclude providers from an exchange?

Ms. SEBELIUS. This is not an issue of providers, this is an issue of which plans will be able to be operated. Plans have their own networks, and we will be——

Mr. BURGESS. So if you don't belong to a particular ACO, you may not be able to see your patient of long standing. Is that correct?

Ms. SEBELIUS. Mr. Burgess, that is not at all what I said. Clearly, determinations will be made about how many providers, how many plans.

Mr. BURGESS. We might infer that from what you said.

Mr. PITTS. The gentleman's time is expired.

Mr. BURGESS. I thank the Chairman.

Mr. PITTS. The Chair recognizes the gentlelady from California, Ms. Capps, for 5 minutes for questions.

Mrs. CAPPS. Thank you, Honorable Kathleen Sebelius, Secretary of Health and Human Services, for your testimony.

You know, we are all so aware of the challenging economic climate in which we are living. However, I believe on the whole that the President's budget does strike an important balance between curbing spending and promoting the public's health. As a nurse, I know that we cannot reach our health care goals without a strong health care workforce made up of a range of health care professionals. So I would like to ask a couple of questions, if you could discuss briefly what steps have been taken in the budget to ensure that we have a health care workforce well equipped, diverse and large enough so as to help us successfully reach these goals. It is a tall order.

Ms. SEBELIUS. Well, I think you are absolutely right, Ms. Capps, about the workforce being a critical part of this effort to transform the health care system, and certainly primary care providers become essential, not just physicians but nurses, nurse practitioners, mental health technicians, dental assistants. We are very pleased that this budget continues the progress we have made. So far in this administration, we have tripled the number of National Health Service Corps providers. This budget intends to continue the training of 7,100 new health care providers who will be serving in the most underserved areas, and I have the privilege of meeting with some of these young people every day who are thrilled with the idea they can both provide service to their communities or underserved communities as well as having their loans paid off so they don't emerge with so much debt.

We are also, as you know, part of the Affordable Care Act is encouraging more providers to deal with Medicaid patients so changing Medicaid rates to Medicare, using our graduate medical resources to focus on slots for primary care, so we are very aware of the looming issue. If we are going to change from a sick care sys-

tem to a health care system, the primary care workforce and an additional community care workforce is essential, and we are trying to use all the leverage that we have, many of which were part of the Affordable Care Act.

Mrs. CAPPS. Thank you. And I want to just highlight the commitment to the nursing workforce, which has clearly been expanded in the Affordable Care Act including funds to train advanced practice nurses, which can take some of the expensive care costs away and transform them into excellent care that can be delivered by nurses and others.

I am going to be circulating a letter in support of these nursing programs and urge my colleagues to join me in support of them.

Just one other topic I would like to get to. In addition to a robust health care workforce, we all know that improving public health requires investments in research, in development and in innovation. However, during the recent economic downturn, I have heard from researchers, many in my district, about the lack of reliable grant funding now available, especially in the private sector. And this limits their ability to pursue the kind of scientific achievements and advancements that we need, and I think it also highlights the importance of the National Institutes of Health, NIH, which has traditionally been such a bipartisan issue. The President's budget only includes flat funding for NIH. However, reports indicate that management streamlining is going to free up money for 8 percent more grants to be awarded. Would you please expound on that a bit and explain what will go into that process and how it can actually improve the economic situation in many of our Congressional districts?

Ms. SEBELIUS. Well, I certainly share your view that biomedical research is a critical component of not only saving lives but lowering costs and improving strategies so that the leadership at the National Institutes of Health led by Dr. Francis Collins I think have reorganized the resources at that very critical institution so that we anticipate with this budget funding 672 new research grants. New research grants will be funded.

Mrs. CAPPS. Wow.

Ms. SEBELIUS. About a 7.7 percent, almost an 8 increase in current grant funding. As you know, there is also a new Center for Translational Science thanks to work that we were able to do with Members of Congress that focuses on some of the most promising areas, a Cure Acceleration Network that is in place, again, moving resources to the most promising strategies. So yes, funding is flat. About 40 percent of our discretionary budget is in the National Institutes of Health so we found ways to make sure that those critical programs go on and I would say that the administrative costs will be diminished and more of those resources will be focused on the research that needs to go forward.

Mrs. CAPPS. Thank you very much.

Mr. PITTS. The Chair thanks the gentlelady and recognize the gentleman from Kentucky, Mr. Whitfield, for 5 minutes for questions.

Mr. WHITFIELD. Madam Secretary, in the health care act, 2010–2011, it provided for basically $1,250,000,000 for the Prevention Fund, and under the Prevention Fund, you have the authority I

guess almost unilaterally to move that money into various accounts at HHS. So I would like to ask you to provide to the committee for the year 2010 and 2011 the amounts of money that were transferred to which particular accounts, and then from those accounts if grants were made to grantees around the country, the name of the grantee, the amount of the money, the purpose of the grant and the date of the grant. Would you be able to do that for us?

Ms. SEBELIUS. I would be happy to do that.

Mr. WHITFIELD. Thank you. Thank you very much.

Now, one of the things that is a little bit troublesome to me in the President's 2013 budget is that he in essence eliminates part of the anti-lobbying provisions of the use of Federal funds. As you know, in the appropriation bills since the mid-1970s, we have had prohibitions against using Federal funds for lobbying, and to define it more specifically, prohibits using Federal funds to influence in any manner an official of any government to favor, adopt or oppose by vote or otherwise any legislation, law, ratification or policy. Why would the President want to omit that from his fiscal year 2013 budget?

Ms. SEBELIUS. Mr. Whitfield, I have to confess, I am not sure exactly what is being referred to. I know that our fiscal year 2012 budget, our budget, and there may be other statements in other budgets that I am not as familiar with, but our fiscal year 2012 budget actually included additional lobbying restrictions which we are actively working to comply with which not only apply to our department, which have been in place traditionally for years and we have complied with in terms of lobbying but also now apply to downstream grantees who receive money through the Prevention Fund. So we are updating our grant language, enhancing our oversight of grantees, retraining——

Mr. WHITFIELD. Well, I mean, I——

Mr. SEBELIUS. So I am not——

Mr. WHITFIELD. I think that is commendable and I do appreciate it, but the prohibition has been very specific about using those funds at the Federal level, State level or local level, and the President explicitly in his 2013 budget allows those funds to be used at the local level, and my question to you would be, do you know why that action was taken by the White House?

Ms. SEBELIUS. Again, I would be—I will provide a more thorough answer in writing. What I have just been told by our staff is that the language that we are proposing be eliminated is duplicative of existing law, that it already exists in statute. I will verify that and get back to you, but I am not aware of any new measures that we are talking about.

Mr. WHITFIELD. So from your perspective, you are already doing that?

Ms. SEBELIUS. That is what——

Mr. WHITFIELD. Now, the reason I am asking the question is because I have seven pages here of 25 specific instances where grantees of HHS receiving money from HHS are explicitly trying to influence laws at the State and local levels relating to all sorts of issues. For example, in one town in California, Baldwin Park, they are using these—the entity, the grantee, is using this money to reduce the density of fast food establishment and convenience stores,

for example, and we have seven pages of this, and it looks to me just on the surface that it is explicitly violating the law as set out in the Appropriation Act.

Ms. SEBELIUS. Again, Mr. Whitfield, the new language in our budget for fiscal year 2012, we have not issued any new grants where that new language would be applicable. We are updating our grantee advice. We are updating but the prospective language has not impacted any of the grants in place. We are going to comply with the law. The language that has been statutory applied to our use of our Federal funds. We have also complied with that law for years. So I can assure you that the new language attached to the fiscal year budget, and it did go beyond statutory language, is one that we are currently updating and updating grantees about but there have been no grant releases where that new language would apply.

Mr. WHITFIELD. Mr. Chairman, I might just make the comment that it was my understanding that this prohibition also applied to fiscal year 2010 and 2011, so——

Ms. SEBELIUS. Not by grantees, Mr. Whitfield. It applied to us but not our grantees.

Mr. PITTS. The Chair thanks the gentleman.

The gentlelady from Illinois, Ms. Schakowsky, is recognized for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Just in regard to family budgets, I wanted to point out and thank you for the fact that 54 million Americans were provided at least one preventive service in 2011 through their private health insurance plan for no cost, and I think that the consequences of that are probably priceless in terms of colonoscopy screenings and flu shots and all the disease that has been prevented, so this is one of the consequences of the Affordable Care Act.

But I also wanted to tell you that I had the privilege of going out with the Fraud Prevention and Enforcement Action Team on a drive-around, which was very interesting, where there is this real effort to make sure that we are spending all the taxpayer dollars correctly, although we didn't have anything quite as exciting as what we learned earlier this week about a Dallas doctor arrested for a shocking $375 million in health care fraud schemes.

So what I wanted to ask is how the Affordable Care Act contributed to greater oversight and enforcement and what kind of additional—how much money was found through that effort, and that is it.

Ms. SEBELIUS. Well, Ms. Schakowsky, I think there is no question that the Affordable Care Act contains provisions that are probably the toughest anti-fraud provisions ever in the history of the Medicare program. Criminal penalties were enhanced. Civil penalties were enhanced. We were given tools to re-credential providers in some of the most fraud-ridden areas, new resources for these law enforcement teams that are a Justice Department-HHS partnership on the ground. We now have teams in seven cities. We are expanding to nine. We intend to continue that. Probably as important as anything are the resources that allow us to for the first time ever catch up with the private sector and put together a data system where real data is pulled together in real time. In the past,

12 different billing systems had various parts of CMS billing data so you could never identify the provider in Texas in one space. It was coming through too many portals. So data analysis is now in 2 years significantly better than it was in the past and we now have a predictive modeling system to look at billing errors—not errors, billing anomalies and be able to target our resources on the ground to immediately investigate and stop money from going out the door.

So the Attorney General and I were able to announce a couple of weeks ago that $4 billion, the largest amount ever, came back to the taxpayers and to the trust funds because of these anti-fraud efforts, and yesterday alone, as you identified, a provider—I am sorry—on Tuesday in Texas, a provider was arrested who has been fraudulently billing we think 28 or 29 home health agencies. We knew that that was an area fraught with problems and we targeted that area, used the new analytics, identified this provider, but I think it is the first of many, many that will follow.

Ms. SCHAKOWSKY. So did the additional resources and tools in the ACA, was it responsible for this increase in recovery, the $4 billion that were recovered?

Ms. SEBELIUS. I think it was enormously helpful. There is an ongoing underlying fraud program but the new resources and the new tools we have allowed us to for the first time put together some of these technology advances that really have been used by the private sector very effectively for a long time but missing in our critical health care programs.

Ms. SCHAKOWSKY. In the moments remaining, there are two issues that I would like to work with you and your staff on. One is, Medicare beneficiaries are often designated as being in the hospital on an outpatient observation status, and they could be in the hospital up to 3 days or whatever under that status, and they are not really admitted as an inpatient, and this affects when they are sent to a nursing home or put in an ambulance, and often they don't really understand what observation status is. You are in a hospital bed. You think you are in the hospital. You think you have full insurance coverage. I would like to work with you on that.

And the other is, the important information, Hospital Compare, that is a useful tool for consumers, but there is also the feeling that some of the safety-net hospitals for reasons, for example, dealing with non-English speakers, that their ratings get lowered and that concern has been brought to me. I would like to work with you on this. These are little tweaks that I think we can fix. And I want to thank you for the fact that you are working with the States, you are working with Members of Congress to make this a better bill and a better policy. Thank you.

Mr. PITTS. The gentlelady's time is expired.

The gentleman from Michigan, Mr. Rogers, is recognized for 5 minutes for questions.

Mr. ROGERS. Thank you, Mr. Chairman.

Madam Secretary, thank you for being here. I have been working with my Democratic colleague Anna Eshoo on the BARDA reauthorization bill. I would hope that we could submit some questions for the record. It is very important to us and I know it is important to you.

Ms. SEBELIUS. That would be great.

Mr. ROGERS. And we look forward to working with you on that.

In the 2013 budget, how many employees are dedicated and committed to getting the health care law up and implemented and coordinated with the States?

Ms. SEBELIUS. I do have those numbers here if you could give me just a moment to make sure I give you the accurate number. We have 210 people in the division that is specifically working on exchanges, health insurance reform and others. We have about another 146 working on the parts of the Affordable Care Act relating to Medicare and Medicaid, and then some department-wide folks who have picked up basically some of this effort, so about 800 people throughout CMS are actually dedicated to this effort.

Mr. ROGERS. And do you expect that number to rise in future budgets just for the implementation and management and regulatory administration of the health care law?

Ms. SEBELIUS. And this is an fiscal year 2013 number that we are supporting so it includes any increase that we are seeing right now. A lot of what we are doing I think is covered by the folks that we have.

Mr. ROGERS. So my concern was, when the chairman went through, and there is no Federal-State exchange rule, there is no—for States—excuse me. There is no Federal exchange rule. There is no guidance and rule on what is an accredited health plan, nothing that outlines benefits. We have about 18 months. And my concern here is—and I understand what you have been saying, but we have insurance agents who have been a bastion for small business being laid off. As a matter of fact, I had 150 workers at one company, 30 of which were in my district alone, we think there are thousands and thousands across the country, because I think the Medical Loss Ratio rule is wrong. We have a very bipartisan effort to fix it. Can you commit to fixing that today?

Ms. SEBELIUS. We are following the guidance from the very bipartisan National Association of Insurance Commissioners. We adopted their rule on the MLR and we intend to stay with their rule.

Mr. ROGERS. So it is OK that we are going to continue to lose these jobs and we are losing them today, we are going to lose more tomorrow, and these are the very people who are going to try to make some sense out of this massive set of rules that is only going to give them a matter of months before they are fined by the Federal government. You understand why I am concerned, I think.

Ms. SEBELIUS. Well, I think that there is a slight mischaracterization about our progress on the rules. We do have a proposed rule that is out, has been for months, on the framework of the exchange, on——

Mr. ROGERS. But I understand that, but——

Ms. SEBELIUS [continuing]. Medicaid. We have a very detailed bulletin——

Mr. ROGERS. And reclaiming my time. I get it. I have heard your answer on that earlier. That does nothing if you are the person who actually has to raise the money, sell the money—excuse me—sell the product, raise the money, hire the people. A proposed rule does nothing for certainty for me, nothing, and so here is, I guess,

my point: It doesn't seem like there is any sense of urgency about what is going to hit these very companies who are fighting for their very survival, and the one sector of that that was at least going to give them some guidance are now eliminated. The Federal Government by that law and by your rule eliminated these broker agents from even having the opportunity to show up at the small cafe and say let me guide you through this before you get slapped with a $2,800 fine.

Ms. SEBELIUS. But there is no elimination of brokers and agents, and having served as insurance commissioner, I can guarantee you that——

Mr. ROGERS. Reclaiming my time——

Ms. SEBELIUS [continuing]. They are valuable folks.

Mr. ROGERS. That is great, except they are losing their jobs.

Ms. SEBELIUS. The Medical Loss Ratio in no way eliminates brokers and agents. It didn't define brokers and agents——

Mr. ROGERS. It just adds to their costs so they are eliminated through the back door, and Secretary, that is——

Ms. SEBELIUS. Exchanges at any point along the way can——

Mr. ROGERS. We ought to at least just be frank with each other and admit the fact that these brokers are going away. Yes, the law didn't directly say you are going away but the impact of this law is, they are going away. I am very, very concerned.

Let me get to the second part here. I don't have much time left. Thirty percent of doctors according to the AMA have already said they are restricting the number of Medicare patients in their practices. Two-thirds of physicians have looked into opting out of Medicare for treating patients. We see this huge cultural shift in the practice of medicine. They are selling to hospitals at an alarming rate. Costs go up. They are reducing the number of appointments per week for senior citizens and they are stopping to take new patients. How are you going to stop this and fix this for the future? This is a disaster for our seniors and it is something I hope you are spending a lot of time trying to get right.

Ms. SEBELIUS. Well, I think the best way to actually make sure that the 97, 98 percent of doctors who currently have contractual arrangements with Medicare continue those contractual arrangements is a long-term discussion and actual fix of the payment rate, which over the last 3 years expires a week at a time, a month at a time, a year at a time. The President has proposed in his budget and paid for in his budget a 10-year fix for the Sustainable Growth Rate. That is the biggest issue that I hear day in and day out from physicians practicing is, they don't know if they are going to get paid. Being a good payment partner for the 48 million Americans who rely on Medicare benefits I think is the most essential thing, and we would love to work with Congress to get that done long term.

Mr. TERRY. And I would agree with you on that. Also, if you talk to those doctors, the Medicare health care bill has made it almost impossible for them to survive.

Ms. SEBELIUS. The Medicare health care bill?

Mr. ROGERS. No, excuse me, the health care law, which is why you see this cultural shift in the way medicine is practiced.

Mr. PITTS. The gentleman's time is expired.

Mr. ROGERS. And I hope that you get a sense of urgency on this, because people are impacted today.

Thank you. I yield back my time.

Mr. PITTS. The gentleman's time is expired. The Chair recognizes the gentleman from New York, Mr. Engel, for 5 minutes for questions.

Mr. ENGEL. Thank you very much, Mr. Chairman.

And Madam Secretary, I want to echo the remarks that Mr. Waxman made. I think you are doing a fine job as Secretary and I want to thank you for the job and the good work that you do.

I am very proud of the fact that my State, New York, trains the largest number of medical residents in this country. We have over 15,000 residents developing all kinds of lifesaving skills in our State as of 2010 and New York also trains the largest number of primary care physicians in the country. Given the increasing age of our Baby Boomer generation and 32 million newly insured Americans projected to enter into our health care system in the next few years, I am concerned about the significant physician shortage that this country is facing.

So I want to echo the statements that Mr. Pallone made earlier. I was disappointed to see that the President's budget included a 10 percent cut to indirect medical education funding and $177 million cut to children's hospital graduate medical education funding. I think we need to be training more physicians and adequately supporting our teaching hospitals, not cutting their funding as they strive to train more providers. Hospitals already see significant cuts to bad-debt and DSH payments, which disturbs me greatly because we fought for DSH payments for New York in the Affordable Care Act. So as a result of H.R. 3630, the Middle Class Tax Relief and Job Creation Act, bad-debt cuts and DSH payments cuts are there. So I would just ask that the administration reconsider additional cuts, especially when it comes to training our physicians.

Ms. SEBELIUS. Well, again, I share your feeling that a critical piece of this puzzle for the United States having better health care, better patient care, better health is certainly a robust workforce focused on prevention and so we would work with you to make sure that we are using all of the assets, all of the resources to do just that.

Mr. ENGEL. Well, on prevention, one of the best parts of the Affordable Care Act, I think, was the establishment of the Prevention and Public Health Fund. I think that should be a priority, and I was also disappointed to see that significant reductions were made to various HHS agencies including the CDC as part of the budget request. The rationale which we read was that the Prevention Fund would help fund these programs facing cuts, but the point of the Prevention Fund was to add to the budgets of various public health programs, not to just supplant their existing funding. So given the fiscal year 2013 budget request and in light of the fact that the Middle Class Tax Relief and Job Creation Act cut over $5 billion from the Prevention Fund, I am concerned that we won't be able to fulfill the goals of the Prevention Fund. So could you please explain how the various programs facing cuts, especially those at the CDC, will be impacted, given the payroll tax extension legislation which is now law?

Ms. SEBELIUS. Well, I think that we are eager to not only have the basic programs of the Centers for Disease Control and Prevention continue on, they are vital, they are vital to States around the country. They are vital to the health of all Americans and some of the prevention funding, you are correct, is paying for those ongoing programs. I would say that also there are some innovative and new programs that are showing great promise that also are part of that prevention funding and we are going to, now that we have an outline for the further reduction of $250 million, be working closely with Congress to make sure that these initiatives don't take even more disabling cuts. Unfortunately, at the State level, as you know, Congressman, the States have made some serious reductions in their public health budgets. So we are really trying to not only make sure that the national efforts go forward but that the State workers who are embedded in state departments across this country doing vital public health are also continued.

Mr. ENGEL. I want to quickly mention dental care. In a report, the Pew Center says that preventable dental conditions were the main cause for over 830,000 emergency visits in 2009, which is a 16 percent increase from 2006, and in New York, we estimate $32 million was spent treating children for dental-related ailments in emergency rooms in 2008 alone.

I introduced H.R. 1606, the Special Care Dentistry Act, which would require Medicaid programs to provide dental services to aged, disabled and blind beneficiaries, and I am just wondering, is HHS working to address the shortage of dentists in both our urban and rural areas, and how can we encourage more dentists to serve children and vulnerable adults on Medicaid?

Ms. SEBELIUS. Well, Congressman, we would be really eager to work with you on this. It is an enormously challenging problem. I think more so than virtually any other provider group, we see a great shortage of dentists who are willing to participate in the Medicaid program. We are working actively with States and others to figure out strategies to engage more dentists but I would say that we would love to have your strategies, your ideas because it is a challenge in virtually every part of the country, rural and urban, where we see this lack of providers who actually deliver incredibly important health services.

Mr. ENGEL. Thank you, Madam Secretary. I will be in touch with your office on this and another bill that I have introduced, the Moms and Babies Act.

Thank you, Mr. Chairman.

Mr. PITTS. The gentleman's time is expired.

The Chair recognizes the gentlelady from North Carolina, Ms. Myrick, for 5 minutes for questions.

Mrs. MYRICK. Thank you, Mr. Chairman. Thank you, Madam Secretary, for being here.

I want to go back to the Medicaid expansion issue again. I know Dr. Burgess touched on it a little bit. Beginning in 2014 under the health reform law, it will expand to include all non-elderly individuals with incomes below 133 percent of the Federal poverty level, and that accounts for more than half of the newly insured population under the law. The CBO, Congressional Budget Office, estimates that by 2022, Federal outlays for Medicaid are expected to

total $605 billion, more than twice the 2012 amount. Obviously, many millions of new people would be covered by Medicaid at that point but it certainly is a pretty disastrous budget outlook.

So, as you know, the President's budget forces about $60 billion worth of additional Medicaid burden on to States, and States already can't afford their Medicaid programs. I know the problems we have in North Carolina. So long as the administration doesn't allow the States more flexibility and insists on enrolling these millions of new Medicaid recipients, how are we going to afford as a country double spending on the program in less than a decade? And I don't see that the budget really addresses it this year.

Ms. SEBELIUS. Well, Congresswoman, the Affordable Care Act laid out a program, as you say, that in 2014 regardless of where an individual lives in the country, the Medicaid enrollment eligibility will be identical so that individuals up to 133 percent of poverty will qualify for Medicaid. Those up to 400 percent will qualify for tax credits in the exchange program. The vast majority of those new enrollees are paid for by the Federal Government. They do not add to the State budget. In fact, the first several years it is 100 percent Federal funding. It decreases over the first 10 years so that the highest level a State would be paying for those additional enrollees is a 10 percent match. The Congressional Budget Office estimated that actual State expenditures on Medicaid populations would go down, not up, and States will also be saving what is estimated to be about $80 billion that they are spending on an annual basis right now in uncompensated care, having a payment system under a lot of the individuals who come into community hospitals, who come into the health system but have no payment strategy whatsoever.

Mrs. MYRICK. Well, most of that money is paid by us, the Federal Government, when we pay the hospitals. The States don't pay that.

Ms. SEBELIUS. We pay some of it, but I can guarantee you as a former Governor, States pick up an enormous amount of that uncompensated care at the State level also.

Mrs. MYRICK. Right. I yield back, Mr. Chairman.

Mr. BURGESS. Would the gentlelady yield?

Mrs. MYRICK. Yes, I will.

Mr. BURGESS. Madam Secretary, let me just ask you, because when the President came out announcing the compromise a couple of week ago——

Ms. SEBELIUS. I am really having trouble. I am sorry.

Mr. BURGESS. When the President came out and announced the compromise on the conscience in contraception a couple of weeks ago, he described that he wanted this to be free, and I got to tell you, I was a little taken aback by the President's seemingly superficial knowledge of health economics. So have you tried to help educate him when things are free that they are really not free if they have health care or medicine stamped on the side of them? Even assume you get the active pharmaceutical ingredient for next to nothing, which under some generic scenarios you might if you were willing to impose a formulary on all the patients in the country, you still have to involve a doctor's office. A doctor's time is still involved with evaluating the patient and writing the prescription. A doctor is still going to be required to manage that patient, hear

about the complications as they occur, answer their phone calls at 2 o'clock in the morning and the doctor still has to buy liability insurance. So none of those things looks free to me, having practiced medicine for 25 years. Have you tried to help educate the President on the fact that health care is generally not free?

Ms. SEBELIUS. Mr. Burgess, I think what the President was referring to, and I think he understands the economics of the insurance industry very well, is that this directive first of all in the law is to insurers, and in an insurance pool, there is a balance of risk. What is estimated by actuaries, by Federal actuaries, by company actuaries to be free is the provision of contraception to women balanced against unintended and in some cases unhealthy pregnancies. That is not only a no cost but estimated by——

Mr. BURGESS. It was already working. Why did we have to interfere? Obviously it was in the marketplace in that instance.

I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from Georgia, Dr. Gingrey, for 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you.

Madam Secretary, thank you for being here this morning. Ranking Member Waxman was quoted in The Hill newspaper yesterday as saying, and this is a quote, "IPAB is a useful backstop to impose some discipline on Congress to stop out-of-control Medicare health spending." Do you agree with that statement?

Ms. SEBELIUS. I do.

Mr. GINGREY. Does the President believe we need to save the Medicare program from bankruptcy like Ranking Member Waxman obviously does and you obviously do?

Ms. SEBELIUS. I think the President believes very strongly, which is why he has proposed in this budget and supported aspects of the Affordable Care Act——

Mr. GINGREY. And my time is limited, so yes or no is fine on this, and your answer to that is yes, and I thank you for that, Madam Secretary.

Ms. SEBELIUS. I didn't give you an answer, sir.

Mr. GINGREY. I know the President has used the slogan we can't wait to highlight Congressional inaction really on many issues. Tell me this, should we take Ranking Member Waxman's advice and start showing discipline to reform Medicare this year or should we tell our seniors to wait until after the next election? Yes or no.

Ms. SEBELIUS. The President's budget has a very positive proposal for Medicare which not only ensures that the 48 million people have the benefits that are committed to them but that we continue to slow the growth rate, which has happened every year since——

Mr. GINGREY. Well, I understand that, and my time is limited, so let me just say this. I asked you the question, does the President think that we need to address this issue now or——

Mr. SEBELIUS. He would ask that you pass his budget, yes, sir.

Mr. GINGREY. And the answer is yes. Thank you.

Are you aware that the CMS Actuary predicts that the Medicare program could become bankrupt as early as 2016?

Ms. SEBELIUS. Mr. Gingrey, I think that again action is required. We are taking that action. We would ask you to pass the budget

which has additional slowdown in the growth rate, adding another 2 years to the trust fund. As you know, the Affordable Care Act added an additional 12 years to the trust fund and we would love to engage in a more comprehensive discussion as long as we don't blow up the benefits that 48 million people rely on, which seems to be the alternative.

Mr. GINGREY. Madam Secretary, I think I just heard you say that the Affordable Care Act according to the Medicare trustees adds another 12 years.

Ms. SEBELIUS. It was according to the Congressional Budget Office.

Mr. GINGREY. According to the CBO, an extra 12 years. Well, I think that is possibly based in part, Madam Secretary, with all due respect, upon your belief that $500 billion in cuts to Medicare under the Affordable Care Act, Obamacare, can be spent twice and other disingenuous accounting gimmicks. What do you say to that?

Ms. SEBELIUS. This was not our number. It was the Congressional Budget Office number, sir, and also numbers that are included in the Republican proposal that was put forward last year. So there seems to be some bipartisan agreement that we could slow the growth rate of Medicare by $500 billion over the next 10 years.

Mr. GINGREY. Thank you, Madam Secretary. Let me shift to the issue of the individual mandate. In December, actually a December 14, 2010, editorial in the Washington Post, you wrote with Attorney General Holder, and here is what you stated, "It is essential that everyone have coverage. Imagine what would happen if everyone waited to buy car insurance until after they got in an accident. Premiums would skyrocket, coverage would be unaffordable and responsible drivers would be priced out of the market." In your opinion, if the individual mandate is found to be unconstitutional by the Supreme Court, would premiums skyrocket or would the cost curve for PPACA remain unchanged?

Ms. SEBELIUS. I can't speculate about that but I am confident that given the review by the majority of justices who have looked at the bill that the Affordable Care Act will be found constitutional.

Mr. GINGREY. Well, that really wasn't my question. So in your opinion, is the individual mandate the linchpin to the other insurance reforms in the bill?

Ms. SEBELIUS. I think having everyone included in the insurance market is an essential component.

Mr. GINGREY. So in other words, the individual mandate is essential to ensuring that everyone has coverage and the remainder of the bill of course would not work effectively without that coverage?

Ms. SEBELIUS. I didn't say that, sir. I think it is an essential component of the bill.

Mr. GINGREY. Close enough, Madam Secretary. Thank you.

Ms. SEBELIUS. Sir, you can't——

Mr. GINGREY. Let me ask you this question about Medicaid.

Ms. SEBELIUS. Could I answer your question, or not?

Mr. GINGREY. You did. I thank you for——

Ms. SEBELIUS. I did not.

Mr. GINGREY. I thank you for your question, and I have only got 15 seconds left, but let me address Medicaid, and this is going back

to what Representative Myrick addressed but taking a step further. Can you assess the impact of the provision of PPACA requiring States to raise Medicare primary care physician rates up to the Medicare level in 2013 and 2014 with Federal funding for States and doctors, especially in 2015 when the requirement and the funding goes away, resulting in an inevitable cut to their reimbursement? Have you thought about that?

Ms. SEBELIUS. We would hope that Congress would work with us to make sure that that cut does not occur in future budgets.

Mr. PALLONE. Mr. Chairman, can I just——

Mr. GINGREY. Madam Secretary, thank you, and I yield back.

Mr. PALLONE. Mr. Chairman, I just want to ask, you know, I think that Mr. Gingrey was asking questions, then not giving the Secretary the time to answer them. I know that he has only 5 minutes, but I really think if she feels that she needs an opportunity to answer his questions, I don't mind if——

Mr. GINGREY. You know, the gentleman, I think I need to respond to him, Mr. Chairman. You make a statement in regard to my approach, and Mr. Pallone, I think you spent 4–1/2 minutes of your 5-minute allotted time giving a speech. So when I ask questions and I want a yes or no answer, I expect a yes or no answer. It is my time, not hers.

Mr. PALLONE. I didn't——

Mr. GINGREY. She gave her opening 5 minutes.

Mr. PALLONE. I understand, but if you don't give her an opportunity to answer the question and then you go back and suggest what she said and she disagrees that she said that, I mean, it is really not an opportunity for her to respond, in my opinion.

Mr. PITTS. The Chair thanks the gentleman and recognizes Dr. Cassidy for 5 minutes for questions.

Mr. CASSIDY. Hello, Madam Secretary, how are you?

Ms. SEBELIUS. Is that a yes or no question?

Mr. CASSIDY. Believe me, that is a greeting, not a true inquiry. I can imagine how you are.

Listen, you said something earlier to Ms. Myrick which I, you know, was intrigued by. You suggested that under the ACA that Medicaid costs for States will decrease. Now, I know I heard that. The reason I find that curious is the New York Times just had an article speaking about how Medicaid costs have gone from 21 to 23 or 24 percent, expected to rise further. There is a blog, Ed Watch, Education Watch, which is, you know, obviously not even part of this fight except that they are saying that they anticipate continued crowd-out of funding for education by the money required for Medicaid expenditures. In my own State, even though you speak of the newly eligible having 90 percent coverage and at some point falling off or 100 percent falling off to 90, my own State, Louisiana, predicts that there will be $7 billion State general funds required to comply with the ACA over the next 10 years. We may quibble whether it is $7 billion or $5 billion but it is a significant expense.

Now, I say that in context, and if I interrupt, I am not trying to be rude, it is only because we have limited, when you mention that the ACA is going to save the States money, that seems to be contrary to objective analyses from those not connected with government.

Ms. SEBELIUS. Well, Mr. Cassidy, I would love to get you a more detailed answer but I can tell you that part of what is going on is overall Medicaid expenditure and State portion of Medicaid expenditure, two very different numbers. Overall Medicaid expenditure will go up with a number of newly insured Medicaid beneficiaries. What I was referring to is the State's share of that newly insured——

Mr. CASSIDY. So if I may, absolute dollars will increase even if these States' percentage of that total spending decreases?

Ms. SEBELIUS. That is correct.

Mr. CASSIDY. But absolute dollars will still increase?

Ms. SEBELIUS. Absolute dollars certainly, sir. If we pay 90 percent of the costs, I mean the absolute dollars are going up.

Mr. CASSIDY. Now, the next issue that arises though of course is important. I am a doctor that works in a public hospital for the uninsured, and they always point out that when more people are put on Medicaid, my lines get longer because the Medicaid dollar is spread more thinly. And California is kind of like a case study in this right now. Just for everybody—you and I know this—but they receive $2 billion a year for the next 5 years to expand Medicaid coverage. Now they are paying but since then their deficit has caused them to now decrease payments to physicians—Mr. Engel spoke about dentists—to $12 a visit that providers have filed lawsuits to stop this but your administration, your office has filed a friend of the court on behalf of California while acknowledging that low reimbursement does affect access. So I have always been struck that we have the form of insurance without the power of it. Can you respond how if California is paying a dentist 12 bucks to see somebody, we don't really have access, how do we defend that, number one, and number two, how will that improve under the ACA?

Ms. SEBELIUS. Well, I think the reference that Mr. Gingrey made to the increase for Medicaid providers to Medicare rates is part of the strategy. We understand that——

Mr. CASSIDY. Now, of course, it doesn't affect dental because dental is not a Medicare-covered benefit, and so dental I presume will stay at 12 bucks.

Ms. SEBELIUS. Oh, I am sorry. Yes.

Mr. CASSIDY. This is heterogeneous. It doesn't cover specialists, for example. It won't cover many other entities. It is just primary care in particular.

Ms. SEBELIUS. Well, it covers primary care.

Mr. CASSIDY. And that is for 2 years, correct, and then it reverts back to——

Ms. SEBELIUS. It is built in for 2 years in terms of the overall budget but there is no question, I think, that the concerns about provider rates and Medicaid are ones that we share. As you know, the court case was——

Mr. CASSIDY. I know we share that, but how can the ACA make it better if it is, one, increasing cost as an absolute dollar? California is already going bankrupt, which is acknowledged by the administration. And yet somehow as we increase absolute cost and put more people on we are going to somehow improve rates. I don't follow that.

Ms. SEBELIUS. Well, I would say a lot of those folks right now are entering the health care system at various points with no reimbursement strategy whatsoever. So Medicaid rates may be too low in many instances but I would suggest that it is better than no rate at all, which is being absorbed in some way in those same budgets that you are talking about.

Mr. CASSIDY. Twelve dollars a doctor's visit is not. Fair statement? I mean, $12 is way below the threshold for somebody covering their cost and so, again, it seems as if the ACA is providing the form of insurance without the power of it.

Ms. SEBELIUS. Again, this is, as you know, a State-Federal partnership. Decisions about provider rates are made at the State basis. We are trying to work with States to make sure that they don't deny access to beneficiaries based on slashing provider rates.

Mr. CASSIDY. It seems inevitable with the policies, but I am out of time. I yield back.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from Kentucky, Mr. Guthrie, for 5 minutes for questions.

Mr. GUTHRIE. Thank you very much. Thanks for coming this morning.

I kind of want to touch on what my colleague from Kentucky, Congressman Whitfield, was talking about on the grants, the community transformation grants, and there is evidence they are being used to advocate or lobby pending positions, and I would agree that if you look at the language in the budget, you are striking the language that was put in the Appropriations Act but you do leave "no part of any appropriation contained in this act shall be used to pay the salary, expenses of Federal, State" but you do leave in for local. So it seems that the proposal would grant access to the local because it says in the law that no money shall be enacted by Congress without express authority by Congress. So it appears the way I read this that you are asking for authority to do local. But anyway, but the current law, the way I read it, now, that is going forward, obviously it is not enacted because it is a proposed budget. But the grants were put out under the existing laws, as you said, and I think you said it applied to you but not the grantee at the end of his comment.

Ms. SEBELIUS. Pardon me?

Mr. GUTHRIE. You said that the language applied to us, I guess meaning the government, but not the grantee. I am not sure exactly what you meant by that. That is what I was going to ask you on that.

Ms. SEBELIUS. The original language that has been part of the law that we have administered and had our grantees administer applied to grantees lobbying the Federal government. That has been prohibited. That is part of the underlying law. What was added to our appropriation bill in 2012 and what I was trying to explain is that no new prevention grants have been issued under this new language and we are retraining grantees is that a prohibition for grantees to lobby at the local level or the State level is now an additional piece of the law that was not part of the underlying statute. So that is new. We will administer the directives to grantees to comply with that. There have been no funds that have been

issued under the new law, and I think the pages of examples which began to be recited were grantees who are lobbying at either the State or local level, not lobbying the Federal Government.

Mr. GUTHRIE. OK. Well, it says in the current law that you cannot use the grant money intended to design or influence in an any manner a Member of Congress or jurisdiction or an official of any government to favor, adopt or oppose or vote otherwise any legislation or ratification, policy or appropriation. So I don't think it just limits—current law doesn't limit you to Congress. It is any lobbying. And U.S. Code 1913. So the point is, that is the way I read it. It says a Member of Congress or jurisdiction or any official of any government or an official of any government to favor or oppose, vote or otherwise, and maybe that is the misunderstanding because in the Recovery Act on the Web site in the Recovery Act, Connecticut said a grassroots coordinator spent 163 hours establishing community support by educating, advocating adoption of smoke-free policies. There is several. In Idaho, to address obesity through nutrition, and it says working for proposals in the 2012 State legislature for vending machines for schools. And I can give these to you. And then in the grants, so that was Recovery Act money. Now it has gone to community transformation grants and the department that has been approved actually in their grant proposal says they want to pass at least 70 regional local institutional policies to—and the New York public fund says they want a tax on lobby for local—they say advocate but lobby for a tax on sugar-sweetened beverages.

Having said that, my reading of the law is that is a ban on any form of government. Does the department think it is only Federal Government?

Ms. SEBELIUS. Again, Congressman, I apologize. I do not have the existing statute here. I would love to answer this question in writing. I can tell you fiscal year 2012 appropriations through Congress that we just have added new language.

Mr. GUTHRIE. Right.

Ms. SEBELIUS. The new language, which was not part of the underlying law, applied to grantees lobbying at the local level. So——

Mr. GUTHRIE. Except you have a grant based on——

Ms. SEBELIUS. The underlying law clearly didn't cover some of what is covered in the new language.

Mr. GUTHRIE. Well, that may be where we are—I am agreeing with you that the money that—you haven't seen grants out with the appropriation language in section 503 but I think the existing law—and maybe that is where we—because it says to me—and I know you didn't have a chance to read it, and I agree with you, you need the time to read it, but it says any Member of Congress, a jurisdiction or an official of any government, so I think that would be city governments, State governments. And if you all don't think that is the case, I would like to have that in writing what your position is.

Ms. SEBELIUS. I would be glad to do that.

Mr. GUTHRIE. I appreciate that. Thank you.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentlelady from Tennessee, Ms. Blackburn, for 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

Madam Secretary, thank you for staying with us to take these questions. I want to ask you about Section 220. And we had Section 220. The President supposedly——

Ms. SEBELIUS. Section 220 of——

Mrs. BLACKBURN. Of the Obamacare bill, you know.

Ms. SEBELIUS. The Affordable Care Act? Is that——

Mrs. BLACKBURN. Yes, ma'am. The President goes back to 2009 saying we are going to have transparency, we are going to have open government, and this was a major push. Fiscal year 2012 appropriations bill that the President signed included Section 220. This was an important thing. We are going to have transparency, going to let you know where the money gets spent on this bill. Yet we get the 2013 budget and Section 220 has been removed in its entirety.

So we have a lot of concerns about what is happening with the transparency components and how the money is going to be spent. So I would encourage you to look at this and see if you can find out what has happened with the money that was going to be designated to transparency. We would like to have an answer to that one if you do not mind.

Ms. SEBELIUS. I would be glad to do that.

Mrs. BLACKBURN. Thank you. I appreciate that.

In light of that, in trying to keep track of where the money is going with this bill, you and I have talked about TennCare and the lessons that should have been learned from TennCare as the test case for public option health care. One of those we repeatedly or I repeatedly discussed, and I know you didn't think TennCare was a traditional public option program, not sure what we think was a traditional public option, but nonetheless, your estimates for the Obamacare bill were to be a trillion dollars in spending, and now I am looking at the figures for 2014 through 2023 as being a $2 trillion estimate. So you are already running ahead of estimates. Forbes is looking at these programs, these grant programs being about 30 percent over budget. Forbes had an article out on that.

So I just want—you know, our problem with TennCare, Madam Secretary, was that within 5 years it had quadrupled in its cost over the original estimates. So how do you see this playing out and what accommodations are you and your team making for this program doubling and then possibly quadrupling in its anticipated cost?

Ms. SEBELIUS. Well, Congresswoman, I would be happy to try and get you an answer. I don't know what you are quoting. I don't know what it is based on. So I would be delighted to get you a specific answer. We don't think the program will double or quadruple in cost. We tried to give as accurate an estimate as we could at every point all the way.

Mrs. BLACKBURN. Let me ask you——

Ms. SEBELIUS. Two years in, we are underspending a lot of the estimates——

Mrs. BLACKBURN. OK. Let me ask you this. As we worked on this legislation, I asked repeatedly if you had any example where spending these near-term, ramping up all these near-term expenses had resulted in long-term savings. To my knowledge, you

had no example of any program that showed where ramping up these near-term expenses would yield a long-term savings. Were you all ever able to find an example? Because you are running over budget. You have got a budget that has increased 25 percent since 2008. Your estimates are running ahead of what they have been, and we are at record spending, record deficits, record debt in this country. So if you ever came up with that example, I sure would like to see it, and I have got some constituents that would certainly like to see it.

Let me shift gears for just a moment. I want to your narrow religious exemption rule and what I think is a fee-for-faith principle that is out there. USA Today had an op-ed, an editorial, and they made the comment that not only had you crossed the line on religious liberty but you had galloped over it. I just have to ask you, Madam Secretary, did you all consult the Department of Justice before you made this decision?

Ms. SEBELIUS. Which decision are you referring to, Congresswoman?

Mrs. BLACKBURN. Religious liberty, the First Amendment.

Ms. SEBELIUS. Which decision are you referring to?

Mrs. BLACKBURN. The mandate to the Catholic churches. I think you know what I am talking about.

Ms. SEBELIUS. We have consulted with a number of people. Did we consult before we finalized the rule on prevention with the Department of Justice?

Mrs. BLACKBURN. Yes, ma'am.

Ms. SEBELIUS. No, we did not.

Mrs. BLACKBURN. You did not? OK.

Thank you. My time is expired. I yield back.

Mr. PITTS. The Chair thanks the gentlelady.

The Chair recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5 minutes for questions.

Mr. MURPHY. Thank you, Madam Secretary. I want to follow up on the religious freedom First Amendment issue as well. I just want to be sure. If an employer is saying that he or she cannot find it in their conscience in terms of practicing their religion that they cannot pay for a plan or have a plan that allows for or requires provision of abortifacient drugs and they therefore do not provide that plan, just clarify for me, do they pay the $2,000 tax for not having it or do they pay the $3,000 tax for having a plan that is in violation?

Ms. SEBELIUS. There is no penalty attached to the provision of preventive care. There certainly are penalties for employers who don't comply with the law. There also is no abortifacient drug that is part of the FDA-approved contraception. What the rule for preventive care——

Mr. MURPHY. Ma'am, that is not true.

Ms. SEBELIUS. Well, the scientists——

Mr. MURPHY. Isn't the morning-after pill or something like that an abortifacient drug?

Ms. SEBELIUS. It is a contraceptive drug, not an abortifacient.

Mr. MURPHY. Yes or no, does it——

Ms. SEBELIUS. It is not an abortifacient. It does not interfere with a pregnancy. If the morning-after pill were taken and a female were pregnant, the pregnancy is not interrupted.

Mr. MURPHY. Ma'am, I appreciate that is your interpretation.

Ms. SEBELIUS. That is what the scientists and doctors inform me, and——

Mr. MURPHY. We are not talking about scientists, we are talking about religious belief.

Ms. SEBELIUS. I am telling you that——

Mr. MURPHY. Ma'am, I am asking about a religious belief.

Ms. SEBELIUS [continuing]. The definition of an abortifacient——

Mr. MURPHY. In a religious belief, that is a violation of a religious belief based upon those within a religion.

Now, let me expand on that then. So if an employer says I cannot have this plan provided for by the employer whether it is paid for directly or someone says it is going to be paid for by somebody else, do they end up paying the $2,000 tax or the $3,000 tax per employee?

Ms. SEBELIUS. The rule which we intend to promulgate in the near future around implementation will require insurance companies, not a religious employer but an insurance company to provide coverage for contraceptives for employees who choose to access that——

Mr. MURPHY. Ma'am, that is not what I am asking about. Ma'am, I am not asking about that. This is very important. This is a First Amendment issue. You keep talking about these things in a different way.

Let me try and help make this clear, because one of the things I think you say is that if an organization has people within that organization that are not part of that same faith value system, that they therefore couldn't claim an exemption. Am I correct in that? So let us say Catholic Charities has other employees who are not Catholic or a Jewish hospital may have other doctors who are not Jewish or Catholic Charities may provide services to non-Catholics that they therefore could not claim a religious exemption. Is that accurate?

Ms. SEBELIUS. They don't fall under the definition that is total exemption from the rule. They will fall under the secondary rule of a religious objection to the service and——

Mr. MURPHY. But under that, they would still have to provide the objectionable medical services.

Ms. SEBELIUS. Absolutely not. The religious employer who objects to contraception because of religious beliefs will not provide, will not pay for, will not refer employees to an objectionable service. On the other hand, the insurance company will——

Mr. MURPHY. Ma'am——

Ms. SEBELIUS [continuing]. Provide the service to employees——

Mr. MURPHY [continuing]. Let me make sure I understand this correctly. So if a child in school——

Ms. SEBELIUS [continuing]. Upholds religious liberty and it makes sure that it doesn't——

Mr. MURPHY. Ma'am, no it doesn't. Ma'am——

Ms. SEBELIUS [continuing]. Access to benefits.

Mr. MURPHY. Ma'am, no, you are wrong. You are wrong for this reason. You know, you are setting up a rule that not even Jesus and his apostles could adhere to. Jesus was Jewish. He recruited Jewish people—tax collectors, sinners, Mary Magdalene and others—and therefore saying you know what, because you are not bringing all Christians into this fold you can't do this. What you are missing here is because someone else is paying for it, somehow that makes sense. If I go to a tire store, which I recently did, it was buy three, one free tires, I know I am paying for that extra tire by the other three being pumped up or someone else is paying for it by their costs going up somewhere else. It is one thing—I have searched for ways of trying to help you understand it, and I don't know, maybe the administration just refuses to understand so therefore can't happen. Whether or not you have someone else pay for it or whether something else is under the guise of being free, as long as it is imposed upon someone to have this available, that it is still a violation of their faith, which gets into the First Amendment. I don't understand why this isn't clear.

Ms. SEBELIUS. Well, first of all, I think the tire analogy is not quite accurate. Insurance is——

Mr. MURPHY. Well, who is going to pay for it?

Ms. SEBELIUS [continuing]. About a balance of risk——

Mr. MURPHY. Who is going to pay for the——

Ms. SEBELIUS [continuing]. We know because it was done in the Federal employees——

Mr. MURPHY. Who pays for it? There is no such thing as a free service.

Ms. SEBELIUS. The reduction in a number of pregnancies compensates for the cost of contraception. The overall plan——

Mr. MURPHY. So by not having babies born, we are saving money? I just want to get this on the record, Mr. Chairman. So you are saying by not having babies born, we are going to save money on health care?

Ms. SEBELIUS. Providing contraception as a critical preventive health benefit for women and for their children reduces——

Mr. MURPHY. Not having babies born is a critical benefit. This is absolutely amazing to me. I yield back.

Ms. SEBELIUS. Family planning is a critical health benefit for——

Mr. MURPHY. You said avoiding pregnancy——

Ms. SEBELIUS [continuing]. Women in this country according to the Institute of Medicine, and that is again——

Mr. MURPHY. I think that is——

Mr. PITTS. The gentleman's time is expired.

The Chair recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes for questions.

Mr. LANCE. Thank you very much, Mr. Chairman.

Madam Secretary, the President's budget requests the level of exclusivity for follow-on biologics, reducing it from 12 years to 7 years, and I think that that might be counterproductive and I am wondering whether you would be willing to reexamine that. On a bipartisan basis, this committee has repeatedly indicated that it favors the 12-year period. There was a bipartisan vote of 47 to 11 on that issue in this committee.

Ms. SEBELIUS. Well, I think, Mr. Lance, this is an important and ongoing dialog. The balance of making sure we protect research and development, making sure that companies can in fact make a profit when they find a successful strategy, and opportunities for patients to have an affordable adoption that may be lifesaving is, I think, what is at risk here, and certainly I think there is a difference of opinion of whether 12 years is the appropriate time, whether 7 years adequately compensates companies and yet makes more cost-affordable options available.

Mr. LANCE. Thank you. I would encourage you to work with us on that.

Ms. SEBELIUS. I would be glad to.

Mr. LANCE. I favor 12 years, and I appreciate any work we might be able to do together on that.

We are hearing from those who have to implement the new summary of benefits and coverage requirements that the time period may be difficult to meet. Given the fact that employers and plans need to get this done and if they don't comply there are significant financial penalties, might the Department consider any sort of delay of the non-enforcement period?

Ms. SEBELIUS. Well, I think, again, the essential health benefits are a critical component. We put out very detailed guidance because we were hearing from a lot of States, from insurers and others saying tell us what is going on. I think the strategy of suggesting that a benchmark plan already marketed and in place in a State is a really accelerated strategy. This is not something that has to be started from the ground up. This is an ability at a State level to choose a plan, the most popular small employer plan, the Federal health benefit plan, a state health benefits plan that is in place, is marketed, is priced at the State level. We made it very clear in the guidance that this is what we intend to propose. We are trying to get as much feedback as possible from insurers, from States. We have had a very robust discussion and in the very near future will be issuing the interim rule.

Mr. LANCE. Thank you. Regarding the Supreme Court argument on the health care legislation, undoubtedly the Solicitor General's Office will be arguing that case. Does your department also have lawyers who will be involved in the oral argument or is it exclusively the Solicitor General?

Ms. SEBELIUS. It is the Solicitor General who will be involved in the oral argument.

Mr. LANCE. Thank you. I am willing to yield back to any member who is interested in further questions. Thank you, Madam Secretary.

I yield to Dr. Burgess.

Mr. BURGESS. Thank you. It is very kind of you to provide a little additional time.

Madam Secretary, you were here before and we talked a little bit about the difference between a voucher and premium support, and you had some difficulty articulating a difference between the two. I am going to try to help you, because of course under the exchanges, you will provide a subsidy, but that subsidy is not coming in the form of a check or cash to a household. There will presumably be some sort of acknowledgement that this help is now avail-

able to you to help you purchase your insurance in the exchange so that might be regarded as a voucher, a coupon that you could take to the exchange and in return you get a discounted price for your health insurance.

Now, premium support, I don't know, you might have your insurance through the Federal Employee Health Benefits Plan. Many people in the administration do. That is premium support where the FEHBP goes out and takes requests for proposals from all these different insurance companies. There is in fact a bill, H.R. 360. Members of Congress are going to be required to buy their insurance in the exchange after 2014. Members of the administration, members of the Federal agencies are exempted from that requirement. You in fact could experience the world of a voucher versus premium support by supporting H.R. 360, which would move all members of leadership, leadership staff and the administration and the agencies from the FEHBP into the exchanges. Would that be a good idea?

Ms. SEBELIUS. We would be happy to look at it.

Mr. BURGESS. I would appreciate your response.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the first round of questioning. We will now go to Dr. Christensen, who is a member of the full committee, who has sat patiently since the beginning of the hearing, for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman and Ranking Member, I really appreciate the opportunity to sit on this hearing and your generosity in allowing me to participate.

Welcome, Madam Secretary.

Ms. SEBELIUS. Thank you.

Mrs. CHRISTENSEN. Your being here gives me an opportunity to formally and publicly thank for you the unprecedented efforts that the Department has taken under your leadership to end inequalities in health care and health status through your national strategy to end health disparities.

On the other hand, I wanted to say briefly that the 2013 budget does raise some concerns about our ability to meet the goals that you have set out, but I also know that across the budget, President Obama has worked with agencies wherever there are cuts to take steps to ensure that important programmatic activities are not really cut as might appear, that they don't suffer but are covered in other ways, and 5 minutes doesn't give me the opportunity to go through those areas of concern, but would you be willing to meet with the Tri-Caucus to go over some of those areas and show us perhaps where steps have been taken to make sure that those programmatic activities have not been cut?

Ms. SEBELIUS. I would be pleased to do that. As you know, we have tried to work carefully with Members of Congress who share our concern about the health disparities issues present around the country, and we have lots of strategies, and agencies hard at work closing those gaps, and for the first time ever have a national strategy on health disparities that is a real action plan. So we would be delighted to go over that with you and meet with you about it.

Mrs. CHRISTENSEN. Thank you. And the President's budget proposes a single blended Federal matching Medicaid rate. I am sure

there are different opinions about that, but I think that the time has come for the territories to have the same methodology used for setting our match, and we did have that included in the House version of the Affordable Care Act, and the Senate actually agreed to it but we weren't able to get it done because of just technical reasons and how both bills were structured. If given the authority, would you be supportive of setting the match according to the way the States are done on the average income? Right now we are a 50/50 match in statute, and that is very difficult. Would you be supportive of having the authority to set our match as the States are set?

Ms. SEBELIUS. Well, we would certainly be happy to work with you. I know it is a huge issue for the territories and the islands and we are working on that. The framework does not allow us to do that, and we do not have the budget to do that currently. So we would be happy to pursue that discussion.

Mrs. CHRISTENSEN. And if we went into the blended rate, if that does take place, it is my understanding you need about 2 years of history to be able to make the determination, so it would be helpful—we wouldn't mind going into the blended rate if that takes—if that is the way we are going to go.

Just one more question. There are two new institutes at the NIH. One is the one you mentioned on translational medicine and the other one is the National Institute for Minority and Health Disparity Research, one created administratively, the latter one, and the Minority and Health Disparity Institute by the Affordable Care Act. The budget for the National Institute for Minority and Health Disparities is one of the lowest of all of the institutes, and that is despite the major initiatives that we have to eliminate health disparities. Is there language in the budget or would you accept language to bring the National Institute of Minority and Health Disparity Research on par with the other institutes? And I do know that the Research Centers of Minority Institutions would—that program was transferred to the institute and even funding with it, but even that funding was insufficient to support the research centers so it remains under underfunded under the institute. So is there language that would bring the National Institute on Minority and Health Disparity Research on par with the others or would you be willing to accept that language?

Ms. SEBELIUS. Well, again, Congresswoman, I think you have identified that the transfer along with staff and budget actually has significantly enhanced this whole effort over where we were 2 years ago. We would be happy to work with you around ideas and strategies for continuing improvement, but there has been kind of a big move forward I would say from where we were when we began this conversation.

Mrs. CHRISTENSEN. OK, but my understanding it is still underfunded even with moving the RCMI in, so we appreciate your willingness to work with us, Madam Secretary, and thank you for your testimony and your answers.

Ms. SEBELIUS. Thank you.

Mr. PITTS. The Chair thanks the gentlelady.

Madam Secretary, we have one follow-up on each side, if you can stay for that.

Mr. PALLONE. And Mr. Markey too.

Mr. PITTS. And Mr. Markey has come in and would like to ask questions. The gentleman, Mr. Markey, is recognized for 5 minutes for questions.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

This is my 36th year on the committee, on the health care committee, so it has been a long time trying to get to this point where we actually have a plan to deal with the long-term health care problems of our country, and amongst those includes the National Alzheimer's Project Act to deal with this very important issue that costs the Federal Government—Medicare and Medicaid last year spent $130 billion on Alzheimer's patients in America. Unbelievable amount of money, and that is with only 5 million Americans having it. By the time all the Baby Boomers have retired, the cost is going up to maybe $600 billion a year just on Alzheimer's patients if we don't find a cure for it, and it is obviously a budgetary crisis that is looming.

And last week, Madam Secretary, we thank you, you issued your draft national plan pursuant to the National Alzheimer's Project Act, which I am the principal House author of along with Congressman Smith, and I think it is great. One thing I wanted to talk about here today is that at NIH there is $6 billion a year spent on cancer research and there is $3 billion a year spent on AIDS research but only $489 on Alzheimer's, even though 15 million Baby Boomers are going to have it. We have to find a cure.

And so Madam Secretary, I congratulate you and the administration on announcing the addition of $80 million more in this coming year's budget on the research for Alzheimer's. I think that that is absolutely critical, and I congratulate you on that and I just think it has to be dramatically higher, and if there is one thing we should just single out and just say this has to be spared, it is the NIH budget, that just has to go up and up and up because the National Institutes of Health are really the National Institutes of Hope, and in Alzheimer's, there is really going to be a medical catastrophe that hits this country when all the diseases that we have been successful in helping to cure lead to people living so long that half our population winds up in retirement with Alzheimer's. It is going to be an absolute disaster and it is going to cost us a fortune.

And the second thing, Madam Secretary, is in the Affordable Care Act, I was able to include language for an Independence at Home pilot project, and there are now more than three times as many applicants, that is, medical institutions, that are applying for those slots in order to conduct this experiment. I would just like to draw to your attention the fact that the VA has already had a wildly successful program that has 10,000, 11,000 people in it that reduced hospital stays by 60 percent and nursing care days by 80 percent, and so I appreciate all of your efforts in this area but I think it could help us to telescope the time frame that is going to take us in order to put together a program to keep people at home, share it with the institutions that are working hard in partnership to keep them at home, making the patients and their families better able to deal with the disease.

So I was just looking for a little wisdom from you in terms of what your agency is doing and how much of an imperative you see this for our country.

Ms. SEBELIUS. Well, first of all, Mr. Markey, I want to thank you for your tenacious leadership on the Alzheimer's issue and continuing to raise it and make sure it is an issue that is focused on. As you know, not only is there 80 million new research dollars in the 2013 budget, there were also reallocated another $50 million in the 2012 budget at NIH. So it is about a 25 percent increase in Alzheimer's research. We also have proposed a portion of those funds, additional funds, not those funds, for care giving and at-home care because we know family care providers are the largest number of providers for family members.

But I would share your interest, and we look forward to working with you on what is the long-term strategy, how fast we can get there. As you know, some timetables were set for the first time in the National Alzheimer's Plan. There is a lot of agreement that we probably need to move ahead of that pace but at least we have a pace and a measurable pace outlined and so we would look forward to working on getting the resources, getting the research, getting the care-giving strategies in place.

Mr. MARKEY. A fully implemented Independence at Home project could save billions of dollars a year if we could just get to the point where we verify what the VA has already determined.

Ms. SEBELIUS. Well, that is a great point, and we will definitely work with our partners at the VA.

Mr. PITTS. The Chair thanks the gentleman.

Mr. MARKEY. Thank you for your great work. I appreciate it.

Mr. PITTS. The Chair thanks the gentleman and recognizes Dr. Burgess for one follow-up for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

I will just point out to Mr. Markey while he is still here, this is one of the rare instances of bipartisanship in the Affordable Care Act where we worked with your office on getting the Independence at Home language refined and included, so perhaps there is hope down the road.

But actually, going back to State exchanges for a moment, some States are concerned that without the final rules on the exchanges, they are bumping up against a deadline that is going to be pretty tough for them to meet. I mean, they need these rules probably within the next couple of months if they are to be able to finalize their issues to meet the deadlines.

Ms. SEBELIUS. And they will have them shortly. We have the interim final rule out and we intend to finalize the rule in the very near future.

Mr. BURGESS. So we can look for that by, what, the Ides of March? April Fools Day? Tax Day? What day can we——

Ms. SEBELIUS. Shortly.

Mr. BURGESS. Shortly? OK.

Ms. SEBELIUS. So if they need them in the next couple of months, they will definitely have them in the next couple of months.

Mr. BURGESS. And then the essential health benefits rule also will be coming out in that same very short time span?

Ms. SEBELIUS. The essential health benefits rule has not yet been proposed as an interim rule. I am talking about finalizing the exchange rule. That will happen in the very near future. They will have the exchange rule. They will have the Medicaid expansion rule. That has been out as interim final rule. The essential health benefits rule will be promulgated in the near future but there is detailed guidance right now that States are working on.

Mr. BURGESS. I will just make a prediction: that won't happen until after Election Day in November, but that is just me being cynical.

For a State like—let us say, for example, there is a State out there that worries about what is happening under the Affordable Care Act and really thinks the Federal Government is maybe going a little too far on this so they are reticent to set up a State exchange. I mean, I can think of a State that might fall into that category. I may be going there this afternoon. So you are preparing a national exchange for those States that will not either because they haven't had time or because they did not have the inclination will not have an operational State exchange?

Ms. SEBELIUS. There will be a Federal facilitated exchange in some cases operating fully the exchange for States and others in partnership.

Mr. BURGESS. But the Federal Government will step in and provide that operational control. Is that correct?

Ms. SEBELIUS. Pardon me?

Mr. BURGESS. The Federal Government will step in and provide that?

Ms. SEBELIUS. Yes, sir.

Mr. BURGESS. Now, will that be administered through your office or through the Office of Personnel Management?

Ms. SEBELIUS. It will be administered through the CMS, through—we will be operating at HHS the federally funded exchange.

Mr. BURGESS. My understanding is, there will be both a for-profit and a non-for-profit offered under the language of the law. Is that correct? Will there be a not-for-profit Federal exchange?

Ms. SEBELIUS. No, there will not.

Mr. BURGESS. I thought the language of the law said there had to be a for-profit——

Ms. SEBELIUS. No, I think you are talking about the co-op situation.

Mr. BURGESS. No, I am talking about the exchanges, or the Federal exchange for public option, whatever we want to call it.

Ms. SEBELIUS. No, there will not be a not-for-profit. States have that option. That is not at the Federal level, sir.

Mr. BURGESS. Let me ask you this. A lot of talk about the contraception issue and the essential benefits. When will we see—are you proposing that an institution that refuses to comply with your contraceptive mandate, what is going to happen to them?

Ms. SEBELIUS. Sir, I am hopeful that the rule that we intend to promulgate in the very near future, which will be informed by conversations with not only religious employers but labor leaders, women's groups and others and actually greatly informed by the 28 States which have a framework like we are talking about already

in place will indeed satisfy the religious liberty issues and make sure these preventive health benefits are provided.

Mr. BURGESS. Are the noncompliers going to be fined?

Ms. SEBELIUS. Sir, we will get—as you know, this is a situation where——

Mr. BURGESS. Well, let me just share with you something. It bothers me that for the first time in this country, regardless of what the issue is, and I personally support the issue of contraception but at the same time it bothers me that there might be a fine for faith. I don't think that has ever happened before in this country, and I am concerned about the direction——

Ms. SEBELIUS. No one will be fined for faith. This is an issue dealing with insurers——

Mr. BURGESS. Well, why did you propose a two-tier system where some churches might be exempt but a Catholic hospital might not? I mean, that sounds like that the direction you are going.

Ms. SEBELIUS. The exemption, which is in the original rule finalized in January—I am sorry—in February is the language used in the majority of State laws which have some religious exemption. That is where we got that language. It is a definition that is in the IRS code. It is not something that we invented. It is a definition of churches and church-affiliated associations.

Mr. BURGESS. If a State required sterilization as a condition of citizenship, would you be prepared to do that at the Federal level?

Ms. SEBELIUS. Sir, I am not going to answer that question.

Mr. BURGESS. Thank you, Mr. Chairman.

Before we finish up, can I have unanimous consent? Mr. Whitfield had a number of observations that he wanted entered into the record, and I would ask to enter those now under unanimous consent.

Mr. PALLONE. Mr. Chairman, reserving the right to object. I know you handed that to us but we haven't had time to really look at it, so if we could take a look at it before we agree to unanimous consent?

Mr. PITTS. All right. We will wait until you take a look at that, and recognize the Ranking Member, Mr. Pallone, for 5 minutes for questions in follow-up.

Mr. PALLONE. Thank you.

Madam Secretary, I just wanted to give you an opportunity to address somewhat of a follow-up to Dr. Burgess and others have said. Clearly the matter of insurance coverage for FDA-approved contraceptives under the ACA has become controversial. Unfortunately, what I think has been lost in the debate is an understanding of how HHS arrived at the decision it has made, and I would just ask you to take a few moments—you know, I have got 4 minutes or so—to provide the broader picture, to tell us about the ACA's provisions on preventive health services and women's preventive health services, the role of the Institute of Medicine study on coverage of women's preventive health services and the HHS's process in developing these regulations that are now under attack. I know you started to get into that with Dr. Burgess but take the 4 minutes to maybe explain it a little more.

Ms. SEBELIUS. Well, Mr. Pallone, the Affordable Care Act had a provision that as part of a definition of essential health benefits

various populations should be looked at. The recommended strategies for children around immunizations would be included. The strategies for preventive health that are recommended by the United States Preventive Health Services Task Force would be included. And recognizing that too many insurance plans often did not include benefits that were specifically recommended for women's health, we were asked to develop a set of preventive health services for women. We turned to the independent scientifically driven Institute of Medicine and asked them to make recommendations to us. They came back with eight various health benefits—domestic violence screening, mental health benefits, well woman visits and the full range of scientifically recommended contraception services.

We promulgated their rules as part of the strategy for women's health as an interim rule and added a religious exemption, and to be informed by what language should be used in that religious exemption, we looked at the 28 States which have some kind of contraceptive mandate in place right now often for a decade or more operationally right now and we included language that was used by the States in the majority of cases that have an exemption. Many States don't have an exemption at all. That language was put out. It was finalized in February and an additional accommodation was made. We announced that we would have an additional year for religious-based organizations who had a religious objection to the provision of contraceptives so that their implementation date would be deferred until August of 2013, and that we would promulgate additional rules around their ability to both uphold their religious freedoms, not refer, not pay for, not provide contraceptive coverage and yet make sure that women who were janitors, teachers, nurses, employees, the spouses of employees, the daughters of employees would have access to this very critical health benefit.

And so we will be promulgating a rule around the implementation strategy for preventive health services, which will be a huge step forward for American women, knowing that contraception is the most frequently taken prescription drug for women 14 to 44. Ninety-nine percent of women of all religions use contraceptives at some point in their health lives and that often if you purchase contraception out of your own pocket, it can be an expensive strategy. If it is provided within an insurance pool, it not only is no cost but often reduces the cost of the pool.

Mr. PALLONE. Thank you very much. I appreciate it.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

I think that concludes all of our questioning. Thank you, Secretary Sebelius, for again taking time to be with us today and for all of your answers.

I ask unanimous consent that all members' opening statements be made part of the record. Without objection, so ordered.

I remind the members that they have 10 business days to submit questions for the record, and I ask the Secretary to respond to the questions promptly. Members should submit their questions by the close of business on Thursday, March 15th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:40 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Rep. Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health Hearing on "FY 2012 HHS Budget"
March 1, 2012

Welcome to you Secretary. It has been a full year since we have had the pleasure of your company, and you have been busy in that year.
I would like to take this opportunity to compliment you on the great work that is underway on the Affordable Care Act. Here are some of the early accomplishments:

- More than 2.5 million young adults under the age of 26 now have health insurance through their parents plan.
- More than 85 million people, including those in Medicare and private health insurance plans, have access to free preventive coverage.
- More than 30 states have begun planning health exchanges – helping make good on the promise of affordable coverage for all.
- More of your premium dollars are going to health benefits, not corporate profits helping consumers get more value for their dollar.

Your testimony goes into more detail on these points, but I think these facts are important and worth repeating. Millions of Americans are benefiting from the Affordable Care Act in ways that are life changing, life saving and cost saving.
Your budget includes important funding to ensure effective administration of Medicare, Medicaid and CHIP, and continued implementation of the healthcare law.

It is essential that Congress meet the President's budget request. Some of my colleagues may wish to deny your agency this funding in an effort to halt the progress of the health reform law. Such politics would jeopardize access to free preventive care, insurance coverage for those with incurable illnesses, and other preexisting conditions, and reduced costs for prescription medicines for the elderly.

We should not let that happen.

Let me now turn briefly to provisions in the President's budget related to public health. First, I want to commend the President for his ongoing commitment to a strong and effective Food and Drug Administration. We cannot have a better, more productive FDA by weakening its authority as some would have us do. What we need instead are adequate financial resources to back up it up; to make it possible for FDA to do its job to protect the health and safety of the American people. The President's budget does just that.

Second, I also want to applaud the President for his support for biomedical research, community health centers, and our primary care workforce. Even in these difficult economic

times, it is critical that we maintain our investment in these programs that will pay big dividends to millions of Americans in the years ahead.

But I would be remiss if I did not note my disappointment with the President's approach to the Prevention and Public Health Fund. His proposed budget not only cuts the Fund; it also uses the Fund to replace resources that have been taken away from other public health programs.

All this, despite what Democrats and Republicans -- and the experts -- have argued for decades: We must shift the focus of our health care system to services and programs that keep people well, rather than continue to simply pay for medical treatments when they get sick. I know you share this view and hope that you will work with the Congress to help make it a reality.

I recognize that the President's FY 2013 budget makes difficult choices and spreads the responsibility for lowering our country's deficits across the board. I don't agree with all of those choices. I don't support increasing costs for beneficiaries served by Medicare and Medicaid. But I do understand he has proposed this only in the context of shared sacrifice with the highest income among us.

We should recognize the President for having this balanced approach unlike the plan offered by Republicans that targets low income and working class families.

And I would be remiss in not mentioning that although healthcare costs overall are going up, Medicare and Medicaid have controlled cost growth better than private insurance over the last decade. The average annual growth rate per beneficiary was 4.6% in Medicaid and 5.1% in Medicare compared to 7.7% in private insurance. The Affordable Care Act provides opportunities to bring private insurance into the discussion of healthcare costs.

Thank you for taking time today to join us to discuss these important points.

Secretary Sebelius Questions for the Record
House Energy & Commerce Subcommittee on Health
March 1, 2012

The Honorable Joseph R. Pitts

1. The law makes clear that health insurance subsidies are only available to individuals and families enrolled in an American Health Benefit Exchange - which is defined in the law as a state-based exchange. Further, the law requires that in order to be eligible for exchange subsidies the individual must be, "enrolled in through an exchange established by the state." It is clear that many, if not the majority, of states will not set up exchanges, which means the federal government will have to set up and run exchanges in these states. The law does not allow subsidies to flow through federal exchanges.

IRS Commissioner Shulman responded to a Congressional letter, signed by three members of the Subcommittee, on this matter stating, "The statute includes language that indicates that individuals are eligible for tax credits whether they are enrolled through a State-based Exchange or a Federally-facilitated Exchange."

a. Secretary Sebelius, exactly where in the 2,200-page health care law is the term "federally-facilitated exchange" used?

Answer: Section 1321(c) of the Affordable Care Act requires that if a state does not elect to operate an Exchange, or if the Secretary determines that a particular state will not be able to implement an Exchange, the Secretary shall establish and operate an Exchange within that State. The definition of "Exchange" in the Exchange Proposed Rule, published on July 15, 2011 at 45 CFR 155.20, provides that "*Exchange* means a governmental agency or non-profit entity that meets the applicable requirements of this part (part 155) and makes QHPs available to qualified individuals and qualified employers. Unless otherwise identified, this term refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange."

b. Can you provide this Committee with the specific language that authorizes the Administration to allocate funds to individuals via the federal exchange?

Answer: The responsibility for issuing regulations related to premium tax credits is the responsibility of the Department of the Treasury. Section 1.36B-2 of the proposed regulations on the Health Insurance Premium Tax Credit, published in the Federal Register on August 17, 2011, describes certain requirements that make an "applicable taxpayer" eligible for the premium tax credit. Among these requirements is that the taxpayer, or the taxpayer's spouse or dependent is "enrolled in one or more qualified health plans through an Exchange." That rule defines "Exchange" by saying that Exchange has the same meaning as in 45 CFR 155.20, the Exchange proposed rule referenced above, including a Federally-facilitated Exchange.

2. Before the Ways and Means Committee on February 28th, you indicated that there is a legal analysis supporting the Administration's interpretation that subsidies could be paid to individuals enrolled in a qualified health plan in a federally-facilitated exchange. You committed to providing the Ways and Means Committee with such an analysis. Can you provide this Committee with any legal analysis done by the Administration on this issue as well?

Answer: The responsibility for issuing regulations related to premium tax credits is the responsibility of the Department of the Treasury. Section 1.36B-2 of the proposed regulations on the Health Insurance Premium Tax Credit, published in the Federal Register on August 17, 2011 describes certain requirements that make an "applicable taxpayer" eligible for the premium tax credit. Among these requirements is that the taxpayer, or the taxpayer's spouse or dependent is "enrolled in one or more qualified health plans through an Exchange." That rule defines "Exchange" by saying that Exchange has the same meaning as in 45 CFR 155.20, the Exchange proposed rule referenced above, including a Federally-facilitated Exchange.

3. The new health care law has created unprecedented and sweeping authorities for the HHS Secretary to regulate the activities of health insurers, providers, drug and device manufacturers, and employers seeking to offer health insurance to their employees. President Obama has called Super PACs a threat to democracy, yet he now says that cabinet secretaries, including yourself, will appear at fundraisers for a Super PAC that is supporting his campaign. Cabinet officials have participated in political activities in the past but never before has a cabinet secretary been given such enormous power to regulate such a huge industry and to reshape the entire landscape of that industry. Will you ask the President to recuse you from appearing at such fundraisers due to the potential that many people in the health care industry may feel coerced into supporting the President's Super PAC because of the enormous regulatory authority you have over their operations?

Answer: Invitations to speak at political events are vetted by agency counsel to ensure compliance with federal laws and regulations that govern the political activities of Senate confirmed presidential appointees. Among those rules is a requirement to ensure that the audience at any political event is not composed primarily of persons who have matters before the department, and organizations are advised of the need to have a diverse group of attendees.

4. Government actions that burden a constitutional right trigger a strict scrutiny standard of judicial review. As such, the government must demonstrate that its action serves a compelling governmental interest and that it is the least restrictive means of furthering that interest. Given that freedom of religious expression is a right guaranteed in the First Amendment to the U.S. Constitution, did you consult with the Justice Department about the constitutionality of mandating that religious employers provide abortion-inducing drugs and other products that violate their religious teachings as part of their employee health plans?

Answer: Churches and other houses of worship are exempt from the contraceptive-coverage rule, and we are in the process of accommodating other religious organizations.

On February 10, 2012, we issued regulations finalizing last summer's amendment to final regulations on the exemption from the contraceptive coverage requirement for churches and similar organizations. The Federal Register publication also discusses the one-year enforcement safe harbor, which is detailed in separate guidance from the Departments. It also describes our intent to initiate a rulemaking to require insurers to offer certain objecting non-profit religious employers plans without coverage for contraceptive services and simultaneously offer the employer's plan participants contraceptive coverage (with no co-pay) at no additional cost. It further indicates our intent to establish a similar policy with respect to self-insured group health plans.

We received more than two hundred thousand public comments from individuals and organizations with different views on this subject. The Administration regularly meets with leaders from the faith community to discuss a wide range of issues. In addition, the Administration has met with over a dozen leaders from the women's advocacy community and spoke with many in Congress. All of the views were considered as we issued the recent final regulation. The Administration will continue to work with faith based organizations, insurers, and other interested parties to develop rules that respect religious liberty and ensure access to preventive services for women.

5. The Food and Drug Administration's labeling for the drug known as "Ella" (ulipristal) states that the drug is contraindicated during pregnancy, citing animal studies showing its capacity to terminate a pregnancy. Yet Ella is on the HHS list of "contraceptives" that must be provided at no cost under your mandate. If you can classify this abort ion-inducing drug as a "contraceptive" now, can't you classify other abortion-inducing drugs as contraceptives in the future, thereby adding them to the list of mandated drugs that must be provided at no cost to employees of religious organizations?

Answer: Items included in the Women's Preventive Services Guidelines do not include abortifacients. FDA considers drug products intended for the prevention of pregnancy as contraceptives. Ella works prior to implantation of a fertilized egg and is considered a contraceptive drug product. Ella's labeling specifically states that it is not indicated for termination of an existing pregnancy and should not be taken in the case of a known or suspected pregnancy.

6. Many religious organizations self-insure, which has enabled them to avoid abortion-inducing drug and contraceptive mandates in California and other states. Under President Obama's so-called compromise these organizations will be required to pay for these things because they are the insurer. Is it your intention to eliminate this "safe harbor" that now exists for religious organizations in California and other states?

Answer: We intend to develop a policy through a collaborative process to achieve the same goals for self-insured non-profit religious organizations with religious objections to contraceptive coverage that we intend to craft for fully insured non-profit religious organizations with such objections.

On February 10, 2012, we issued regulations finalizing last summer's amendment to interim final regulations on the exemption from the contraceptive coverage requirement for churches and similar organizations. The Federal Register publication also discusses the one-year enforcement safe harbor, which is detailed in separate guidance from the Departments. It also describes our intent to initiate a rulemaking to require insurers to offer certain objecting religious employers plans without coverage for contraceptive services and simultaneously offer the employer's plan participants contraceptive coverage (with no co-pay) at no additional cost. It further indicates our intent to establish a similar policy with respect to self-insured group health plans.

We are listening to the concerns of religious organizations and are taking them seriously. As Secretary, I specifically called for a one-year enforcement safe harbor when I originally announced the Departments' plans for moving forward. The Administration has an open door when it comes to ideas. We look forward to engaging with all interested parties, especially those in the faith communities, the insurance industry, and women's health advocates, during the enforcement safe harbor to achieve the best possible outcome for all concerned.

7. After all of the publicity surrounding the president's February 10 press conference and after all of your media interviews following the president's announcement, the final rule that was submitted to the *Federal Register* that day said that there had been no change to the interim final rule. In other words, you did not make any change to the rule despite all the concerns expressed by religious organizations. Why should religious organizations trust you to fix these problems after the presidential election when you have declined to make any tangible change so far? Should they expect the president to disappoint abortion advocacy groups after the election when he has not responded to the concerns of religious organizations before the election?

Answer: This Administration takes seriously the concerns of religious organizations. As Secretary, when I originally announced the Departments' plans for moving forward, I specifically called for a one-year enforcement safe harbor period during which we intend to amend the preventive services coverage regulations to further accommodate non-exempt religious organizations with religious objections to covering contraceptive services. The Administration has an open door when it comes to ideas. We look forward to engaging with all interested parties, especially those in the faith communities, the insurance industry, and women's health advocates, during the enforcement safe harbor to achieve the best possible outcome for all concerned.

8. The proposed accommodation continues to allow the Administration to force employers who are not religious in their official capacities to cover sterilization, abortion-inducing drugs and contraception in their insurance plans, regardless of their personal beliefs. Does the Administration mean by this, to imply that the First Amendment protection for religious freedom only applies to government-recognized religious organizations?

Answer: On February 10, 2012, we issued regulations finalizing last summer's interim final regulations on the exemption from the contraceptive coverage requirement for churches and similar organizations. The Federal Register publication also discusses the one-year enforcement safe harbor, which is detailed in separate guidance from the Departments. It also describes our

intent to initiate a rulemaking to require insurers to offer objecting non-profit religious employers plans without coverage for contraceptive services and simultaneously offer the employer's plan participants contraceptive coverage (with no co-pay) at no additional cost.

There are some religious organizations that would not be covered by the religious employer exemption and that do not currently cover contraceptives due to religious objection. Several such organizations submitted comments expressing concern about adjusting their plans to cover contraceptives and suggested they might simply cease offering insurance coverage. The enforcement safe harbor, during which additional rulemaking will yield additional accommodations for such organizations, responds to these particular concerns. While the safe harbor is in place, the Administration will continue to work with faith based organizations, insurers, and other interested parties to develop rules that respect religious liberty and ensure access to preventive services for women.

Unlike churches, religious hospitals and universities employ and serve people of all different faiths. The policy goal is to ensure that women who work for such employers with religious objections to contraception coverage and who may not share their employers' religious objections to contraception would have access to it without cost sharing, even while ensuring that their employers do not have to pay for it. For example, a nurse working at a Catholic hospital should have the same access to contraceptive services as a nurse working at a public hospital, even if the Catholic hospital should not have to pay for such services. This is about making sure that employees of these organizations get the care they need while ensuring that these organizations that object to contraception on religious grounds do not pay for it.

9. Has HHS assessed the PPACA provision requiring states to raise Medicaid primary care physician rates up to Medicare levels in 2013 and 2014? Has HHS analyzed what the financial impact on states will be to sustain those increases after the Federal mandate expires and if so, please provide that analysis.

Answer: The Centers for Medicare & Medicaid Services (CMS) is currently in the process of drafting a proposed rule to provide guidance on the implementation of the new requirements of sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Social Security Act as required by the Affordable Care Act. While it is anticipated that the proposed rule will provide estimates of the costs/savings of the Affordable Care Act provision to both the Federal and State governments for Calendar Years 2013 and 2014, we do not anticipate providing an estimate of the potential costs to States that choose to sustain the level of payment beyond 2014.

10. One of the President's Medicaid proposals calls for a manipulation of the Federal match or a limitation of revenue sources States can use for their Federal Match. Under the President's proposed budget, states would receive a lower Federal match rate for the PPACA-mandated beneficiaries than originally promised in PPACA. Please provide additional information to the Committee on how the blended rate would work for states. Specifically, please provide the Committee with the data and assumptions used to achieve the projected $18 billion in savings.

Answer: The Administration no longer supports the Medicaid blended FMAP proposal. We continue to seek efficiencies and identify opportunities to reduce waste, fraud and abuse in Medicaid, and we want to work with Congress, states, and stakeholders to achieve those goals while expanding access to affordable health care. The Supreme Court decision has made the higher matching rates available in the Affordable Care Act for the new groups covered even more important to incentivize states to expand Medicaid coverage. The Administration is focused on implementing the Affordable Care Act and providing assistance to states in their efforts to expand Medicaid coverage to these new groups.

11. The President's health care law included the creation of the CLASS program. HHS claims it has halted operations on the CLASS program after it concluded it had no path forward toward sustainability last fall. In light of the Administration's October 2011 announcement that it had halted work on the CLASS program (after concluding the program could not sustainable over a 75-year period), the Committee is concerned the Department should not use any resources to further promote the failed-CLASS program. However, as of February 16, 2012, the National Clearinghouse for Long-Term Care website still maintained information about the non-existent CLASS program services. Are you aware of such content and can you agree to please direct the Administration on Aging to remove this information and any information regarding CLASS from the HHS website?

Answer: The information on the website has been updated. It provides only the following information, "The Affordable Care Act authorized the creation of the CLASS Program a national, voluntary insurance program. Due to the October 14, 2011, announcement by HHS Secretary Sebelius that implementation of the CLASS Program has been suspended, the CLASS Program is not available." There is a link to the copy of the October 14, 2011 CLASS Report.

The Honorable Michael C. Burgess

1. In 2011, the cost of caring for those with Alzheimer's disease to American society will total an estimated $ 183 billion but only spends $450 million on Alzheimer's research. Despite the relatively low level of funding, the Alzheimer's research community has come a long way in moving Alzheimer's science forward, particularly in the last ten years. It's my understanding that we are at a scientific tipping point -- there are huge scientific opportunities that are waiting to be undertaken in order to save millions of lives and result in significant returns on our investment. The President's Budget includes an $80 million request specific to Alzheimer's disease at the National Institutes of Health to meet the vast scientific opportunities available to us -- can you explain how the additional $80 million will be used to fund new scientific opportunities? Are you essentially saying that as a public policy matter it is not only in the interest of millions of patients and their families, but also in the interest of taxpayers to do something about Alzheimer's now? Patients win and the cost curve will be bent if we delay or prevent the costs and complications of the disease? Given that we've seen this crisis coming for years, why hasn't the National Institute on Aging, the primary Federal agency supporting and conducting Alzheimer's research, requested increases in their budget in the last five years? Will any of the new funds be directed towards the newly established National Center for Advancing Translational Sciences to push discovery closer to therapies for people living with this disease?

Answer: Alzheimer's disease (AD) continues to be a major public health issue. Currently, between 2.4 million and 5.1 million Americans suffer from the disease, and this number is expected to increase dramatically with the aging of the American population. The development of interventions to prevent or delay the onset of AD, or to ameliorate the symptoms of the disease, remains a high priority for the National Institutes of Health (NIH) and the Department.

Research on Alzheimer's disease and cognitive aging is conducted throughout the NIH, with the National Institute on Aging (NIA) serving as lead federal agency for AD research. Similar to the NIH budget request as a whole, the NIA budget request reflects multiple compelling programmatic priorities and balances needs and scientific opportunities within the context of the funds made available through the annual NIH appropriation.

In Fiscal Year 2012, NIH will invest an additional $50 million in funding to accelerate research on Alzheimer's disease. In addition, the President's Budget request for FY 2013 includes a further investment of $80 million for Alzheimer's disease research from the Prevention and Public Health Fund. Planning for initiatives supported by these FY 2012 funds will be informed by the National Alzheimer's Plan and from the recommendations from the National Alzheimer's Summit, which will be held May 14-15, 2012. We anticipate that new NIH-supported research projects will focus on key areas in which emerging technologies and new approaches in clinical testing allow for a more comprehensive assessment of the disease. This research holds considerable promise for developing new and targeted approaches to prevention and treatment.

Specifically, two major clinical trials are being funded with the increased FY 2012 funds. The first is a study of an insulin nasal spray for treating Alzheimer's disease, following up on encouraging results of a pilot trial reported late last year. The other will study whether an

antibody treatment, crenezumab, designed to bind to and possibly clear away abnormal amounts of amyloid protein in the brains of people with Alzheimer's, can prevent decline in cognitive function in people at high risk of developing the disease. This will be the first clinical trial to focus on people who are cognitively normal but have an elevated risk of developing AD.

The $80 million allocation from the Prevention and Public Health Fund for NIH-supported research on AD in FY 2013 would be used to support the full spectrum of research with a focus on early diagnosis and prevention. The investment would be used to further the basic science required as a foundation for new interventions, advance translational research, and support clinical trials of prevention interventions. Basic research, translational research, and clinical trials of new intervention strategies would be solicited, received, and subjected to expert peer review to determine merit for funding.

2. Regarding CMS's plans for a prior authorization for power mobility devices - as we have discussed, physicians will play a huge role in the success of this program. We share the same concerns-ensuring their patients receive the appropriate medical care without unnecessary delays. We want to work with all affected stakeholders to ensure this demonstration program does not jeopardize access to this important benefit. As you know, In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress mandated a face-to-face examination be conducted of the beneficiary prior to any payment for a power mobility device. Medicare contractors, however, routinely seek the "longitudinal history" of the patient, rather than give greater weight to the actual physician face-to-face examination and often times; the results of the face-to-face examination are disregarded, largely because the Medicare contractors ignore information contained on physician templates. The contractors have stated in the past that they do not consider such templates to be part of the medical record. If the carriers conduct the prior authorization program in this manner, very few beneficiaries will receive mobility assistance. My office continues to have concerns with the reported 50-90% audited error rates being released by CMS' contractors. I am advised that this error rate is a direct result of confusion among physicians as to the proper paperwork needed to properly prescribe mobility devices on behalf of their patients. In fact, I regularly hear from stakeholders regarding a lack of clarity and consistency associated with the paperwork needed to properly file claims on a beneficiaries behalf. Although CMS has agreed to develop such a template, it has yet to be released. When will CMS release the PMD face-to-face evaluation template that physicians can rely on to establish medical necessity and validates that the treating physician conducted the congressionally mandated face-to-face medical evaluation of the patient?

Answer: CMS is in the process of developing an electronic clinical template as part of provider's electronic health records (EHR). An initial draft of the template is available on the CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/ElectronicClinicalTemplate.html CMS is actively seeking input on this template and stakeholders can submit comments on the draft to eclinicaltemplate@cms.hhs.gov. In addition, CMS will host a series of Open Door Forums to allow suppliers to comment and submit feedback on the draft template; the schedule for future ODFs can be found on the CMS website.

3. It's been almost 2 years since enactment of PPACA, yet the Administration has not issued any of the critical rules states and others need for 2014. Given the immediacy of the exchange implementation timeline, when can we expect the final rule on state health insurance exchanges to be released? Will the final rule address implementation issues vital to launching successful insurance exchanges including: granting states flexibility with regard to meeting consumer needs, streamlined exchange requirements and certainty with regards those requirements necessary for federal approval of state exchanges?

Answer: HHS released the final rule for State Innovation Waivers on February 22, 2012 which gives states the flexibility to find the health care solutions that work best for them, and pursue innovative strategies to ensure their residents have access to higher quality, affordable health insurance. The Department has also issued proposed rules, and plans to release final rules on Medicaid Eligibility, Exchange Establishment and Premium Stabilization in the near future. In addition, we will release sub-regulatory guidance on the Federally-Facilitated Exchange, Exchange Certification, and the operations of the federal risk adjustment and reinsurance programs. The Department will continue to consult with stakeholders and issue necessary guidance as we continue to implement the Affordable Care Act.

4. When will all the other rules be released? The assumption is open enrollment will begin 10/1/2013. States, employers and insurers can't be expected to invest the hundreds of millions of dollars required to implement the law without final rules, can they? And how can they move forward with only a few rules.

Answer: We agree that States, issuers, and other stakeholders need final rules in order to move forward on Exchanges, and we expect to finalize the Exchange rule in the near future. The intent of the proposed rule is to afford States substantial discretion in the design and operation of an Exchange, with greater standardization provided where directed by the statute or where there are compelling practical, efficiency or consumer protection reasons, and give all stakeholders a chance to provide feedback and see what approach that HHS intends to take with Exchange establishment and implementation. The final rule will set forth the minimum Federal standards that States must meet if they elect to establish and operate an Exchange.

5. What are some proposals in the Administration's FY13 budget request that would address these issues:

> **a. Specifically, would the proposed increase for the Biomedical Advanced Research and Development Authority (BARDA) fund additional antibiotic R&D? Given that a report card issued last October by the WMD Center gave the U.S. a grade of "F" for our ability to respond to a bioterror attack involving drug-resistant pathogens, I believe BARDA must strengthen its investment in antibiotic R&D. Do you agree?**

Answer: BARDA's Broad Spectrum Antimicrobial Program is focused on developing novel antibacterial and antiviral drugs for the treatment or prevention of disease caused by currently defined and future biological threats. Recognizing the immediate value of new antimicrobials in addressing the increasingly prevalent public health threat of antibiotic resistance, as well as the likelihood that antimicrobial resistance will complicate primary treatment of a wide array of

threats, BARDA is supporting the development of public-private partnerships for the development of novel antimicrobials. Through these partnerships, BARDA will support the development of candidate antimicrobials for their commercial, clinically prevalent infectious disease indications, as long as our private sector partners concomitantly support the development of these products for biodefense threat agent indications. By adopting this approach, BARDA will support the development of new classes of antimicrobials, increase the number of antimicrobial drugs in the developmental pipeline, address the important and immediate threat of antimicrobial resistance, and prepare the nation for the predictable threat of biological terrorism and the unpredictable threat of emerging infectious diseases.

b. The Administration proposed flat funding for the National Institutes of Health (NIH) and only a small ($ 10 million) increase for the National Institute of Allergy and Infectious Disease (NIAID)--the institute with the responsibility for research on antibiotic resistant infections. Why doesn't the Administration feel it is necessary to increase our investment in this critical area?

Answer: The FY 2013 President's Budget prioritizes NIH biomedical research as an investment that promises to deliver better health and drive economic growth. Within the FY 2013 President's Budget request, the National Institute of Allergy and Infectious Diseases (NIAID) will continue to support basic research to identify new antibiotic targets, translational research to develop new medical countermeasures (drugs, diagnostics and vaccines) and clinical research to study strategies to combat antibiotic-resistant infections. As part of this effort, NIAID provides a broad array of preclinical and clinical research resources to researchers in academia and industry to help facilitate product development. By providing these critical services to the research community, NIAID can help to bridge gaps in the product development pipeline and lower the financial risks incurred by industry to develop novel antibiotics. NIAID plans to continue this important work in FY 2013.

A significant amount of NIAID's drug development portfolio, including research and development of novel antibiotics, is supported by grants awarded through the Institute's Partnerships Program. NIAID's Partnerships Program supports collaborative efforts and multidisciplinary approaches to advance candidate products or platform technologies through the product development pathway, and has supported numerous grants addressing antibiotic resistance since its inception in 2000. Recent awards include work to advance the development of diagnostics and therapeutics for drug-resistant pathogens and pathogens that are at risk for developing drug resistance. In FY 2011, NIAID issued the "Targeting Resistance in Select Gram-Negative Pathogens" phased innovation award research initiative. This initiative targets early-stage research towards the development of novel therapeutic approaches to treat resistant Gram-negative bacteria. NIAID anticipates making awards for this initiative in the spring of 2012. In FY 2012, NIAID issued the "Partnerships for Development of Therapeutics and Diagnostics for Biodefense" which focuses, in part, on the development of new therapeutics targeting antibiotic-resistant pathogens. Partnership awards are anticipated to be made in FY 2013.

NIAID also supports the preclinical development of new antibacterial agents through contracts to companies involved in novel drug design and synthesis. These contracts were solicited through a

Broad Agency Announcement entitled "Development of Therapeutics for Biodefense." Work under these contracts aims to develop four different classes of drugs that have the potential to treat multi-drug resistant (MDR) bacterial infections. A similar Broad Agency Announcement is planned for FY 2013.

To foster clinical research on antibiotic resistance, in January 2012, NIAID released a Request for Applications to support a new leadership group for an antibacterial resistance clinical trial network similar to the existing NIAID HIV/AIDS clinical research networks. The award will be made in FY 2014. The antibacterial resistance leadership group will develop and implement a comprehensive clinical research agenda to address the pressing problem of antibacterial resistance, and will have the capability to test new antibiotics as well as currently available antibiotics in clinical studies; the latter studies will help inform the rational use of existing antibiotic drugs to help limit the development of antibiotic resistance. This work will complement current NIAID-supported clinical trials designed to determine proper antibiotic dose, treatment duration, and whether antibiotic treatment is necessary in all cases.

6. Please provide more information about the assumption that the contraceptive and sterilization mandate on the whole is cost neutral for insurance companies. These questions are directed to the contraceptive/sterilization mandate as a whole, not just those covered by plans purchased by religious employers.

a. Will plans will be required to cover all FDA approved methods of contraception including name brand methods and high cost methods such as sterilization, IUDs and implants? If so, by how much will cost increase for plans that currently cover generics and lower cost methods to now cover name brands and higher cost methods? Please provide an estimate for the increased cost of such a switch. In addition please provide studies showing that the increased cost of covering higher cost and name brand methods in a plan is offset by marginal savings within that plan even though they already cover some form of contraception.

b. According to the Alan Guttmacher Institute's webpage "Virtually all women in the United States aged 15-44 who have ever had sex have used at least one contraceptive method (99%). Currently, only 7% of sexually active women who are at risk for unintended pregnancy are not using contraceptives." How much additional "marginal" cost will be added by individuals in the 93% of sexually active women switching from a low cost generic method to a high cost method? Please provide studies demonstrating the cost of individuals switching to a more expensive method.

c. Please indicate what percentage of the 7% not using contraception are doing so because they have no insurance or their insurance company doesn't cover contraception at all, what percentage of the 7% are not using a method because they cannot afford a co pay, and what percentage of the 7% are not using contraception for non-financial reasons. Please provide the specific studies you used to answer this question.

d. Please provide studies or cost-benefit analysis that specifically studied the marginal cost of individuals switching from a low cost method to a high cost method versus the marginal benefit of those who had not used a method starting to?

Answer: The women's preventive services guidelines include all FDA-approved contraceptive drugs and devices, including both brand name and generic. The Affordable Care Act and its implementing regulations allow plans to use reasonable medical management techniques to control costs. Plans may use reasonable medical management techniques to steer patients towards a generic version of a prescription medication that is part of a recommended preventive service, provided the plan accommodates any individuals for whom it would be medically inappropriate by having a mechanism for waiving the otherwise applicable cost-sharing for the branded version.

Considering that many of the recommended services are already covered by most group health insurance plans – already with low or no copayments – the estimated average impact on employer plan premiums is very small. Actuaries and experts agree that covering contraception actually saves money for insurance companies. The cost of contraception coverage is low and tends to be more than offset by the savings that result from improved health and fewer unplanned pregnancies. For example:

- A study by the National Business Group on Health estimated that it would cost employers 15-17% more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and indirect costs such as employee absence and reduced productivity.

- When contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase.

- And 22 States including Pennsylvania have family planning waivers in Medicaid that have significantly expanded coverage of these services without increasing State or Federal costs (i.e., they are budget neutral).

As such, it is hard to argue that insurers need to raise premiums for coverage that lowers costs.

7. Texas submitted a 111 5 Demonstration Waiver renewal of the Women's Health Program to CMS this past fall. This program provides low income Texas women with family planning and certain preventive screenings including breast and cervical cancer screenings. CMS sent Texas a letter that mentions that Texas cannot deviate from the requirements of section 1902(a)(23) of the Act in order to restrict beneficiary choice of qualified family planning providers under the program. Texas believes that states have been delegated the authority to determine qualified providers are under the Medicaid program.

a. The Texas Women's Health Waiver program saves money and provides preventative care and family planning to low income women, why is CMS delaying approval of the Waiver?

Answer: As you know, Texas has elected to move forward with a state rule that will restrict freedom of choice of health care providers for women enrolled in the Women's Health Program effective March 14, 2012. Consistent with longstanding statutory provisions that assure free choice of family planning providers, the Demonstration does not provide the State the authority to impose such a limitation, and we advised the state in letters dated December 12, 2011, and March 15, 2012, that such authority would not be granted. In light of the State's preference to move forward in implementing the state rule, the Centers for Medicare & Medicaid Services (CMS) stated that it is not in a position to extend or renew the current Demonstration, except for purposes of phasing out the Demonstration.

b. CMS has had concerns over access and provider choice after the implementation of the state law prohibiting abortion providers and affiliates from participating in the WHP program. However, Texas has over 2500 WHP providers, of which only are 44 planned parenthoods, in over 4600 sites. Texas Health and Human Services Commission reports that there are over 2500 WHP providers and over 4600 sites, excluding abortion providers. I have heard that you are concerned about access. Since Texas Health and Human Services Commission has proven that access to care will not be limited across the state by these numbers, why would you effectively deny low income women access to this care by denying the waiver?

Answer: Federal law prohibits federal Medicaid dollars from being spent on abortion services. Federal law also prohibits states from restricting access to providers simply because of other services they may offer. CMS was unable to extend or renew the current Demonstration, except for the purposes of phasing out the Demonstration, because Texas has elected to move forward with a state rule that will restrict the freedom of choice of health care providers for women enrolled in the Women's Health Program, which violates federal law.

c. States limit who can be a qualified provider under the Medicaid program. In Texas, we prohibit providers that are delinquent on taxes, child support or providers that under investigation for suspected abuse. Since you are disagreeing that Texas can prohibit abortion providers and their affiliates from being a qualified provider, do you disagree that Texas has the authority to prohibit these other categories?

Answer: One of the fundamental aspects of the Medicaid program is the statutory provision at section 1902(a)(23)(A) of the Social Security Act which provides that Medicaid beneficiaries may obtain covered services from any qualified provider willing to undertake the service. Section 1902(a)(23)(B) sets forth additional protections for a beneficiary's free choice of family planning providers. Texas requested approval to limit access to specific providers for reasons not related to their qualifications to provide such services.

The Honorable John Shimkus

1. There has been a lot of discussion about the cost of Medicare fraud, waste and abuse; estimates indicate between $48 billion and $60 billion are stolen out of the Medicare system each year. While I would not suggest that efforts to investigate improper payments and fraud should be discontinued, resources should be allocated to the prevention and detection of fraud and abuse. Stopping the fraud before it happens better protects the Medicare system, and allows us to be good stewards of taxpayer funds. Additionally, identity theft has been an increasing scourge our seniors have had to suffer because the Centers for Medicare and Medicaid Services (CMS) insists on printing each Medicare recipient's Social Security number directly on the Medicare card. Lastly, legitimate Medicare providers the doctors and medical professionals dispensing front-line Medicare services to our seniors - are likewise impacted by gross inefficiencies and inaccuracies in the billing system allowing their Medicare provider numbers to be stolen and used by criminals and thieves to scam Medicare.

The number of participants in the Medicare system is projected to swell to over 79 million beneficiaries by 2030. It is clear that the Medicare system will need to do more with less. I am a cosponsor of H.R. 2925, the Medicare Common Access Card Act, which will verify Medicare transactions before paying providers, as well as modernizing the Medicare card to take the Social Security number off the front.

> **a. Please explain to the Committee to what extent HHS and CMS have investigated other smart card programs around the world as a possible solution to prevent fraud-and abuse within the Medicare system.**

Answer:: I share your commitment to stopping waste, fraud and abuse in the Medicare program and your interest in learning what technologies can help us fulfill that commitment. CMS has begun investigating the potential application of smart card technology to the Medicare program, including the possible benefits in preventing fraud, and the costs of implementation.

> **b. In 2006, Congress, through the Labor Health and Human Services and Education appropriations bill, directed HHS to remove the Social Security number from the Medicare card and your agency has resisted. Can you please tell the Committee why HHS has seemingly been uninterested in addressing this critical issue, and what plans you have to remedy this serious problem?**

Answer: I certainly share your concerns about protecting Medicare beneficiaries from identity theft. We have taken many important steps to eliminate unnecessary display of Social Security Numbers (SSNs), such as removing SSNs from various notices and publications sent to beneficiaries and from beneficiary reimbursement checks. We have also taken action to educate beneficiaries about steps they should take to prevent identity theft and fraud.

> **c. Please explain to the Committee to what extent HHS and CMS have investigated and the inefficiencies surrounding the current Medicare reimbursement system, and**

what kind of waste can be eliminated by moving to a system where beneficiaries and provider are authenticated and verified before payments are made.

Answer: The Affordable Care Act provided the Centers for Medicare & Medicaid Services (CMS) with significant new authorities to enhance its oversight of Medicare, helping shift the focus to fraud prevention by providing new authorities to increase screening of providers and suppliers before they enroll in any of these health programs, implement temporary moratoria on new providers in high risk areas, and establish requirements for compliance programs. These new activities are complemented by the passage of the Small Business Jobs Act of 2010, which required CMS to implement predictive analytics technology, and provided financial resources to do so. CMS is now deploying predictive analytics technology in its Fraud Prevention System (FPS) to review all Medicare fee-for-service claims prior to payment. For the first time, CMS has a real-time view of fee-for-service claims across claim types and the geographic zones of its claims processing contractors. This allows CMS to more easily identify fraudulent providers by detecting patterns and aberrancies.

The Honorable Mike Rogers

1. The Administration has recognized the severity of the nuclear threat on multiple occasions. Yet BARDA's attempts to procure medical countermeasures for Acute Radiation Syndrome (ARS) under Project BioShield thus far have been unsuccessful. The majority of BARDA 's Advanced Research and Development (AR&D) funding to address ARS has gone to very early stage products or academic institutions. And there appears to be a lack of prioritization of future AR&D funding in addressing this threat. Can you explain the apparent disconnect between the Administration's goals and BARDA's actions?

Answer: HHS has sought from the beginning to make available medical countermeasure products to treat unfortunate individuals exposed to ionizing irradiation. In the early days of Project BioShield DTPA, Potassium Iodide, and Prussian Blue were acquired to remove radionuclides from affected persons. Since acute radiation exposure results in multiple syndromes affecting the immune system, gastro-intestinal tract, skin, lungs, and the brain, different medical countermeasures were sought for each or several associated illnesses. Until recently, there have not been medical countermeasures candidates for treatment of the illnesses associated with ARS that are mature enough for regulatory acceptance or available from the manufacturers of licensed products for other indications. To this end, BARDA has invested in the early development of 23 product candidates since 2009 investment to treat these different ARS-associated illnesses. From this portfolio, some of these small molecule and recombinant-based drug candidates or cell-based therapies will succeed through advanced development and become mature enough for acquisition under Project BioShield in FY 2014-2018. Thus the country will be prepared to treat more than just one ARS-associated illness.

For the ARS-associated illness – neutropenia – that drugs may be available, BARDA sought to acquire in 2008 licensed cytokine drug products under Project BioShield, however the primary manufacturers of these licensed products did not respond to the solicitation. They did not wish to seek regulatory approval of their products for an ARS anti-neutropenia indication fearing that an adverse event or untoward side effect might endanger their multi-billion dollar franchises. Today, after several years of constant interaction, manufacturers of these FDA-approved anti-neutropenia drugs, which are used to treat immune disorders, have expressed an active interest in working with BARDA to expand the use of their licensed products to treat radiation illness. To support this acquisition, a solicitation under Project BioShield will be issued by BARDA in the summer of 2012 for the purchase of anti-neutropenia products and funding of late-stage development studies to make the products available, if it is determined that this is necessary, under Emergency Use Authorization and to support approval or licensure for the ARS indication. Contracts for one or more these products are expected in 2012, and products would be available, through approval or through authorization for use in an emergency, for radiation-induced neutropenia by next year.

2. A key objective of the Pandemic and All Hazards Preparedness Act was to ensure continued involvement of innovative biotechnology companies in the badly underserved biodefense sector. Yet, we understand BARDA has informed companies willing to develop their products to address high priority threats that there will be no new Advanced

Research & Development (A R&D) contracts in FY 2012 and possibly FY 2013 due to prior commitments. What is the reason for this decision?

Answer: After a boom year for introducing 23 new MCM candidates into the CBRN MCM development pipeline in FY 2011 to reach a total of 80+ product candidates, available funds ($415 million) in FY 2012 will cover expenses of existing MCM candidates already under support from BARDA (>90%) and only a few new product candidates. If the President's Budget in FY 2013 for BARDA ARD programs ($587 M) is approved by Congress, then both existing and additional new MCM candidates can be supported to fill the remaining gaps in broad spectrum antimicrobials and antivirals and chemical antidotes.

3. Along with Representative Lois Capps, I personally championed the Pain Care Policy Act, major portions of which became law in 2010. One result of that effort was the landmark Institute of Medicine Report on "Relieving Pain in America" issued in June of last year. The IOM found that chronic pain is a public health problem in this country of enormous proportions, and called on HHS to develop by the end of this year a comprehensive population level strategy to address it, with specific focus on prevention, treatment, management and research. Can you briefly tell us what your office is doing to implement this recommendation, who is in charge of it, and when we might see such a strategy to guide future efforts at the Department?

Answer: More than 100 million Americans suffer from migraines, arthritis and other chronic pain conditions with an annual economic toll of nearly $600 billion in medical bills and lost productivity. To help address this problem, Congress directed the U.S. Department of Health and Human Services, through the Affordable Care Act, to create a new Interagency Pain Research Coordinating Committee. Its members, announced on February 13, 2012, by the National Institutes of Health (NIH), include biomedical researchers, representatives from nonprofit public advocacy organizations, and representatives of seven federal government organizations that deal with pain research and patient care. The Federal agencies comprise the Department of Health and Human Services (HHS), including NIH, the Centers for Disease Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality; the Veterans' Administration; and the Department of Defense. This is a Secretarial Committee reporting to the Secretary, HHS, which is chaired by Dr. Story Landis, Director, National Institute of Neurological Diseases and Stroke, NIH.

The committee will work to identify critical gaps in basic and clinical research on the symptoms, causes, and treatment of pain and will recommend federal research programs in these areas. The focus will be to coordinate pain research activities across the federal government with the goals of stimulating pain research collaboration, fully leveraging the government resources dedicated to supporting pain research, and providing an important avenue for public involvement. The committee will explore public-private partnerships to broaden collaborative, cross-cutting research and consider best practices in disseminating information about pain to public and professional audiences. The committee has been specifically charged with making recommendations on how to best disseminate information on pain care, and NIH is working together with other member federal agencies to collect information on current dissemination efforts in order to inform these recommendations.

The committee appointees include leading federal officials together with six non-federal scientists, physicians, and other health professionals, as well as six members of the general public who are representatives of leading research, advocacy and service organizations. After tracking the work of several government agencies that conduct and support pain research, the committee will develop a report on scientific advances in the diagnosis, prevention, and treatment of chronic and acute pain.

4. As you know, Osteogenesis Imperfecta (OI) is a rare inherited disorder caused by a genetic mutation that affects the body's production of collagen. Approximately 25,000 - 50,000 Americans may be affected by OI, which is characterized by fragile bones that break easily and related connective tissue symptoms. The most severe form of the disease usually leads to death shortly after birth; while most affected individuals survive into adulthood, it is not uncommon for persons with OI to experience several-hundred debilitating breaks over the course of their lifetime. In addition to fractures, it is thought that OI causes many other serious chronic conditions, such as pulmonary and cardiovascular disease, which appear to increase in severity with age. Unfortunately, the impact of OI on adults, in particular, is not well understood. There is a great need for natural history studies that will facilitate the development of clinical practice guidelines for adults living with OI. What are the plans of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) with regards to its OI research portfolio in FY 2012, FY 2013, and beyond? To what degree are NIAMS and the National Institutes of Health (NIH) in general focused on working with scientific investigators and clinicians with expertise in OI on addressing the specific concerns of adults with OI?

Answer: The NIH supports research identified by its peer review process as being scientifically meritorious and impactful. Applications for projects, including those involving natural history studies of OI, are welcomed. The success of this rigorous two-stage peer review process has been a critical and highly respected component in the development of the NIH research portfolio.

The NIAMS has funded two conference grants to the Osteogenesis Imperfecta Foundation in 2010 and 2012. These two meetings have brought together leading OI researchers and clinicians, as well as adults living with OI to review current knowledge regarding the impact of OI on a wide range of body systems during the aging process, identify major information gaps, and make recommendations to expand the OI research agenda.

The NIAMS supports a broad portfolio of bone biology and musculoskeletal research that is relevant to OI. Advances in these programs help to inform the field of OI research and, ultimately, improve the quality of life of patients. In addition, NIAMS-funded research supports work aimed at applying the tools of genetic and stem cell technology to develop therapies that could correct the underlying genetic defects in OI. For example, scientists have shown that it is possible to inactivate the abnormal copy of the collagen gene in isolated cells. If a way can be found to reintroduce the modified cells into the patient, this could provide therapy for some of the most severe forms of OI. However, the many steps required for the inactivation of the disease-causing gene result in a loss of proliferative capacity, making it unlikely that the modified cells could grow into large enough populations in patients to improve outcomes. Most

recently, using support provided by the American Recovery and Reinvestment Act, researchers have shown that the methods used to produce induced pluripotent stem cells (sometimes said to "reprogram" mature cells to resemble their progenitors) can markedly increase the proliferative capacity of the modified cells. This could improve chances for long-lasting therapeutic benefit in OI patients of all ages.

Researchers at other NIH Institutes who have an extensive history studying connective tissue disorders including OI have been valuable partners with the NIAMS to support studies on the disease. Most recently, a team of investigators within the NIH's intramural research program collaborated with NIH-funded scientists from outside institutions to discover the third in a sequence of genes that accounts for previously unexplained forms of OI. The newly identified gene contains the information needed to make the protein Cyclophilin B. This protein is part of a complex of three proteins that modifies collagen, folding it into a precise molecular configuration, before it is secreted from cells. Collagen functions as molecular scaffolding that holds together bone, tendons, skin, and other tissues. Most types of OI result from a dominant mutation in collagen itself, requiring only one copy of the mutated gene to bring about the disorder. OI involving the Cyclophilin B gene, however, is a recessive trait, requiring two defective copies of the gene to cause the disorder. The discovery provides insight into a previously undescribed form of OI and provides new information on how collagen folds during normal bone formation, which may also lead to greater understanding of other bone disorders.

The NIAMS Advisory Council, a second tier of the NIH peer review system, is comprised of scientific and lay members who have expertise in the mission areas of the Institute. The Council provides advice on broad policy issues, as well as making recommendations on research proposals. Ms. Michelle Hofhine, a registered nurse and parent of a child who has OI, was recently added to the Institute's Council.

The Honorable Marsha Blackburn

1. Secretary Sebelius, last year 104 House Members wrote to you about the National Diabetes Prevention Program (NDPP), a successful, targeted, public-private financed and community-based intervention (between the YMCA, UnitedHealth Group, and the CDC). It has been demonstrably successful in reducing participants' risk of developing diabetes (58% overall; 71 % for people 65+). Well, I am pleased to hear that you did release $ 10 million in FY 12 funding to the CDC for NDPP implementation. So, my question to you is, will you please maintain this commitment in FYI3?

Answer: The National Diabetes Prevention Program (National DPP) is a public-private partnership of community organizations, private insurers, employers, health care organizations, and government agencies working collectively to deliver, scale up, and sustain evidence-based lifestyle change interventions to prevent type 2 diabetes. In FY 2012, $10 million from the Prevention and Public Health Fund will support the National DPP. With this funding, CDC is working to expand the reach of the program by providing awards to non-profit organizations, for-profit organizations, Indian/Native American Tribal Governments, and faith-based organizations.

The FY 2013 Budget includes an increase of $129 million above FY 2012 for the Coordinated Chronic Disease Prevention and Health Promotion Program to consolidate disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including diabetes, heart disease and stroke, obesity, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases, including diabetes. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self- management, and improving effective delivery of clinical and other preventive services.

In addition to supporting awards to state, tribal, and territorial health departments to build and strengthen health department capacity and expertise to effectively prevent chronic disease and promote health, competitive awards will be made to national organizations, national networks, and other entities to disseminate best practices and effective interventions – like the National DPP.

2. In his 2009 memo on Transparency and Open Government President Obama states he is "committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration."[1]

In his 2011 SOU address, President Obama made the following statement "...In the coming year, we will also work to re build people's faith in the institution of government. Because

[1] *2009 Presidential Memo on Transparency* - http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment

you deserve to know exactly how and where your tax dollars are being spent, you will be able to go to a website and get that information for the very first time in history."[2]

The FY 2012 Appropriations bill, signed by the President on December 23, 2011, included a provision (Sec 220) that kept this promise.

The bill required HHS to post on a public website how the billions of dollars from the Prevention and Public Health Fund (PPHF) are being spent. ["Section 220 (a) The Secretary shall establish a publicly accessible website to provide information regarding the uses of funds made available under section 4002 of Public Law 111 - 148."]

Yet, alarmingly, the President's FY 2013 Budget proposes to eliminate this reporting requirement for the Prevention and Public Health Fund. His proposal would remove Section 220 in its entirety. Secretary Sebelius, how does eliminating the public reporting website fulfill the President's commitment to transparency? In my mind, it does just the opposite.

Answer: The FY 2012 enacted appropriations bill (Section 220) specifies various reporting requirements for activities funded with resources from the Prevention and Public Health Fund. Administrations, often as a matter of principle, do not seek to tell the Congress on what issues the Executive Branch should be required to report to Congress. Consistent with that general principle, the Administration did not include this requirement in the FY 2013 President's Budget. However, the Department takes transparency very seriously, and HHS developed a web page which reflects information requested in statute. The site reflects information on the funds transferred to various agencies as well as funding solicitations as they become available.

3. Recently, there has been a lot of coverage in the news about prescription pain medication and abuse, even fraud. In fact, in 2011, the White House released a document entitled: "Epidemic: Responding to America's Prescription Drug Crisis" which highlighted the increase in opioid use and recognized the need for increased efforts to educate physicians and patients to control the over-prescription and abuse of these drugs.

> **a. So can you tell me why, with such a focus on limiting the use of narcotic pain killers, that the Centers for Medicare and Medicaid Services (CMS) has initiated a coverage review to possibly limit access to a cost-effective, non-invasive alternative for pain treatment for Medicare patients called TENS or Transcutaneous Electrical Nerve Stimulation?**

Answer: CMS recognizes the burden of chronic pain and the importance of supporting pain management strategies that are founded on scientific evidence. Following the publication of a report by the American Academy of Neurology in 2010, which found that TENS was ineffective for chronic lower back pain, we believed it was important to open a national coverage analysis to review the available evidence.

---

[2] *2011 State of the Union Address* – http://www.whitehouse.gov/the-press-office/2011/01/25/remarks-president-state-union-address

A description of the proposed review was posted on the CMS coverage website on September 13, 2011, as the first step in the national coverage determination process. Public comments were invited on the review proposal for a 30 day period and 359 comments were received. We are continuing to review the comments received and will move forward with the coverage determination process in the future.

b. This therapy has been available to Medicare patients for decades and has even been supported by CMS thru a National Coverage Determination in 1995. TENS is available to all federal employees through the government health plans, to Veterans thru the VA and Tricare, and to most Americans thru their private health insurance. So tell me, how do I explain to seniors, when almost everyone else has access to this therapy that they may not?

Answer: CMS continues to review the comments received and will determine if any changes in current coverage are necessary.

Medical Loss Ratio Rebates:

4. Why is it necessary to send out notices to those NOT getting a rebate?

a. By your own accounting, that one notification to those NOT receiving a rebate will add $71 million/year to the cost of health insurance. How does this assure value?

Answer: Whether or not a person is receiving a rebate, MLR notices will help ensure greater transparency for consumers regarding how their premium dollars are used, educate consumers about the MLR standards, and provide an incentive for issuers to maximize the percentage of premium dollars they spend on health care and activities that improve health care quality. The Department solicited comment on this issue in the December 7, 2011 interim final rule with public comment period and expects to issue additional rules in the near future.

b. Is there any provision of law that would suggest that MLR rebates need to be accompanied by federally-prescribed letter that sounds more like PPACA promotional materials?

Answer: HHS worked with the National Association of Insurance Commissioners (NAIC) to develop MLR notice requirements. Use of a standard template will ensure that all consumers receive the same information in clear, easy to understand language. Since many consumers may not be familiar with the MLR standards implemented through the Affordable Care Act, the notices will help them understand MLR and the rebate requirements, and why they may or may not receive a rebate. MLR notices will help ensure greater transparency for consumers regarding how their premium dollars are used, promote informed decision-making in the purchase of health insurance and provide an incentive for issuers to maximize the percentage of premium dollars they spend on health care and activities that improve health care quality.

5. Each Letter spells out how much can be spent on administrative costs such as "salaries and advertising."

a. Why didn't you choose to highlight costs such as "combating fraud, developing and ensuring a high-quality provider network, and operating consumer call centers?"

Answer: Each model rebate notice uses examples to describe types of expenses most familiar to consumers, such as medical claims, activities that improve health care quality, and administrative costs. Since the MLR regulations allow issuers to classify fraud recovery activities up to the amount of fraudulent claims recovered as quality improving activities, it would not be accurate to highlight combating fraud as an administrative expense only.

b. If 80 or 85 perfect of all premium dollars must be given directly to providers, do you know what percentage providers receive goes toward costs such as "salaries and advertising?"

Answer: The medical loss ratio applies to licensed health insurance issuers in the individual and group markets, and requires such issuers to spend 80 to 85 percent of premium dollars on medical care and quality improvement activities. This provision does not apply to providers.

i. Is it reasonable to expect that patients also "get value for [their] health care dollars" when visiting a provider?

Answer: The Affordable Care Act puts American consumers back in charge of their health coverage and care. By increasing the value of the health coverage, through provisions such as the medical loss ratio, elimination of lifetime limits, and free preventive services, the Affordable Care Act is shifting the burden of paying for provider visits to insurance companies instead of the patient's pocketbook.

The health reform law also equips consumers with new tools to help them select high-quality and efficient providers, including adding new quality measures to Hospital Compare and adding new categories of providers, including long-term care facilities, to that transparency tool. Consumers can now go online and see which providers in their communities provide the highest quality and the best value.

The Affordable Care Act also includes a large number of provisions that will improve health care quality and efficiency and provide greater value for every patient. These include several provisions that link a portion of payments to the quality of health care provided, allowing Medicare to pay hospitals for the first time based on the quality of care they deliver, the Medicare Shared Savings Program, the many new models from the CMS Innovation Center, and others. Thousands of providers around the country are already participating in these new payment models and quality improvement initiatives and their patients are getting to spend more time with their doctors and are experiencing more coordinated, high-value care.

ii. How does this law assure that providers are delivering the care for which patients are being billed?

Answer: The Affordable Care Act has improved the availability, affordability, and accountability of private insurance. To continue the goal of supporting and improving the private health insurance market, we have steadily worked towards establishing the Affordable Insurance Exchanges. Beginning in 2014, the Exchanges will provide improved access to insurance coverage choices for an estimated 20 million Americans by 2016. Individuals will be able to access qualified health plan insurance options through the Exchange market, including when they do not receive insurance through their employers, are self-employed, or are currently unemployed.

c. How does the average rebate compare to the new tax on those purchasing insurance that starts in 2014?

Answer: The Department estimated that in 2011 rebates (in all markets) would range from $587 million (low) to $1.456 billion (high). The mid-point estimate was $868 million. In addition, up to 9 million Americans could receive rebates. The implementation of new taxes on insurance is outside of my Department's purview and is being implemented by the Department of Treasury.

Conscience Protections & Religious Freedom

6. On February 10, 20 12, HHS issued guidance on a "temporary safe harbor" or one year delay in implementation for religious entities that are opposed to providing certain coverage. Under this delay I understand some employers are exempt from the contraceptive and sterilization mandate for one year. Please answer the following questions regarding the delay in implementation.

a. Two weeks ago at the Oversight and Government Reform Committee, Dr. Laura Champion, Medical Director for Calvin College testified about Calvin College's health plan. She said, "Contraception is not controversial at our school. Clinicians write prescriptions that include contraception for a variety of reasons, including the prevention of pregnancy. However, abortifacient agents are not prescribed, nor are they covered in our health care plan." She specified that Calvin College does not cover Plan B or *ella*. The guidance issued by your department on February 10, 201 2 indicates that the one year delay is available to non-profit institutions that have not provided contraceptive coverage "at any point" after February 10, 2012.

I understand the guidance issued by your department has caused some confusion as to whether institutions such as Calvin College will qualify for the one year delay. Please clear up this confusion. Will religious institutions that oppose the morning after pill, but provide other contraceptives qualify for the delay in the mandate?

b. Would a religious small business person who provides health insurance to their employees also be eligible for the "safe harbor?"

c. Would individuals be eligible for the "safe harbor?"

d. Does the "safe harbor" only apply to non-profits if they oppose the mandate on religious grounds?

e. Would a non-profit that opposes the mandated coverage for a drug like, *ella*, on the moral grounds not directly associated with their religious beliefs be protected under the "safe harbor?"

Answer: On February 10, 2012, we issued regulations finalizing last summer's interim final regulations on the exemption from the contraceptive coverage requirement for churches and similar organizations. The Federal Register publication also discusses the one-year enforcement safe harbor, which is detailed in separate guidance from the Departments. It also describes our intent to initiate a rulemaking to require insurers to offer objecting non-profit religious employers plans without coverage for contraceptive services and simultaneously offer the employer's plan participants contraceptive coverage (with no co-pay) at no additional cost. It further indicates our intent to establish a similar policy with respect to self-insured group health plans.

There are some religious organizations that would not be covered by the religious employer exemption and that do not currently cover contraceptives (all or some) due to religious objection. Several such organizations submitted comments expressing concern about adjusting their plans to cover contraceptives and suggested they might simply cease offering insurance coverage. The enforcement safe harbor, during which additional rulemaking will yield additional accommodations for such organizations, responds to these particular concerns. While the enforcement safe harbor is in place, the Administration will continue to work with faith based organizations, insurers, and other interested parties to develop rules that respect religious liberty and ensure access to preventive services for women.

The Honorable Cathy McMorris-Rodgers

1. Down syndrome is a non-terminal, non-treatable condition. Prenatal testing simply identifies the fetus as having Down syndrome, but does not prevent Down syndrome or allow for treatment prenatally. As the current recommendations are part of preventative services, please tell me how prenatal testing prevents Down syndrome?

Answer: Prenatal testing does not prevent Down syndrome. Babies born to mothers who received no prenatal care are three times more likely to be born at low birth weight, and five times more likely to die, than those whose mothers received prenatal care. Because of the Affordable Care Act, prenatal care, including preventive services such as folic acid supplements, gestational diabetes screening, and breastfeeding counseling, are covered without cost-sharing in most health plans. These services will help ensure women and their babies are healthy. We encourage women to speak with their care providers regarding the appropriate services.

2. Studies have concluded that the current administration of prenatal testing does not result in informed decisions being made. This is due to physicians lacking training on the testing itself and on counseling patients; an insufficient number of genetic counselors to counsel patients; inaccurate, outdated, and negative information being provided to patients; and all options following a diagnosis, notably adoption, not being discussed with patients. Moreover, surveys and professional guidelines recognize the referral to parent support organizations is very helpful. Since 2008, the Prenatally and Postnatally Diagnosed Conditions Awareness Act, commonly referred to as Kennedy Brownback, after its two lead sponsors in the Senate, has been the law of the land. The Act recognizes a need for accurate information about prenatal testing, the tested for condition, and support for parent support organizations. How does HHS' regulation require these informational resources to be made available together with the prenatal testing?

Answer: The Guidelines recommend a well-woman preventive care visit for women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception and prenatal care. We encourage women to speak with their care providers regarding the appropriate services. We look forward to continuing to work with you to ensure accurate information is available regarding this and other important health issues.

3. It is our understanding that not all FSMA rules have been issued. Some are at OMB and some are still being developed at FDA. In the FY 2013 Budget Request, FDA proposes approximately 1,200 additional FTEs, depending on if you count the 180 reimbursable, PEPFAR, and IDDA FTEs. Many of these proposed new FTEs are to assist in the writing of FSMA rulemaking and guidance and will be paid for through user fees. I have two questions regarding these FTEs:

> **a. On Friday, February 17, in an interview with Food Chemical News (Part I published February 24), Michael Taylor, FDA's deputy commissioner for foods stated, "I think with current resources we can continue the rulemaking process. We can get the regulations on the books." If that is the case, why are you requesting to tax the food industry to pay for these additional FTEs?**

Answer: In the 2013 President's Budget, FDA's request includes user fee revenue for 42 FTEs to support the development of FDA Food Safety Modernization Act (FSMA) regulations and guidances. While FDA can develop the regulations mandated by FSMA with its current workforce, this only entails writing and finalizing the regulations. It does not include their implementation, including the significant number of guidance documents, model plans, and other outreach materials that will need to be drafted to implement the preventive controls rule and assist industry with implementation.

Regarding the proposed registration fee, FDA is having discussions with the food industry and other food safety stakeholders to determine what type of fee structure could be implemented that could get broad support within the food industry, other stakeholders, and Congress. As FDA intends for the user fee to support food safety activities that provide benefit to the industry paying the fee, it would be considered a "user fee" rather than a "tax."

These fees will allow FDA to reduce the risk of illness associated with food and feed, decrease the frequency and severity of food- and feed-borne illness outbreaks, reduce instances of contamination, and greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events. Without sufficient and reliable fee revenue, we can expect the unacceptably high human toll of foodborne illness to continue, with the resulting disruptions to the food system and the economic burdens to the food industry that result from foodborne illness outbreaks.

These proposed user fee investments are quite modest compared to the economic value of the nation's food and feed supplies and the costs that the public, industry, government, and the health care system experience during an outbreak

b. If you do increase size of FDA in this manner, what are you going to do with these additional employees after the rulemaking and guidance process is complete? Would you then reduce the number of additional employees and the user fees paying for them? If the four most significant proposed rules are already at OMB, haven 't you already completed the most labor-intensive part of the process?

Answer: Implementing the new preventive controls framework that will be established with the FSMA-mandated regulations will take new resources now and into the future. The development of the regulations is just the start of a process which includes developing significant numbers of commodity-specific guidance documents, model plans, and other outreach materials to assist industry with implementation. We will also need to train our inspectors and support them in implementing the new preventive controls framework. The subject matter experts who help develop the regulations and guidance will serve as a resource for implementation for both FDA and stakeholders.

4. Our office has received many constituent communications in opposition to a specific section of the Medicare Physician Fee Schedule Final Rule which went into effect on January 1, 2012. A good number of constituent radiologists have opposed the inclusion of a 25 percent multiple procedure payment reduction (MPPR) to the professional component

of certain advanced diagnostic imaging services interpreted by the same physician, on the same patient, during the same session. A recent study published in the Journal of the American College of Radiology determined that any efficiencies that exist in the professional component of advanced diagnostic imaging are in the 3-5% range. Are you aware of CMS conducting any statistical or data analysis that justifies the ultimate decision to apply a 25% MPPR on the professional component? If so, would you be willing to share the specific data set that was used in support of the MPPR?

Answer: CMS adopted this policy based on sound data analysis; this analysis showed that there is duplication and efficiencies in physician work when multiple images are taken in the same session. While CMS acknowledged that efficiencies may vary across code pairs, the analysis demonstrated that a 25 percent reduction in the professional component is reasonable. The data even suggest that the efficiencies may be higher than the 25 percent reduction policy that was adopted. This is further affirmed by the comments the Medicare Payment Advisory Commission (MedPAC) submitted on the CY 2012 Physician Fee Schedule proposed rule, in which they supported the originally proposed reduction of 50 percent to the professional component.

CMS has also seen a trend that Medicare spending for imaging services paid under the physician fee schedule has grown dramatically over the past decade due to an increase in the number and intensity of these services. MedPAC has stated that this volume growth may signal that these services are mispriced.

Further, CMS described the data that we used and included a description of our methodology in the Calendar Year (CY) 2012 Physician Fee Schedule final rule. Additionally, in December 2011 (subsequent to publication of the final rule) CMS met with industry representatives to further describe our methodology.

5. As you may know, the Washington Legislature is considering a bill, HB 2330, to mandate abortion coverage in all health insurance plans. According to the bill, any health plan that provides coverage for maternity care or services must also provide abortion coverage. If enacted this mandate would appear to violate the Hyde-Weldon conscience clause, which states that no Labor-HHS appropriations funds may be made available to a state that discriminates against a health insurance plan for refusing to provide, pay for, provide coverage of, or refer for abortions. There is the real concern that this law would put the state in serious jeopardy of losing all federal assistance appropriated under the L-HHS bill. As a result of those concerns a provision was added indicating that the bill would not go into effect if it would result in noncompliance with the Hyde-Weldon amendment. It would be extremely helpful, if you would provide clear guidance to the State on this matter.

Would you clarify the following:

a. Would HB 2330, if enacted, violate the Hyde-Weldon amendment?

b. Would L-HHS funds be withheld from the state of Washington if this bill were enacted?

Answer: As a former Governor, I am very respectful of the state legislative process, and I decline to take a position on state legislation

6. States are facing a "squeeze" from both federal and local governments and Medicaid costs are forcing states to make tough policy choices. According to the National Association of State Budget Officers, increasing federal mandates are forcing states to spend more on Medicaid than K-12 and higher education and public safety.

Do you believe the President's budget, which forces nearly $60 billion onto states without any additional flexibility, is appropriate during this tough time for states?

Answer: State fiscal situations are beginning to turn around, and the Administration is optimistic that steps we have taken toward economic recovery will result in substantial further improvement by FY 2015 when states will also receive significant benefits from covering the Medicaid expansion population in the form of reduced costs for uncompensated care and improved health outcomes.

In addition, for the first three years of the Medicaid expansion (CY 2014-2016), States will receive 100 percent FMAP for expenditures related to the newly eligible adult population. After that, the Federal government will continue to fund at least 90 percent of the cost of the newly eligible population. States that had expanded Medicaid eligibility levels prior to the Affordable Care Act also will receive significant Federal support beginning in 2014.

7. The President has called on states to focus greater investment on education, yet Medicaid is increasingly consuming a significant portion of state budgets. Under the Maintenance of Effort, states are limited in what changes they can make to their program to ensure only the truly eligible actually receive benefits for the program. As a former Governor, I am sure you understand the importance of giving states maximum flexibility to balance their budgets while promoting key initiatives such as K-12 education.

> **a. Are you concerned that states do not have the flexibility they need to balance Medicaid spending with education priorities in their state?**

Answer: There are a number of steps States can take to reduce costs and squeeze waste, fraud and abuse from their programs. States have many choices they can make including limits on some benefits, changes in cost-sharing, and greater use of managed care.

Medicaid cost issues largely reflect the cost issues facing our health care system as a whole. Like other payers, States can save considerable dollars by focusing on improving the safety and quality of care. Efforts to reduce and eliminate unnecessary hospital readmissions are a great example. Preventing one hospital readmission of a disabled adult with Medicaid can save enough money to cover three adults without disabilities for an entire year.

> **b. Moreover, how do you expect states to handle existing Medicaid costs with the added billions that will come on their tab after 2014?**

Answer: The Affordable Care Act asks that all sectors of the nation come together to contribute to the shared goal of reducing the uninsured and improving health care. As part of that initiative, the Medicaid program is expanded to cover individuals with incomes at or below 133 percent of the Federal poverty level. Congress recognized that this critical new step could not be accomplished without Federal support. Therefore, the Affordable Care Act provides substantial financial support for States to help them accomplish the task. For the first three years of the expansion (CY 2014-2016), States will receive 100 percent FMAP for expenditures related to the newly eligible adult population. After that, the Federal government will continue to fund at least 90 percent of the cost of the newly eligible population. States that had expanded Medicaid eligibility levels prior to the Affordable Care Act also will receive significant Federal support beginning in 2014.

At the same time, States will also receive significant benefit from covering this new population in the form of reduced costs for uncompensated care and improved health outcomes.

8. States, such as Washington, are faced with a situation in which they are being asked to move forward with implementation of exchanges. Yet, there is a lack of guidance at the federal level as to what is expected of states at this point and what impact the Supreme Court's decision will have. In fact, I've been contacted on multiple occasions by legislators in WA State with regard to implementing an exchange because of the lack of information at HHS. Moreover, it is our understanding that many states have decided to wait until the Supreme Court rules to move forward on an exchange. What advice is HHS giving to states?

Answer: As we proceed through implementation, HHS is aware that different states are operating on different timeframes. We are working hard to finalize existing proposed rules and release guidance and other information about HHS's operational procedures and intended approach to a variety of topics so that states and stakeholders have an understanding of future opportunities and potential obligations.

We expect to finalize the series of proposed rules related to Exchange establishment, premium stabilization policies and Medicaid eligibility in the near future. In addition, I would like to point out that in December, HHS released a bulletin on our intended approach to defining essential health benefits and just recently we released a bulletin regarding our intended approach to implementing the Actuarial Value and reduced cost-sharing provisions of the law. We stand ready to assist all states, regardless of where they are in the Exchange development process.

The Honorable Leonard Lance

Medicare Advantage Program and Quality Demonstration

1. The Administration has touted the success of the Medicare Advantage program over the last several months, claiming credit for increased enrollment and lower premiums on average, as well as for higher quality plan options. The Administration has also claimed that concerns about the cuts to Medicare Advantage plans in the PPACA were overblown or inaccurate as evidenced by continued participation of plans in the program and the aforementioned enrollment and premium numbers.

a. Please state which payment changes mandated by the PPACA for the Medicare Advantage program have been implemented, what phase are they in and when will full implementation occur.

Answer: Currently, CMS has implemented all the payment changes mandated by the Affordable Care Act for the Medicare Advantage (MA) program according to the timeframes required by the law. CMS provided detailed information about these enacted MA payment changes in the 2011 Rate Announcement, 2012 Advance Notice, 2012 Rate Announcement, 2013 Advance Notice and 2013 Rate Announcement. They are available on the CMS website at:

http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html

CMS will continue to post future MA plan payment information to its website annually each February (Advance Notice) and April (Rate Announcement).

The Affordable Care Act made the following changes to provisions in title XVIII of the Social Security Act that impact payment to MA Organizations:

Section 3201[3]

Modified Benchmarks

- This section froze Medicare Advantage (MA) benchmarks in 2011.
- Beginning in 2012, MA county-level benchmarks are to be set on a sliding scale using quartile rankings based on current average fee-for-service (FFS) costs in an area. The new benchmarks are being phased in on a two, four, or six year schedule beginning in 2012 (fully phased in for all counties in 2017).
    - The specific quartiles are: 25 percent of counties with highest level of per-capita FFS spending have benchmarks set at 95 percent of FFS, second quartile benchmarks set at 100 percent of FFS, third quartile benchmarks set at 107.5 percent of FFS, and fourth quartile benchmarks set at 115 percent of FFS.
    - The modified benchmarks are capped at the applicable amount.
    - This provision uses two alternative phase-in schedules: 1) Four year phase-in beginning in 2012 and completed in 2015 which targets areas with benchmark

[3] The Senate bill version of section 3201 was repealed and replaced by Section 1102 of HCERA. We describe the final version here.

changes of at least $30, but less than $50; and 2) Six year phase-in beginning in 2012 and completed in 2017 which targets areas with benchmark changes of at least $50. The provision continues to phase out indirect medical education (IME) payments to MA plans and exempts PACE plans from this new payment methodology.

Quality Bonus Payments; Application of Increase for Low and New Enrollment Plans
This provision provides for quality based payment adjustments for plans having 4 stars or more under a 5-star rating system, beginning in plan year 2012. For qualifying plans (those with 4+ stars) in qualifying counties (generally counties with low FFS costs and MA penetration rates exceeding 25 percent) those plans are eligible for double bonus payments.

CMS implemented final regulations in CMS-4144-F in accordance with this bonus system. However, under the authority of Section 402(a)(1)(A) of the 1967 Social Security Amendments (as amended), CMS is currently conducting a demonstration to test an alternative method for computing quality bonus payments (QBPs) for plan years 2012 through 2014.

For plan year 2012, low enrollment plans are deemed under the Affordable Care Act to be a qualifying plan. For subsequent years, the Secretary is to develop a quality star rating system for low enrollment plans. New plans meeting criteria specified by the Secretary are to be treated as a qualifying plan and receive the following percentage increase to their benchmark: 2012, 1.5 percent; 2013, 2.5 percent; and 2014 and subsequent years, 3.5 percent.

HCERA 1102

Repeals the Comparative Cost Adjustment Program
This provision also repeals the comparative cost adjustment program established by the MMA.

Sec. 3202[4]

Benefit Protection and Simplification and adjustments to rebate percentages
Beginning with plan year 2011, MA plans may not impose cost sharing charges on beneficiaries for certain services that are greater than what is charged under Original Medicare. These services include chemotherapy, renal dialysis, skilled nursing care, and other services as determined by the Secretary.

Beginning with plan year 2012, beneficiary rebate amounts (based on the difference between the plan bid and the benchmark amount for the county) are to be determined using a phased-in approach (fully in place for plan year 2014) that reduces the amount of rebates available for premium reductions or additional benefits depending on the plan's quality rating based on CMS' five star rating system. Previously, 75% of the difference between the plan bid and the benchmark (if the bid is lower) was to be paid in rebates. Under section 3202, plans with a quality rating of at least 4.5 stars would receive a rebate percentage of 70; plans with a quality rating of at least 3.5 stars and less than 4.5 stars would receive a rebate percentage of 65; and plans with a quality rating of less than 3.5 stars would receive a rebate percentage of 50. For

[4] As amended by Section 1102(d) of HCERA

2012, low enrollment plans shall be treated as having a star rating of 4.5 stars. For 2012 and subsequent years, new MA plans would be treated as having a star rating of 3.5 stars.

Sec. 3203[5]

Application of Coding Intensity Adjustment During MA Payment Transition
This provision extends indefinitely (absent certain steps to ensure against coding differences) the explicit statutory requirement that CMS conduct analysis of the differences in coding patterns between the FFS and MA programs, and adjust MA plan payments on an annual basis. Beginning in plan year 2019 and subsequent plan years, the adjustment shall be no less than 5.7 percent. In calculating each year's adjustment, the adjustment factor for 2014 shall not be less than the adjustment factor applied for 2010, plus 1.3 percentage points (4.71 percent total). For plan years 2015 to 2018, the adjustment factor shall not be less than the adjustment factor applied for the previous year, plus a .25 percentage point increase.

Sec. 3205

Extension for Specialized MA Plans for Special Needs Individuals
Beginning in plan year 2011, improves payment accuracy for new SNP enrollees and individuals with multiple co-morbid chronic health conditions, and, for certain SNPs, allows the Secretary to adjust payment for costs associated with caring for frail populations who are similar to those in the PACE program.

b. What are the HHS actuary's estimates of Medicare Advantage enrollment after full implementation of PPACA?

Answer: On February 10, 2011, the CMS Chief Actuary in his testimony before the House Committee on Ways and Means reported that the estimated effect of Affordable Care Act changes on Medicare Advantage payment would reduce enrollment by about 50% in 2017, once fully phased in. Specific enrollment estimates are provided in the President's FY 2013 Budget.

I am happy to report that these predictions about reduction in enrollment have not come true and in fact the MA program remains stronger than ever. Today, on average there are 26 MA plans to choose from in nearly every county across the country. Access to MA remains strong with 99.7 percent of Medicare beneficiaries enjoying access to a MA plan. Since 2010 when the Affordable Care Act was passed, MA premiums on average have fallen 16 percent and enrollment has climbed by 17 percent to over 12.8 million beneficiaries.

c. Please describe the PPACA quality bonus program whereby 4 and 5 star plans would receive additional bonus payment? Has this bonus program been able to mitigate current plan payment changes as well as provide an incentive for plans to improve their quality rankings, in part in order to receive the bonus?

[5] Repealed and replaced by Section 1102 of HCERA

Answer: The Affordable Care Act of 2010 provides for Quality Bonus Payments (QBPs) to MA plans that achieve at least four stars in a five-star quality rating system. The Affordable Care Act also changes the share of savings that MA plans must provide to enrollees as the beneficiary rebate, mandating that the level of rebate is tied to the level of a plan's star quality rating. These QBP ratings, beginning in 2012, directly affect the monthly payment amount MA organizations receive from CMS.

In addition to the Affordable Care Act QBPs, CMS is currently conducting a demonstration using authority of Section 402(a)(1)(A) of the 1967 Social Security Amendments (as amended), to test an alternative method for computing QBPs for plan years 2012 through 2014. As part of the evaluation and analysis of the current Quality Bonus Demonstration program, CMS intends to determine the impact on quality improvement by comparing MA plans' performance with that of non-MA plans. The evaluation of plan performance improvement will inform how best to structure the MA program for the long term.

d. With statutory bonus payment in place, why did the Department use demonstration authority under Section 402 of the Social Security Act to add over $8 billion into Medicare Advantage plan payments - awarding these bonus payments to 3 star plans and expanding the scope/amount of the bonuses to all plans? Please explain your response to the GAO's questions about whether this can be truly considered a "demonstration" program, given that it is being implemented nationwide and is therefore not testing any real policy change, and even if successful, will not be allowed to continue.

Answer: Building on the quality bonus payment provisions in the Affordable Care Act, CMS developed a Quality Bonus Payment (QBP) demonstration to further test whether stronger financial incentives and investments in quality plans will lead to more rapid increases in quality among MA plans. While the Affordable Care Act methodology provided for a new bonus payment to be awarded if a MA plan rating improved from 3 stars to 4 stars in 2012 and thereafter, under the current nationwide demonstration, there are financial incentives for MA plans to improve from 2 to 3 stars, from 3 to 4 stars, and from 4 to 5 stars. With respect to the early years of the demonstration, this approach provides investments in plans that have quality ratings across a broader spectrum, as they have proven their ability to use resources effectively, and could be expected to improve quality more effectively. These incentives encourage, and the investments enable, quality improvement for a larger number of plans, positively affecting a larger number of beneficiaries. This demonstration is based on the premise that improved quality results in improved health outcomes, and thus savings over time from more effective and efficient delivery of needed health care.

Section 402 of the Social Security Amendments of 1967, 42 U.S.C. 1395b-1, is the authority for this Medicare payment demonstration. Subsection 1395b-1(a)(1)(A) authorizes HHS to develop and engage in "experiments and demonstration projects" to determine whether changes in methods of payment or reimbursement would increase the "efficiency and economy of (Medicare) health services…through the creation of additional incentives…without adversely affecting the quality of such services."

The Department fully supports this initiative and does not agree with the GAO's findings on the QBP demonstration's design and evaluation or the recommendation to cancel the demonstration. The Department believes that the MA-QBP demonstration is consistent with the precedent established by other demonstration projects. For example, under the prior Administration, CMS conducted several large scale demonstrations that were national in scope:

- The Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans;
- The Medicare Demonstration to Revise the part D Low Income Benchmark Calculation; and

e. Will an additional $2.8 billion be spent on MA plans in 2012 alone as a result of this demonstration? How much of the phased-in payment changes does this amount offset?

Answer: The CMS Office of the Actuary (OACT) estimates the net cost of the demonstration for 2012 to equal $2.7 billion. OACT estimates that the cost to the Medicare program to extend the QBPs to additional MA plans and accelerate the phase-in of QBPs is about $8.3 billion. In contrast, at the time of enactment, CBO estimated that the Affordable Care Act's MA payment changes would reduce payments to MA plans by over $130 billion by 2019. It is important to note that these bonus payments allow plans to invest in quality improvement. Organizations receiving bonuses can take the availability of these new resources into account in submitting their bids for A and B benefits, while still having a margin available to provide additional benefits to enrollees based on the difference between their bid and the higher benchmark amount produced by the bonuses.

f. Please confirm whether this is the most expensive demonstration ever done by CMS under Section 402 authority - and if not, please describe any more expensive 402 demonstrations and where this one ranks.

Answer: While the projected costs under this demonstration are higher than under previous Medicare payment demonstrations, it is possible that over the longer term, higher quality could lead to better treatment outcomes and lower costs.

g. Prior to this quality bonus demonstration project, what was the most expensive demonstration done by HHS that used the Section 402 authority? Could you document for this committee the history of Section 402 demonstrations, their costs, the length of the demos, etc.?

Answer: The Department has a history of using Section 402 authority in Medicare programs during the last 40 years. Demonstrations initially conducted under authority in section 402 were the foundation for all of the following into the Medicare program: the original HMO risk contracting program upon which Medicare Part C is based, Inpatient Hospital Prospective Payment System (PPS), Skilled Nursing Facility PPS, Home Health PPS, Durable Medical Equipment Competitive Bidding, Medicare HMOs, Medicare Preferred Provider Organizations

(PPOs), and the Program of All-Inclusive Care for the Elderly (PACE), as well as the hospice benefit.

Below are two examples of demonstrations that were national in scope including the most expensive done under Section 402 authority prior to the MA Quality Bonus Demonstration:

- In 2007, CMS implemented the two-year demonstration, "Demonstration to Limit Annual Change in Part D Premiums", which affected the premiums for all Part D beneficiaries in all Part D plans. Under this demonstration, CMS delayed the implementation of a statutory calculation used to determine beneficiary premiums and federal direct subsidy payments. Specifically, the demonstration allowed for a multi-year transition to a weighting methodology required by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) that otherwise would have significantly increased Part D beneficiary premiums in 2007. The total cost of this demonstration was $830 million due to the increased federal direct subsidy payments made in 2007 and 2008.

- In 2010, CMS implemented a one-year "Demonstration to Revise the Part D Low-Income Benchmark Calculation". This nationwide demonstration tested an alternative method for calculating the low-income premium subsidy amounts. The alternative method was successful in increasing the LIS benchmarks in regions that previously had relatively low premium subsidy levels. Beginning in 2011, the methodology tested under the demonstration was codified in statute as part of the Affordable Care Act. The cost of the demonstration was approximately $110 million due to the increased low-income premium subsidy amounts provided by the federal government.

The Honorable Bill Cassidy

CDC Guidelines

1. The CDC's Division of Viral Hepatitis recently released a study in the *Annals of Internal Medicine* that looked at the cost-effectiveness of birth-cohort screening for the Hepatitis C virus as compared to the current risk-based approach. There are four million Americans infected with HCV today and "baby boomers" account for two out of every three cases. Of the four million Americans infected, 75% are unaware of their condition, which tells me that the risk-based approach to HCV screening is highly ineffective. I understand that the CDC has been working to update their screening guidelines by recommending a one-time screening for all Americans born between 1945 and 1965. I applaud these efforts, but there needs to be some urgency behind the release of these guidelines. The *Annals* study included some devastating statistics on the mortality rate associated with HCV. In 2007, HCV surpassed HIV/AIDS with 15,106 deaths attributable to the virus and the *Annals* study forecasts that this number will increase to 35,000 annually by 2030.

Secretary Sebelius, this is the time to take action. When can we expect the CDC to release these new draft guidelines on HCV screening?

Answer: The Department of Health and Human Services has, under my leadership and that of Dr. Howard Koh, the Assistant Secretary for Health, prioritized action against viral hepatitis. To this end, we have released an action plan, "Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care and Treatment of Viral Hepatitis." The Action Plan calls for CDC to revise its guidelines for hepatitis C testing and linkage to care. CDC will conduct a thorough analysis of the epidemiology of hepatitis C to identify those populations most likely to be affected, as well as a thorough review of the available evidence on the cost and benefits of testing and treatment and is expected to issue revised guidelines in the near future.

Medicaid Expansion

2. CBO estimated in its March 2011 baseline that the Medicaid program would reach $4.6 trillion in federal spending over a 10-year period. Estimates show that Medicaid enrollment will reach 80 million people or more - signaling that one in four Americans will be on what was intended to be a "safety net" program for the poorest and sickest Americans. At the state level, Medicaid is expected to consume an increasing share of state budgets and grow much more rapidly than state revenue growth. In short, Medicaid is in trouble and the most vulnerable people in America are set to suffer if we cannot return the program to its original mission, which I believe is to help our nation's poorest, sickest old and young.

As I discussed during the hearing on March 1, 2012 I am concerned about the financial burden this expansion places on the States. I do think that the States must have more flexibility on how to implement their Medicaid programs. I mentioned the California state Medicaid program directly. I have been following Gov. Jerry Brown's plan for Medi-Cal. The governor has proposed to save the state more than $500 million a year. The governor wants co-pays from recipients for emergency-room visits as well as routine trips to the doctor and dentist, beginning in October. The Obama Administration has rejected this idea.

An independent study commissioned by the California Medical Association (CMA) found that 36 percent of Medi-Cal enrollees said they were unable to see a doctor because the provider did not participate in Medi-Cal. That is four times the number of privately-insured Californians who were turned down by doctors due to their insurance carrier (9 percent).

Secretary Sebelius, what is your view on the Obama administration's OK of 10% across-the-board physician payment cuts in Medi-Cal, one of the poorest paying Medicaid programs in the nation. Are you concerned that physicians will no longer be able to afford to participate in the Medi-Cal program?

Answer: I am committed to ensuring access to care for Medicaid beneficiaries. The Affordable Care Act provision that helps States boost their payment rates to primary care providers for two years (2013 and 2014) is a good first step. The Affordable Care Act also takes important and significant steps to boost the number of primary care providers, including bonus payments for primary care practitioners in Medicare and new residency slot allowances, traineeships for nurse practitioner and physician assistant students, and support for public health workforce and development. In addition, the Affordable Care Act makes investments in the National Health Service Corps, which puts primary care health practitioners in areas with limited access to health care. These investments help expand the primary care workforce and meet the health care needs of underserved communities across the country. Combined, these Affordable Care Act provisions help boost the supply of health care providers who treat patients across the country, particularly in high-need areas where many patients may have Medicaid.

The Honorable Edolphus Towns

My office continues to have concerns with the reported 50-90% audited error rates being released by CMS' contractors. I am advised that this error rate is a direct result of confusion among physicians as to the proper paperwork needed to properly prescribe PMDs on behalf of their patients. In fact, I regularly hear from stakeholders regarding a lack of clarity and consistency associated with the paperwork needed to properly file PMD claims on a beneficiaries behalf. To that end, physicians and physician associations have long recognized the significance of utilizing clinical templates for patient examinations. Likewise, several members of Congress, in an attempt to reduce the error rate, have specifically requested that CMS develop a standard template for doctors to use in prescribing a PMD. Although CMS has agreed to develop such a template, it has yet to be released. When will CMS release the PMD face-to-face evaluation template that physicians can rely on to establish medical necessity and validates that the treating physician conducted the congressionally mandated face-to-face medical evaluation of the patient?

Answer: CMS is in the process of developing an electronic clinical template as part of provider's electronic health records (EHR). An initial draft of the template is available on the CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/ElectronicClinicalTemplate.html. CMS is actively seeking input on this template and stakeholders can submit comments on the draft to eclinicaltemplate@cms.hhs.gov. In addition, CMS will host a series of Open Door Forums to allow suppliers to comment and submit feedback on the draft template; the schedule for future ODFs can be found on the CMS website.

The Honorable Eliot Engel

I want to thank the Administration for the recently announced Strong Start Initiative to improve maternal and newborn health. Recognizing that rapid gains in maternity care quality and outcomes are both necessary and within reach similarly led me to introduce H.R. 3620, the Quality Care for Moms and Babies Act at the end of last year.

I believe that there are excellent provisions in Strong Start -- including the maternity care home piece which also is in my legislation -- that will have a significant impact on improving material and newborn health.

As we all know, maternal and newborn care is the leading hospital conditions covered by Medicaid. However, there are many quality measurement gaps for this large vulnerable population that are not being covered in the Adult Medicaid and CHIP programs. I believe quality measurement offers the potential to curb overuse, reliably deliver effective care, and improve the value of our considerable investment in this population.

Could you please comment on what additional administrative opportunities exist for developing quality measurements, including the possible adaptation of Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys to measure the experiences of childbearing women and newborns?

Answer: The Initial Core Sets of Child and Adult Medicaid Health Care Quality Measures contains eight measures related to maternal and reproductive health, including a measure to capture the postpartum care rate, which serves as a complement to the measure in the Initial Core Set of Children's Health Care Quality Measures, timeliness of prenatal care (see below for listing of eight measures). Over the next year, CMS will phase in an Adult Medicaid Quality Measures Program to address measurement gap areas of the Initial Core Set for Medicaid-eligible Adults, begin testing the collection of some of the measures, and focus on refining measures, where needed. One of the 26 Initial Core Health Care Quality Measures for Medicaid-eligible Adults, is the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan survey version 4.0, including the Adult Questionnaire Supplemental Items 4.0H. CMS will use the data from the CAHPS survey to assess Medicaid beneficiaries' access to and experiences with care. The technical specifications for these measures will be available in fall 2012 to support States that seek to voluntarily collect and report the Initial Core Set of Health Care Quality Measures for Medicaid-eligible Adults. CMS also has other initiatives that relate to children's quality measures, including a Pediatric Quality Measures program (PQMP) launched in 2011, to enhance quality measurement for children.