

Secretary Sebelius Questions for the Record
House Energy & Commerce Subcommittee on Health
April 18, 2013

The Honorable Joseph R. Pitts

1. Would you support legislation that places HHS employees in the exchanges?

Answer: The Health Insurance Marketplaces are modeled after the Federal Employees Health Benefits Program (FEHB) where most HHS employees currently obtain health insurance. Like the FEHB, which permits federal employees to choose from various health benefits coverage options, the Marketplaces will allow individuals and small businesses to shop for a variety of affordable health insurance plans that provide comprehensive benefits. Current law does not allow for Federal Executive Branch agencies to provide health insurance coverage to their employees by contributing to coverage obtained through the Marketplaces.

2. As you know GAO and MedPAC have examined the in-office ancillary Service Exception in depth and neither group has recommended repealing IOASE. I am concerned that the Administration's proposal would result in more patients receiving care in the more expensive hospital setting, thus undermining an integrated delivery of care and lead to more hospital acquisitions of physician practices.

Would you provide the quantitative analysis that supports the \$6 billion score for the proposal? How much is attributable to each service?

Answer: The estimate of \$6 billion in savings over 10 years was developed by the independent CMS Office of the Actuary based on its assumptions about predicted reductions in spending on services and behavioral changes related to the policy.

3. With regard to radiation, are you aware that radiation utilization from 2007-2011 has been flat at the precise time physician offices have acquired the IMRT technology? Doesn't that suggest that there would be no savings from prohibiting physician ownership of radiation?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer for services to be performed by their group practices for patient convenience. While there are many appropriate uses for this exception, evidence suggests that this exception may have resulted in overutilization and rapid growth of certain services over time, including radiation therapy. Effective calendar year 2015, this proposal would seek to encourage more appropriate use of select services by amending the in-office ancillary services exception to prohibit certain referrals for radiation therapy, therapy services, and advanced imaging, except in cases where a practice meets certain accountability standards, as defined by the Secretary.

- 4. The President's budget would equalize payment rates for certain conditions that can be treated in both rehabilitation facilities and skilled nursing facilities. In the budget brief, this balancing of payment rates is described as "improving financial incentives to encourage efficient and appropriate provision of care by reducing the disparity in Medicare payment rates between settings." Please explain what the President hopes to accomplish by this?**

Answer: Currently, treatment of certain knee, hip and pulmonary conditions that do not require intensive therapeutic post-acute care can be performed in either an inpatient rehabilitation facility (IRF) or a skilled nursing facility (SNF), but Medicare payments are much higher if the treatment occurs in an IRF. This proposal would encourage care delivery in the most clinically appropriate and cost-effective setting. It would, beginning in 2014, reduce the differences among settings in Medicare payments for certain knee, hip, and pulmonary conditions, as well as other conditions selected by the Secretary.

- 5. The proposed budget would also implement bundled payments - beginning in 2018 - for post-acute care providers including long term care hospitals, and home health providers. Has your department already begun work to prepare for implementation and, if so, would you please describe such work? If not, how do you envision such a roll out in 2018?**

Answer: The President's FY 2014 budget includes a proposal to implement bundled payment for post-acute care providers, including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and home health providers, beginning in 2018. Payments would be bundled for at least half of the total payments made to post-acute care providers. The Secretary would specify the payment rate for an episode of care based on patient characteristics that covers the cost of all SNF, LTCH, IRF, and home health services. The Secretary has the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate.

Payments for a bundled episode of care would be reduced 0.95% in each of the years 2018, 2019, and 2020, with a 2.85% cumulative reduction by 2020. Beneficiary coinsurance levels would remain the same as those under current law (for instance, to the extent beneficiaries use SNF services, they would be responsible for the current law copayment rate).

CMS is interested in hearing from stakeholders about the implementation of this proposal and, chose the implementation date of 2018 so that CMS would have adequate time to prepare and apply lessons learned from the Center for Medicare and Medicaid Innovation's Bundled Payments for Care Improvement Initiative, which began earlier this year.

- 6. Today, hospitals receive reimbursement from the federal government for bad debts. Changes were made in PPACA to lower that amount to 65% of the total bad debt amount a hospital incurs. The proposed budget would seek to further reduce this amount by 25% (to 40%). Can you explain the rationale behind this change?**

Answer: The National Commission on Fiscal Responsibility recommended gradually putting an end to payment for Medicare bad debt. Congress's action last year to reduce coverage of bad debt to 65% for all entities represented an important first step towards aligning Medicare's bad debt policy with private sector practices. However, even after this change, Medicare's reimbursement of bad debt remains unusually generous. We believe making further adjustments constitutes a smart, targeted approach to achieve further Medicare savings.

7. The Office of Management and Budget (OMB) directed all federal agencies to “use any available flexibility to reduce operational risks and minimize impacts on the agency’s core mission in service of the American people” and to “identify and address operational challenges that could potentially have a significant deleterious effect on the agency’s mission or otherwise raise life, safety, or health concerns.”

On what legal opinion did HHS base its decision to apply the 2 percent cut to ASP?

Answer: Based on an assessment conducted by the Department of Health and Human Services (HHS), we do not have the authority to exempt Medicare payment for Part B drugs under the Budget Control Act of 2011. The sequestration exemptions, which are specified in 2 U.S.C. sections 905 and 906, do not apply to payment for Medicare Part B drugs.

8. Does HHS believe applying the sequester three times to an oncologist’s payments will raise life, safety or health concerns? If so, why hasn’t HHS used its discretion to modify the sequester with respect to reimbursement for cancer treatment?

Answer: We do not have the authority to exempt Medicare Part B drug payments from the sequestration cut. We share your concern about the potential adverse impacts of the payment cuts mandated by sequestration. We will continue to monitor the impact of provider payment cuts mandated under the Budget Control Act to assess their impact on Medicare beneficiaries and we are happy to share our results.

9. Open enrollment in the Health Insurance Marketplace (State Exchanges) begins October 1, 2013. Will individuals shopping in these state marketplaces have complete transparency to and the ability to compare options for cost and availability of medical and pharmaceutical coverage?

Answer: Yes, Marketplaces will make purchasing private health insurance easier by providing qualified individuals and qualified employers with one-stop shopping where they can choose qualified health plans that best fit their needs. Specifically the Marketplace will allow consumers to:

- Shop for private health insurance with comprehensive benefits

- See what their premium, deductibles, and out-of-pocket costs will be before they decide to enroll
- Make apples-to-apples comparisons of costs and coverage between health insurance plans
- Find out if they qualify for premium tax credits to help lower the costs of their monthly premiums, and cost-sharing reductions to lower their out-of-pocket expenses
- Learn if they can get free or low-cost coverage from Medicaid or CHIP

10. In response to reports from AHRQ and MedPAC regarding the health savings generated by Comprehensive Medication Management and Medication Therapy Management (CMM/MTM), will HHS commit to supporting a CMM/MTM component within Medicare?

Answer: Under the MMA, Part D plan sponsors were required to establish MTM programs to optimize therapeutic outcomes for targeted Part D beneficiaries through improved medication use. The initial CMS regulations established few requirements and a general framework that allowed sponsors flexibility to promote best practices. After an extensive analysis of the industry's best practices, the requirements were expanded in 2010 for increased consistency among plans, and CMS pushed the industry forward. Significant changes were made to the targeting criteria and CMS required a minimum level of MTM services that must be offered to the Part D beneficiaries who qualify for these programs. Additionally, Section 10328 of the ACA specified changes to Part D MTM programs to further strengthen the MTM programs offered to Part D beneficiaries. For the coming years, we expect increased standardization and industry consensus. CMS would like to expand access to better target the beneficiaries who most need MTM. In addition, through expanded data collection, we want to be better positioned to evaluate the impact of MTM at the beneficiary level.

11. Your administration has raised many expectations that PPACA will improve the health of Americans, because health insurance will improve access to health care. An important factor in healthcare access and delivery is the size of the healthcare workforce, which is currently inadequate. Would you explain why in the proposed HRSA budget, funding for Health Workforce and Children's Hospital GME has been reduced? And, would you explain who would provide the care in all those new community health centers that will be funded?

Answer: With regard to the CHGME program, while the program has benefited many facilities across the country, we are working within the context of a budget that requires tough choices. A challenging budget environment required a closer examination of how resources are spent. The FY 2014 budget provides \$88 million to fund the CHGME payment. This funding is adequate to support expenses that directly support the residents and faculty so that training of pediatricians and other medical specialties can continue, but does not provide funding for the indirect costs.

Our investments in the health care workforce reflect our efforts to ensure Americans have access to health care in their communities. As a result of historic investments by both the Recovery Act and the Affordable Care Act, the numbers of primary care providers in the National Health

Service Corps (NHSC) are at all-time highs, nearly tripling between 2008 and 2012. Today, 10.4 million people in communities nationwide receive health care from nearly 10,000 National Health Service Corps clinicians. The National Health Service Corps has invested nearly \$900 million in providing scholarship and loan repayment incentives to primary care providers and students in return for service in underserved areas, including many community health centers that serve those areas.

12. In the proposed HHS budget, the discretionary funding for the Vaccines for Children and the Breast and Cervical Cancer Program is reduced to reflect expanded access to health insurance. Yet funding increased for other programs, such as Ryan White and Family Planning that will also be affected by the expansion. Would you explain why, in this fiscal environment, these programs were not only spared from cuts, but received increases?

Answer: The FY 2014 budget request reflects continued support for the Ryan White HIV/AIDS Program (RWHAP) while HHS conducts an in-depth assessment of the interaction between the Affordable Care Act and RWHAP's continued provision of HIV services, and the potential for achieving one of the National HIV/AIDS Strategy's key goals: improving health outcomes for people living with HIV/AIDS.

While HHS does not expect a significant shift in the demand for clinical services in FY 2014, nonetheless, in FY 2014, the number of insured Ryan White clients is expected to increase to some extent. The FY 2014 Budget also supports Ryan White funded services not covered by public or private insurance, but which are essential to linking people living with HIV into care and maintaining them on drug regimens. These "continuum of care" services are critical to preventing the spread of the domestic HIV epidemic as recent studies have found that anti-retroviral (ARV) treatment reduces HIV transmission by 96 percent. Examples of these services include case management, transportation assistance, and treatment adherence, which are critical to keeping people in care and on drug regimens that decrease viral load and prevent the spread of the virus. Ryan White dollars are also used to support cost sharing, which leads to more consistent access to ARV drugs and increased adherence to treatment. Ryan white grants are also used by clinics to fund several core medical services not consistently covered by insurance, including comprehensive substance use treatment, mental health services, and care coordination services.

The FY 2014 budget request also reflects continued support for the Title X Family Planning program, which provides community-based preventive health services, including family planning, to approximately 5 million individuals annually, the majority of whom are low-income and uninsured. Services range from the provision of FDA-approved contraceptive methods to cervical and breast cancer screening to a host of other preventive health screenings. Title X services sites are considered the usual source of medical care for six in 10 women who seek services through them. The Title X program accomplishes its mission in a highly efficient manner, and are estimated to provide \$5.3 billion in government savings. Studies have found that for each dollar invested in the program, approximately \$5.68 is saved, through averting costs to Medicaid for prenatal care, delivery, and postpartum and infant care.

13. To the American public and Congress, the Prevention and Public Health Funds appears like your own personal slush fund. Since 2010, we learned that the first wave of funding was used by States to fund lobbying, park signage, dog neutering, and other questionable activities. By 2012, the fund has morphed into a budgetary tool to prop up discretionary programs or Obamacare implementation. Instead, would you support directing these funds to help patients with pre-existing conditions? Don't these Americans deserve to get the relief that this administration promised them?

Answer: The Prevention and Public Health Fund (PPHF) has been used to fund important investments in our nation's health, including improvements in our ability to immunize children, reduce health-care acquired infections, improve laboratory systems at the state level, and detect and respond to disease outbreaks. The PPHF also supports the Community Transformation Grant (CTG) program, which supports evidence and practice-based efforts in states and communities to reduce chronic diseases. Awardees are addressing the priority areas of 1) tobacco-free living; 2) active living and healthy eating; and 3) high quality clinical and other preventive services, including prevention and control of high blood pressure and high cholesterol.

HHS remains committed to proper oversight and monitoring of appropriated funds, and to awardees' compliance with all applicable regulations and statutes. HHS awardees, including those in the CTG programs, are informed about the applicable federal laws, regulations, and policies relating to the use of federal funds, including applicable anti-lobbying provisions.

The Administration strongly supports policies that ensure all Americans with pre-existing conditions have access to affordable health care. This is why the Affordable Care Act banned insurance companies from charging more or excluding coverage based on an individual's pre-existing condition starting in 2014. It is also why the health care law adopted the PCIP Program to provide a bridge to the new system between 2010 and 2014.

The PPHF provides for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Assisting Americans in gaining affordable health care aligns with the purpose of the funds, which may be used for prevention, wellness, and public health activities. Implementing the Health Insurance Marketplace is the Administration's top public health activity, which has large potential to improve prevention in the next year by enabling individuals to enroll in coverage through private health insurance. The FY 2013 allocation reflects a broad and strategic portfolio of activities that supports the Administration's highest prevention and public health priorities.

14. Our nation continues to faces serious national security threats, and the need remains to protect the American people against chemical, biological, radiological and nuclear (CBRN) events. What impact has the availability of the Project BioShield Special Reserve Fund had on the development and procurement of medical countermeasures for national security threats over the past decade?

Answer: Project BioShield (PBS) has utilized the Special Reserve Fund (SRF) for nearly a decade to ensure the Nation is better prepared with new medical countermeasures (MCM) to address the dire medical consequences of catastrophic chemical, biological, radiological, and nuclear events in the civilian population. PBS has afforded eleven (11) new medical countermeasures for treatment or post-exposure prophylaxis against anthrax, smallpox, botulism, illnesses associated with radiological and nuclear events, and chemical agent intoxication (**Table 1**); recently two of these MCMs were the first products approved by the FDA under the Animal Efficacy Rule authorized under PBS. Additionally the SRF has supported the Biomedical Advance Research and Development Authority's (BARDA) establishment of a robust and diverse medical countermeasure development pipeline of 80+ product candidates for these threats. The future for PBS is even brighter, as this MCM development pipeline is expected to render at least twelve more new MCMs under PBS over the next five years to address anthrax, other biothreats including glanders and melioidosis, other illnesses associated with Acute Radiation Syndrome, thermal burns and blood replacement, and volatile chemical agents.

15. We are losing the fight against drug resistant pathogens. Our current antibiotic armamentarium is low and not regenerating fast enough. In the President's budget proposal, BARDA acknowledged this and is interested in helping advance new products. But manufacturers are fleeing the business, and only a few major companies are working in the field—it just doesn't make fiscal sense: the drugs are used infrequently—a good thing to keep resistance in check—and are meant to eradicate a pathogen in only a few doses. The FDA is putting in tremendous work to speed up product development, but what else can we be doing to further this critical therapeutic arena?

Answer: HHS agrees with your assessment of the emergence of drug resistant organisms and lack of new antibiotics. As the emergence of drug resistant organisms continues to increase, financial incentives for pharmaceutical companies to venture into this arena become scarcer. BARDA adopted in 2010 a strategic approach to incentivize companies developing novel antimicrobials for biothreats while having secondary public health benefits especially in the fight against antimicrobial drug resistance. Today BARDA supports the advanced development of seven (7) antimicrobial drug candidates for biothreats by partnering with five (5) companies and some clinical studies to evaluate these candidates for public health indications (e.g., MRSA). One obvious benefit to this strategy is the eventual availability of these new antibiotics in the commercial market will reduce the need to stockpile as much of these or similar antibiotics in the event of a biological attack. BARDA formed public-private partnerships with industry to share in the investments necessary to bring new drugs to market. **Figure 1** highlights BARDA's investment strategy in products that have the potential to impact both biothreats as well as emerging drug-resistant public health pathogens.

BARDA's investment strategy has received accolades from the Infectious Disease Society of America (IDSA) stating in public meetings "BARDA is keeping the antibiotic industry on life support". In addition, the PEW Charitable Trust sent a letter to Chairman Upton and Ranking Member Waxman stating "[BARDA's] program has become an important source of funding at a time when there are few promising new antibiotics in late stage development"...."the broad

spectrum antimicrobial program at BARDA is supported by industry and is a promising pathway for incentivizing new antibiotic development.” BARDA is currently supporting multiple manufacturers developing products for both biothreat pathogens and public health concerns:

- Achaogen – completed Phase II preparing for a large Phase III for CRE
- Tetraphase/CUBRC – in Phase II for MRSA, Gram(-) acinetobacter
- GlaxoSmithKline – a portfolio of three candidates at various stages Gram (+) and atypical Gram (-) bacteria
- Cempra – Phase I CRE and MDR Gram(-) Pseudomonas, acinetobacter
- Baselia – Phase I CRE, MDR Gram(-), Pseudomonas, acinetobacter

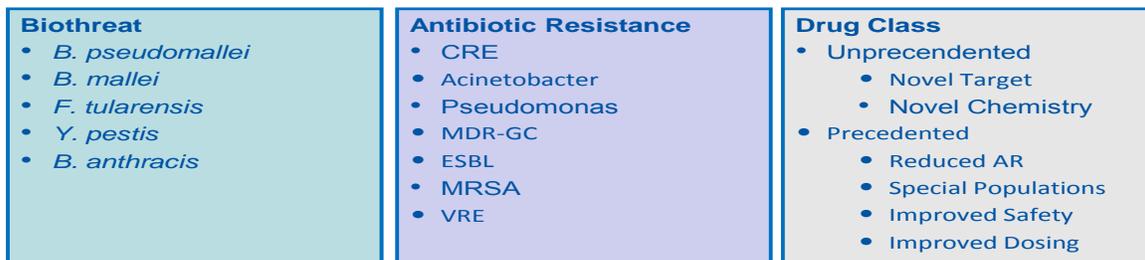
The partnership with GlaxoSmithKline (GSK) utilizes Other Transactional Agreement, an authority provided to HHS under the Pandemic All-Hazards Preparedness Act (2006). This is BARDA’s first use of this authority for product development and allows BARDA to invest in a portfolio of products instead of awarding a FAR-based contract for each candidate product. The agreement allows BARDA to participate on a GSK advisory board. Additionally, BARDA will have a say in how GSK invests their own capital in this portfolio of products.

The FDA has been proactively working with sponsors to explore innovative approaches to developing antibacterial drugs, particularly those intended to treat infections caused by antibiotic-resistant organisms and that otherwise address unmet medical needs. For example, FDA is currently drafting guidance to industry to assist sponsors in the development of antibacterial drugs for patients with unmet medical need for the treatment of serious bacterial diseases. FDA is also actively implementing the Generating Antibiotic Incentives Now (GAIN) Act, which, among other incentives, provides for an additional five years of market exclusivity for certain drugs that treat serious or life-threatening bacterial and fungal infections, including those caused by resistant organisms. These efforts represent BARDA, the FDA and Congress working in concert to incentivize manufactures to develop products to address the emergence of antibiotic resistance.

Table 1. Medical countermeasures acquired under Project BioShield in FY2004-FY2013.

MCM	Start Date	SNS Delivery	Industrial Partner	Funds Obligated
ANTHRAX				
Anthrax Antitoxin Monoclonal Antibody (Raxibacumab®) FDA approved (2012)	9/2005 7/2009	Completed Completed	GlaxoSmithKline (formerly Human Genome Sciences)	\$174 M \$160 M
Anthrax Antitoxin Anthrax Immune Globulin (AIG®)	9/2005	Completed	Cangene	\$160M
Anthrax Antitoxin	FY2013	Active Solicitation - Procurement Sensitive		
Anthrax Vaccine (BioThrax®)	5/2006 9/2007	Completed Completed	Emergent Emergent	\$243M \$465M
SMALLPOX				
Smallpox MVA vaccine (IMVAMUNE®)	6/2007 4/2013	Ongoing 2014	Bavarian Nordic	\$541M \$110M
Smallpox antiviral drug (Arestvyr®)	5/2011	Ongoing	SIGA Tech, Inc.	\$433M
BOTULISM				
Botulinum antitoxin (HBAT®) FDA approved (2013)	9/2006	Completed	Cangene	\$476M
RAD/NUC THREATS				
Potassium Iodide (ThyroShield®) FDA approved	3/2005	Complete	Fleming	\$18M
DTPA - Ca FDA approved	12/2005	Completed	Akorn	\$22M
DTPA - Zn FDA approved	12/2005	Completed	Akorn	
Anti-neutropenia cytokines	FY2013	Active Solicitation - Procurement Sensitive		
CHEMICAL THREAT				
Anti-convulsive drugs	FY2013	Active Solicitation - Procurement Sensitive		

Figure 1. BARDA strategic approach to antibiotic drug development for biothreats with secondary benefits towards antimicrobial drug resistance in the public health sector.



- Investment Strategy:
 - Alignment to pathogens that have a chance to significantly impact public health (relevance to both biothreat and public health)
 - Focus on novel targets/chemistry (higher risk)
 - Balance portfolio with established classes in advanced stages of development (lower risk)
 - Cost share in Phase III to reduce risk (mitigation)
 - Diversify investment around disease indications (reduces regulatory risk)

16. In August 2012, CDC found that three-fourths of all persons infected with Hepatitis-C are among the baby boom birth cohorts, with the vast majority unaware of their infection, and recommended that every boomer get screened once in their life regardless of risk factors (risk based screening was deemed of "limited success.") Meanwhile a sister agency, USPSTF, issued its draft guidelines for HCV screening that wants to continue on using risk-based screening and ignores the high density of HCV positive people in the baby boom generation. HCV costs are about to explode on Medicare—even though it's easy to test and then treat these populations, with new treatments literally curing people of the disease—and the ACA requires health plans to follow the USPSTF guidelines, and HHS does not seem ready. What is the Department doing to navigate and head off this looming medical and fiscal crisis?

Answer: In regard to Medicare coverage of screening for Hepatitis C Virus amongst the baby boom birth cohort, CMS has limited authority to consider coverage of new preventive and screening services. Specifically, the Medicare statute authorizes the Secretary to add coverage of “additional preventive services” – that is, preventive services not already covered under specific statutory provisions – if the service is recommended at the “A” or “B” level by the U.S. Preventive Services Task Force (USPSTF), and the service is determined through the Medicare national coverage determination (NCD) process to be appropriate for Medicare beneficiaries.

As you noted, the USPSTF recently initiated a reconsideration of their 2004 recommendation on routine screening for Hepatitis C Virus and issued a draft updated recommendation for public comment in November 2012. Until the USPSTF issues a final recommendation, Medicare lacks authority to consider coverage of this service. When a final recommendation is available, we will consider whether it warrants the opening of a national coverage analysis (the first step in the NCD process). The status of the Task Force’s work on this subject can be monitored at <http://www.uspreventiveservicestaskforce.org/uspstf/uspshcpc.htm>.

In regard to the Affordable Care Act provision for private insurance coverage of preventive services recommended by the USPSTF, the law requires that non-grandfathered plans cover services with an A or B recommendation without cost-sharing. Screening for Hepatitis C does not currently have an A or B Recommendation from USPSTF, and it is therefore not required to be covered.

17. The President's Budget proposal uses language suggesting ACA expansion efforts will take over much of the medical services of HIV patients, currently provided under Ryan White programs, ostensibly freeing up federal support for ancillary services for HIV patients—but what are the actual funding needs of this population, how should funds be used appropriately? What is HHS doing to help Ryan White grantees become federally qualified health centers to help beneficiaries in providing health services after ACA implementation?

Answer: The Affordable Care Act will provide coverage for primary medical care through Medicaid expansion and access to private insurance for many PLWH. As the Affordable Care Act is implemented, HHS anticipates changes in how Ryan White Program funds are utilized. The RWHAP will continue to provide core medical and “continuum of care” services to clients as needed. Core medical services not covered by insurance, include comprehensive substance use treatment, mental health services, and care coordination services. The details of this will vary from state to state depending on coverage decisions in Marketplaces and Medicaid. The RHWAP will also continue to have an important role in supporting community-based systems of care responsive to local needs and will support “continuum of care” needs of PLWH. Examples of services include case management, transportation assistance, and treatment adherence, which are critical to keeping people in care and on drug regimens that decrease viral load. Providing such services leads to improved clinical outcomes and prevents the spread of the domestic HIV epidemic, as recent studies have found that anti-retroviral treatment reduces HIV transmission by 96 percent.

By statute, the RWHAP is the payer of last resort. The program will only pay for eligible services that are not covered or minimally covered by other private or public insurance. The program currently provides, and will continue to provide, medical coverage completion and continuum of care services for those patients with or without insurance to ensure that vulnerable populations receive the full range of services necessary to remain in care and improve health outcomes.

HRSA’s Bureau of Primary Health Care (BPHC) received increased funding for the Health Center Programs. In FY 2013, an estimated \$19 million will be awarded to establish approximately 25 new health center access points. The Health Center Program New Access Points is a competitive Health Center Program funding opportunity to support new service delivery sites for the provision of comprehensive primary and preventive health care services. All applicants must demonstrate a high level of need in their community/population, a sound proposal to meet this need by ensuring the availability and accessibility of essential primary and preventive health services, including oral health, mental health and substance abuse services, responsiveness to the health care environment, collaboration and coordination with other area

health care providers, and readiness to rapidly implement the proposal. HRSA Ryan White grantees interested in becoming a health center were eligible to apply. To support this effort, HRSA conducted a training session for Ryan White grantees interested in applying for Health Center Program funding in November 2012. The President's budget for FY 2014 includes funding for New Access Points. New funding opportunities are posted on the HRSA Grants Web site at <http://www.hrsa.gov/grants> and www.Grants.gov. Additionally, organizations may apply at any time to receive designation as a Federally Qualified Health Center (FQHC) Look-Alike. FQHC Look-Alikes must meet the same requirements as section 330 grantees, but do not receive Health Center Program funds. FQHC Look-Alikes are eligible to receive cost-based reimbursement for services provided under Medicare, be reimbursed under their State Medicaid Prospective Payment System (PPS), and participate in HRSA's 340B Drug Discount Program, among other benefits. Other webinars that have been hosted by HRSA include: Protecting the Health Safety Net: Models to Help Non-FQHCs Prepare for Health Care Reform Implementation. This webinar focused on models for safety net providers in adapting to the new payer and provider environment under the Affordable Care Act.

HRSA's RWHAP National Technical Assistance Cooperative Agreement funded the HIV Medical Homes Resource Center (HIV-MHRC) whose overarching goal is to provide training and technical assistance to assist Ryan White HIV/AIDS Program grantees to understand, develop and successfully apply to become recognized Patient-Centered Medical Homes (PCMH). HRSA and CMS have co-sponsored webinars designed to orient Ryan White HIV/AIDS Program grantees and providers to the changing healthcare landscape of 2014. The webinars have focused on coordination across Medicaid and the Ryan White HIV/AIDS Program and highlight the differences between the current and future health care system for Ryan White providers.

HRSA also funded the AIDS Education and Training Center National Center for HIV Care in Minority Communities to provide intensive technical assistance to community health centers to increase the capacity of selected health centers to provide services or increase their level of services to PLWH. HRSA has also launched new Affordable Care Act website sections to house many resources and tools useful to Ryan White grantees to learn about, help enroll their patients in new coverage options, and get prepared as providers under the Affordable Care Act.

The Honorable Joe Barton

- 1. Given recent reports from China about what could be a very serious emerging threat from a new flu virus, how will the Department of Health and Human Services (HHS) make sure its recently awarded Centers for Innovation and Advanced Manufacturing are fully utilized, including removing any unnecessary burdens from bureaucratic processes within the Assistant Secretary for Preparedness and Response (ASPR) office that seem to plague other similar contracts?**

Answer: The outbreak of novel H7N9 influenza virus in China is being closely monitored by HHS. Since February 2013, over 130 cases of infection caused by the H7N9 influenza virus have

been reported in China with an estimated 30% fatality rate. However, with the closure of the live animal markets in China, and the onset of summer, there has been a dramatic drop in the number of cases. The last reported case was in mid-May.

The Department has taken several steps to respond to the H7N9 outbreak, as BARDA has engaged nine influenza vaccine manufacturers to develop H7N9 vaccines and possibly establish a small pre-pandemic H7N9 vaccine stockpile. New vaccine technologies – cell- and recombinant-based vaccine technologies - supported by HHS over the past decade and resulting in FDA-licensure over the past six months are available now to make more and better vaccine sooner in the U.S.

Manufacturers, CDC, and others developed vaccine seed candidates for vaccine production and distributed to all FDA-approved influenza vaccine manufacturers. BARDA supported development of several vaccine seeds using a state-of-the-art biosynthetic technology affording rapid one-week turnaround and without the actual H7N9 virus. Clinical investigational lots of H7N9 influenza vaccine are under production presently for clinical evaluation with adjuvants later this summer by the NIH and vaccine manufacturers to determine safety and immunogenicity, and dosage

If the H7N9 influenza virus were to emerge into pandemic, then HHS would direct these vaccine manufacturers to produce vaccine (and the delivery of supplies) needed to protect the public. During a pandemic situation, HHS contracting and technical personnel work closely to ensure timelines are compressed so that HHS can rapidly respond to the public health emergency.

The three Centers for Innovation in Advanced Development and Manufacturing (CIADM) established by HHS under BARDA leadership (2012) are an important component of the HHS response to infectious disease outbreaks, such as pandemic influenza. The three Centers will support on a daily routine basis the advanced development and manufacturing of CBRN medical countermeasures and will produce in an emergency at least 50 million doses of pandemic influenza vaccine within four months of the declaration of a public health emergency using novel and flexible modern manufacturing technologies. This pandemic vaccine production capability is completed already at the Novartis-based Center located in North Carolina. The other two Centers in Texas and Maryland will utilize the expertise of GlaxoSmithKline and VaxInnate, respectively, to produce pandemic influenza vaccines later this decade.

2. I am routinely informed that the contracting function handled by the office of the Assistant Secretary for Preparedness and Response is inefficient and lacks transparency. This has not only delayed procurement of needed medical countermeasures but also results in wasted effort, increased expense and deterred participation. What can HHS do to improve the performance by the contracting office within ASPR?

Answer: HHS/ASPR has instituted numerous business practices since the MCM Review (2010) to make the contracting activities for medical countermeasures more efficient and accountable. The usage of Broad Agency Announcements to solicit proposals from potential offerors at any

time of the year has greatly encouraged new and better proposals and reduced the cycle time from proposal submission to contract award by more than 25%. In-Process Reviews with PHEMCE interagency panels that started in 2011 have held BARDA programs and industrial partners more accountable to timelines and milestones. The usage of Other Transaction Authority in 2013 for public-private partnership agreements for MCM development may provide another avenue to streamline the contracting process. Lastly ASPR regularly monitors and adjusts many other business practices affecting program and contracting activities.

- 3. HHS has the authority under the recently reauthorized Pandemic and All Hazards Preparedness Act to use "other transaction authority" to allow contracts to run more efficiently. It has had this authority since 2006, yet has never used it. The Department of Defense (DOD) has similar authority and has used it to great effect. Why has HHS not used this authority? Aren't the new Centers for Innovation and Advanced Manufacturing precisely the type of effort that should be conducted under Other Transaction Authority? Has this been considered?**

Answer: BARDA utilized OTA in May 2013 to reach an agreement with GlaxoSmithKline (GSK) to develop antimicrobial drugs against biothreats using a portfolio approach. This was the first use of OTA by BARDA in product development since the authority was provided in 2006. The use of OTA with GSK allows BARDA to develop multiple drug candidates in parallel with this industrial partner and have input on the usage of resources by GSK towards development of these and other antibiotic drug candidates in the pipeline. Previously, BARDA awarded traditional FAR based contracts for each product candidate and terminated contracts if the product failed – an unfortunate but common occurrence in drug development. Under the OTA, BARDA and GSK share development costs over a portfolio of product candidates. If one fails, then GSK and BARDA decide its discontinuation and addition of other candidates in the GSK pipeline. Under this agreement BARDA will also participate on an Advisory board with a voice on how GSK will invest their own capital to support the products. Supporting a portfolio of candidate products is an excellent use of OTAs.

In many other instances such as manufacturing facility retrofitting with sanofi Pasteur and MedImmune, new manufacturing building with Novartis, and the CIADMs, BARDA was able to utilize the FAR to reach long-term and successful agreements by conventional FAR-directed contracts. Agreements using the OTA were considered in each of these instances, but a better solution was achieved using FAR-based contracts.

The Honorable Ed Whitfield

- 1. For the past two years, about 100 bipartisan Members of Congress have signed a letter in support of the NDPP because it is one of the most innovative, evidence-based models we have to prevent a disease that is expected to impact one in two adults by the end of this decade. It has been estimated that this program could save the nation between \$100-\$191 billion over the next decade. That said, it is not mentioned in your FY 2014**

budget. Can you please explain the decision to not fund this important public-private partnership that will teach people personal responsibility while bending the cost curve?

Answer: CDC's National Diabetes Prevention Program (National DPP) was authorized in 2010 by the Affordable Care Act. In fiscal year (FY) 2012, CDC was awarded \$10 million through the PPHF to implement the National DPP, evidence based program, which has been proven to prevent the onset of type 2 diabetes for individuals with pre-diabetes.

With the PPHF allocation, six awardees were funded to establish a network of structured, evidence-based lifestyle change programs. As part of this expansion, organizations are meeting with employers to discuss offering the lifestyle change program as a covered health benefit for employees and will work with third-party payers, including public and private health insurance companies, to facilitate reimbursement directly to organizations delivering the lifestyle change program. Over the life of the award, grantees are expected to achieve the lifestyle change program as a covered benefit for a minimum of 500,000 employees. CDC's initial efforts have resulted in five insurers and over 280 self-funded employers who provide coverage and access for the lifestyle change program.

A key component of the National DPP, CDC's Diabetes Prevention Recognition Program (DPRP), which sustains data analysis, provides technical assistance to organizations, and assures quality, consistency, and broad dissemination of the lifestyle intervention. The DPRP assures quality and fidelity of the intervention by recognizing programs that have shown they can effectively deliver a lifestyle change program to prevent type 2 diabetes.

No PPHF funding was committed to this program in FY 2013. CDC will partially sustain these activities with limited use of FY13 budget authority to maintain the essence of the program. In FY 2014, the President's Budget proposes \$10 million in budget authority to the Diabetes line to support the National DPP activities. Additionally, through a Center for Medicare and Medicaid Innovation (CMMI) grant awarded in 2013, the National YMCA (Y-USA) was awarded \$12 million over three years, to work with their local Y affiliates to conduct a demonstration project in 17 communities in 8 states (MN, NY, AZ, OH, TX, FL, IN, DE) to deliver the National DPP to 10,000 Medicare FFS enrollees and assess cost savings.

2. The Centers for Medicare and Medicaid Services (CMS) currently covers the fasting blood glucose test and oral glucose tolerance test to screen for diabetes in Medicare enrollees at risk for diabetes or those already diagnosed with prediabetes. However, physicians and other primary care providers are finding that the A1C test is actually the most convenient way to screen patients for diabetes. In a letter to Senator Hagan in December 2011, you said "this test has been recommended by the ADA for diagnosis and is under consideration by CMS for coverage by Medicare." Yet, in 2013, CMS does not cover the cost of an A1C test for purposes of screening. What can be done to encourage use of the A1C test for screening?

Answer: CMS has had several contacts with the American Diabetes Association (ADA) in regard to the ADA's recommendation that the A1C test be added to the options covered by

Medicare for diabetes screening purposes, including a meeting with CMS' Chief Medical Officer in August 2012. CMS concluded that Medicare's transparent, evidence-based National Coverage Determination (NCD) process would be the best avenue for CMS' consideration of this issue. However, we have not, to date, received a complete formal coverage request for coverage of the A1C test as a diabetes screening test from the ADA or any outside party. If the any stakeholder decides to pursue such a request, including the submission of relevant evidence, we will consider it.

- 3. I thank the CDC's Division of Diabetes Translation for releasing the first-ever Diabetes Report Card in 2012. This initial Diabetes Report Card is a baseline, and law requires it to be updated every two years and to include national and state trend data. In light of continual improvement, areas that could be expanded include additional data on gestational and undiagnosed diabetes (including state data), inclusion of average A1c level data trends among individuals with diagnosed diabetes, and the mention of Medical Nutrition Therapy counseling as a Medicare benefit proven to positively impact diabetes outcomes. How can we work with you to continue to improve the Report Card before it is next issued in 2014?**

Answer: CDC is preparing for the 2014 Diabetes Report Card. The Report Card will be responsive to the requirements of Section 10407 of the Affordable Care Act. This section directs the Secretary, in collaboration with the Director of CDC, to biennially prepare a national diabetes report card that aggregates data about health outcomes related to individuals diagnosed with diabetes and prediabetes.

CDC continues to look for ways to improve future Report Cards. Currently, CDC is reviewing our established data sources to prioritize and select information that best represents national and state diabetes data about prevalence, preventive care practices and the quality of care, risk factors, health outcomes and national progress in meeting Healthy People goals. CDC will consider including national estimates for A1c, gestational diabetes and undiagnosed diabetes. CMS receives claims data related to Medical Nutrition Therapy counseling, which is covered for Medicare beneficiaries with diabetes or renal disease. CDC will explore opportunities to incorporate relevant information on this benefit in future Report Cards.

- 4. As you know, this Committee has been very concerned about CDC grantees using CPPW funds to engage in activity to change laws and regulations at the state and local level. Unfortunately, CDC grantees across the country appear to be continuing to engage in similar activity with PPHF funds.**

For example, the State of Minnesota advised its CTG grantees that their Community Transformation Grant (CTG) funds could be used to make changes to state ordinances. A Q & A document available on the State's website reads "...a CTG strategy could include updating the ordinance to increase the price of tobacco retail licenses to pay for the program..." Similarly, the County of Fairfax, Virginia includes the following CTG strategy on its website, "increase the tax on packs of cigarettes purchased in Fairfax

County”. Houston/Harris County, Texas encouraged their CTG sub-grantees to “*limit density of fast food outlets and other outlets featuring high calorie, high sodium, and low nutrition foods*” through “*zoning: regulate the number of fast food restaurants in a given area.*”

In order to fulfill our Congressional oversight responsibilities, I would like to respectfully request the following documents in relation to the CDC grants identified in Appendix A in the document attached to this letter:

- copies of all documents associated with the grants, whether competed or not, solicited or unsolicited, including your proposals and award documents.
- copies of the grant program files pertaining to the funded activities, including but not limited to budget detail and worksheets and regular progress reports including narratives, budget information and all correspondence with CDC grantees and subgrantees regarding the intent, purpose and use of the grant dollars.
- copies of all communications involving or by grantees or subgrantees, describing meetings or correspondence with public officials at the state and local level.
- copies of all materials received re training, educating and monitoring grantees’ use of the grant, including Powerpoint presentations, background preparatory materials and memoranda describing the programmatic goals and success of changing laws and policies at the state and local level.
- copies of all materials addressing or analyzing whether grantees or subgrantees have violated any anti-lobbying statutes (*e.g.*, 18 USC §1913; 31 USC §1352(a), appropriations bills (www.gpo.gov/fdsys/pkg/BILLS-111hr3288enr/pdf/BILLS-111hr3288enr.pdf) or administrative regulations (*e.g.*, AR-12).
- copies of all materials addressing proposed or actual remedies for violating anti-lobbying statutes or regulations, including all materials describing or listing grantees or subgrantees that have violated anti-lobbying statutes or regulations.
- Copies of any correspondence or notes regarding minutes of meetings or public or private reports describing the intent, purpose and use of the grant dollars, including any reference to descriptions of activity involving efforts to change policy, laws, regulations at the state and local government level.

Answer: The Communities Putting Prevention to Work (CPPW) program, primarily funded in FY 2010 through American Recovery and Reinvestment Act (ARRA), is essentially completed. Through the program, the CDC has worked with award recipients in all 50 states, the District of Columbia, Puerto Rico, and six Pacific Island territories to address chronic disease risk factors, including obesity and tobacco use. These grantees made substantial progress on priorities identified by communities across the United States, tackling significant public health problems and achieving real results to improve the health of communities.

In 2010, Congress established the PPHF as part of the ACA. The PPHF has been used to fund important investments in our nation’s health, including improvements in our ability to immunize children, reduce health-care acquired infections, improve laboratory systems at the state level, and detect and respond to disease outbreaks. This Act also established the Community Transformation Grant (CTG) program, which supports evidence and practice-based efforts in

states and communities to reduce chronic diseases. Awardees are addressing the priority areas of 1) tobacco-free living; 2) active living and healthy eating; and 3) high quality clinical and other preventive services, including prevention and control of high blood pressure and high cholesterol.

We will work with the Committee to respond to your requests, but it is important to note that not all activities proposed in an application were ultimately funded by CDC. Following the initial application (proposal), CDC worked with the applicant to review and identify funded activities. We can assure you that HHS remains committed to proper oversight and monitoring of appropriated funds, and to awardees' compliance with all applicable regulations and statutes. HHS awardees, including those in the CPPW and the CTG programs, are informed about the applicable federal laws, regulations, and policies relating to the use of federal funds, including applicable anti-lobbying provisions.

HHS and CDC staff continue to follow rigorous procedures for monitoring all grant awards, including those funded from the ARRA and PPHF. As a result of CDC's oversight of awards, CDC has identified a total of three grantees that engaged in impermissible lobbying activities with CDC funds through the CPPW program, and enforcement actions have been taken. CDC followed its risk mitigation procedures, conducted calls with the grantees, and elevated the issue within CDC to determine whether the activities were conducted with CDC funds, and whether the activities were impermissible. After a thorough review, CDC determined that these three grantees conducted impermissible lobbying. In accordance with applicable grant regulations, CDC has taken enforcement actions against the grantees and disallowed these costs.

We have provided a substantial amount of additional education and guidance in the past several years to both grantees and staff on the appropriate use of federal funding, particularly related to anti lobbying restrictions. In July 2012, the HHS Office of Inspector General (OIG) recommended that we reinforce our efforts in the CPPW program to inform grantees of applicable restrictions through multiple avenues. CDC has embraced and implemented OIG's recommendations and has applied them to all agency grants. CDC's response to the Inspector General is attached. More recently, over the past year the Government Accountability Office (GAO) conducted a performance audit on CDC's policies on lobbying and CPPW award recipients' activities. The final report was released on May 31, and documented the robust procedures CDC has in place to ensure appropriate use of CDC funds by grantees. GAO's report is available at <http://www.gao.gov/assets/660/654272.pdf>.

Congress added language to section 503 of the Labor, HHS, and Education Appropriations Act for FY 2012. In June 2012, CDC distributed written guidance reflecting the changes in the Appropriations Act to its staff and to CDC grantees. This more detailed CDC guidance document includes the revised CDC anti-lobbying policy (AR-12), which is consistent with the provisions in the HHS Appropriations Act. This new guidance, a copy of which is attached, also provides specific examples of restricted and allowable activities. CDC undertook an intensive effort to communicate the new guidance to all of its grantees, and has incorporated the revised AR-12 into all new grants.

At HHS, we are committed to fulfilling the mandate from Congress to empower communities to pursue high-quality programs that make a real difference in the health of Americans. Awardees are working to reduce the impact of chronic diseases on our population and health system. The Department will continue to enable their success and to ensure that federal funds are used efficiently and appropriately.

The Honorable Mike Rogers

1. **Recently, we have had some frightening reminders of the threats we continue to face in this country. The bombs in Boston and the ricin laced letter addressed to our Senate colleague and President Obama demonstrate that we must remain committed to preparing for the threats we know about, as well as build capacity to respond to those we cannot anticipate.**

In that vein, reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA) was a top priority for the Committee over the last two years. One of the key components of the recently enacted legislation is a provision to reauthorize the Project BioShield Special Reserve Fund (SRF) at \$2.8 billion to be available for the next 5 years. The SRF was originally created as a guaranteed market incentive to encourage companies to develop and produce medicines and vaccines to protect Americans from identified threats, since there is no commercial demand for these products.

I am very concerned by the level of funding provided to the SRF in the President's Budget. Shifting to an annual appropriation, and at only \$250 million, would create extreme uncertainty in the medical countermeasures market. The funding provided is not even one fifth of the five year authorized level of \$2.8 billion and is less than many individual BioShield procurement contracts. In addition, the new multi-year contracting language is NOT sufficient to make up for the lack of funds.

In your professional opinion, what has been the impact of the Project BioShield Special Reserve Fund over the last 10 years? How will you ensure that the Project BioShield Special Reserve Fund is available for the next 5 years to give confidence to the pharmaceutical and biotechnology companies that are developing and delivering essential medicines to our national stockpile?

Answer: The Special Reserve Fund has resulted in HHS's creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

Over the past nine years, HHS has developed additional tools to foster its relationship with the provision of ARD funding, and the expansion of authorities under Project BioShield – most notably the introduction of milestone payments in contracts. More recently, per

recommendations from the Secretary's Review of the Public Health Emergency Medical Counter Measure Enterprise (PHEMCE) following the 2009 H1N1 pandemic, came the establishment of Centers of Innovation for the Advanced Development and Manufacturing (CIADM). These public-private partnerships allow BARDA to pair large established pharmaceutical companies with smaller firms. These pairings mitigate the scientific and manufacturing risks associated with MCM development by providing the necessary expertise to bring promising technologies to the marketplace. Additionally, the PHEMCE Review recommended the establishment of a MCM Strategic Investor, an independent non-profit entity, which would use HHS funding to support capital investments in private companies with promising technologies. By providing critical capital in exchange for a strategic role in the management of these small firms, HHS would be able to mitigate the financial and management risk that some small firms face, thereby increasing the probability of successful technologies and products.

Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multi-year budgeting practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies (e.g., Amgen, GlaxoSmithKline, etc.) are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress' continued support for these future activities.

The Department agrees that providing industry with a clear indication of long-term support of medical countermeasure development is important to the success of Project BioShield. The Budget explicitly states the FY 2014 request represents a multi-year renewed commitment to Project BioShield. Additionally, as an added incentive, the FY 2014 President's Budget proposes language to provide BARDA with the authority to modify the standard government-wide authority for multi-year contracting (41 USC 3903). This sends a clear message of commitment because the modified language included in the FY 2014 President's Budget authorizes BARDA to enter into an "incrementally-funded", multi-year contract for up to ten years. Additionally, the language modifies the existing authority's requirement of set-aside contract termination costs by allowing BARDA to repurpose any un-used termination costs to pay contract invoices in subsequent years. This differs from traditional multi-year contracting authority, which specifies termination costs can be used for that purpose alone. These modifications allow BARDA to effectively utilize the valuable tool of multi-year contracting authority to engage in long-term contracts with companies that develop medical countermeasures.

The Honorable Michael C. Burgess

- 1. The Administration's proposed budget includes legislative proposals pertaining to rehabilitation hospitals, one of which seeks to pay rehabilitation hospitals nursing**

home-based rates for certain conditions because, according to the President's budget, IRFs are services that "may not be appropriate" for certain conditions. A second proposal would elevate the IRF "60% Rule" to a "75% Rule" to "ensure that [IRFs] are classified appropriately."

As you know, Medicare expenditures for IRF services have remained relatively flat for the past 6 years, the number of IRFs is not increasing, and the number of beneficiaries treated in IRFs is not growing faster than the overall growth in Medicare beneficiaries. What specific data or evidence does HHS have to justify support for these proposals?

Answer: Studies by MedPAC and the Institute of Medicine indicate that there is wide variation in the utilization of post-acute care services.¹² This overutilization is driven, in part, by Medicare payments that significantly exceed costs in certain post-acute care settings, and by higher payments for care provided in more intensive care settings (for example, IRFs), even though the care provided is similar to that provided in other types of post-acute care facilities (for example, SNFs).

One of the goals of the post-acute care proposals in the President's FY 2014 Budget is to encourage care delivery in the most appropriate care setting. Under current law, IRFs receive higher payment rates than other medical facilities, including SNFs, which often provide care similar to that provided by IRFs for those IRF patients that are not part of the "60 percent rule." We believe that facilities that are paid as IRFs should predominantly provide services to patients requiring more intensive care than can be provided at other medical facilities. As you know, the classification criteria for IRFs require that at least 60 percent of an IRF's patients need intensive rehabilitation services for treatment of one or more of 13 specified conditions. After an initial phase in period, this classification requirement was originally set to peak at 75 percent, but was later reduced to no more than 60 percent by the Medicare, Medicaid, and SCHIP Extension Act of 2007. If adopted, the proposal would return the classification standard maximum to 75 percent to ensure that Medicare-paid IRFs are even more focused on treating patients who require specialized, intensive care that would justify the higher payments to IRFs.

The proposal to equalize payments for certain conditions treated in IRFs and SNFs also seeks to distinguish between different post-acute care settings by defining which conditions are best treated at IRFs—and which are not. Currently, treatment of certain knee, hip and pulmonary conditions that do not require intensive therapeutic post-acute care can be performed in either an IRF or an SNF, but Medicare payments are much higher if the treatment occurs in an IRF. This proposal would, beginning in 2014, make Medicare payments more equal for certain knee, hip, and pulmonary conditions, as well as other conditions selected by the Secretary. These conditions are commonly treated at both IRFs and SNFs.

¹ MedPAC (January 2011). Regional Variation in Medicare Service Use. pp 6-7. Retrieved (May 24, 2013) at http://www.medpac.gov/documents/Jan11_RegionalVariation_report.pdf

² Institute of Medicine (2013) Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Health Care: Preliminary Committee Observations. Retrieved (June 3, 2013) at <http://www.iom.edu/Reports/2013/Geographic-Variation-in-Health-Care-Spending-and-Promotion-of-High-Care-Value-Interim-Report.aspx>

- 2. If either or both of these proposals were adopted by Congress, more Medicare beneficiaries would be shifted into nursing homes. In light of repeated concerns expressed by the HHS-OIG, MedPAC, and CMS that Medicare may be overpaying nursing homes for rehabilitation and therapy services, why would Congress enact policies that would effectively compound the problems underlying these concerns, especially without quality and outcomes measurements in place to ensure that beneficiaries are not receiving substandard care in a nursing home, relative to what they would receive in an IRF?**

Answer: The President's Budget proposal to equalize payments between IRFs and SNFs for certain types of patients is not requiring patients to be moved from one setting to another but to make payment more nearly equal for similar services provided in different post-acute care settings. One of the goals of the post-acute care proposals in the President's FY 2014 Budget is to encourage care delivery in the most clinically appropriate and cost-effective care setting. Under current law, the classification criteria for inpatient rehabilitation facilities (IRF) require that at least 60 percent of an IRF's patients need intensive rehabilitation services for treatment of one or more of 13 specified conditions. The President's Budget proposal to change this criteria to 75 percent is to ensure that these IRFs are primarily furnishing services for patients who need intensive therapy and therefore eligible for the significantly higher payments for their patients.

To help beneficiaries choose a quality nursing home, Medicare.gov has a Nursing Home Compare that has a Five-star rating system based on a nursing home's performance in health inspections, quality measures, and hours of care provided by nursing staff. This is an important tool for beneficiaries to ensure they choose high quality nursing home for their needs.

- 3. In the past your agency has stated its priority to ensure diversity in the health professions as well as to ensuring health professionals practice in underserved communities. How do the cuts to Title VII in the agency's FY 2014 budget, which eliminate these programs, achieve the agency's diversity objectives and increase the number of diversity of health professions?**

Answer: While the FY 2014 Budget required difficult choices, it includes a strong commitment to HRSA's priorities. Increasing the diversity of the health professions workforce is an area of focus for HRSA. For the most recent academic year, 46% of graduates from HRSA-funded programs were disadvantaged and/or underrepresented minorities.

The FY 2014 budget request maintains funding for several programs that specifically aim to boost the diversity of the health professions workforce:

The Centers of Excellence program: This program assists eligible schools in supporting programs of excellence in health professions education for underrepresented minority (URM) individuals and to strengthen the Nation's capacity to produce a culturally competent healthcare workforce. COE grantees use grant funding to increase the pool of competitive URM student applicants; enhance URM students' academic performance; improve recruitment and retention of URM faculty; improve clinical education, curricula, learning resources and cultural competence

as they relate to minority health issues; and facilitate faculty and student research on health issues affecting URM groups.

Scholarships for Disadvantaged Students program: The purpose of this program is to increase diversity in the health professions workforce by providing grants to eligible health professions and nursing schools for use in awarding scholarships to financially needy students from disadvantaged backgrounds.

Nursing Workforce Diversity program: The purpose of this program is to increase nursing education opportunities for individuals who are from disadvantaged backgrounds, including racial and ethnic minorities who are underrepresented among registered nurses.

The National Health Service Corps (NHSC):

The NHSC is a network of primary care providers serving communities with shortages of medical, dental, or mental/behavioral health care. The Affordable Care Act (ACA) significantly increased funding for the NHSC, which made it possible to nearly triple the number of clinicians in the NHSC, and broadened the NHSC's racial and ethnic diversity of doctors, nurses, and other health care professionals. For example:

- NHSC African American physicians represent 17.3% of the Corps physicians and exceed their 6.3% share in the national workforce.
- NHSC Hispanic physicians represent 16.2% of the Corps physicians and exceed their 5.5% share in the national workforce.
- NHSC Asian dentists represent 14.7% of the Corps dentists and exceed their 11% share in the national workforce.

Diversity is an integral part of the NHSC recruiting strategy. The NHSC is national in scope and conducts outreach to target underrepresented minorities for recruitment. Overall, NHSC participation compared to national workforce and student averages remain strong.

In addition, other HRSA grants help increase diversity through eligibility requirements, funding priorities and/or required activities, depending on the authorizing statute. These programs include, for example, the Primary Care Training and Enhancement program, the General, Pediatric and Public Health Dentistry and Dental Hygiene Program, and the Mental and Behavioral Health Education and Training Grants program, and the Advanced Nursing Education program. The President's FY 2014 budget has maintained or requested additional funding to support these programs.

4. NIH has recently acknowledged problems with the availability of resources for awarding minorities with R01 grants. How will your agency deal with this issue in the midst of your proposed cuts to the Research Centers at Minority Institutions (RCMI) program at NIH's National Institute on Minority Health and Health Disparities program in the FY 2014 budget?

Answer: As a leader in scientific discovery and innovation, NIH not only recognizes the underrepresentation of individuals from underserved communities in biomedical research, but it is committed to supporting and developing a diverse cadre of scientists from all sectors of the nation. NIH has initiated the implementation of several recommendations from the Advisory Committee to the Director (ACD), which recently formed a Working Group on Diversity in the Biomedical Research Workforce. This working group was charged with evaluating the diversity of the biomedical research workforce and making recommendations to the ACD for improvement in recruitment and retention.

The FY 2014 NIH Congressional Justification includes a decrease for the RCMI program due to the need to balance the scientific investments of the National Institute on Minority Health and Health Disparities (NIMHD), by identifying and reducing areas of duplication in its program portfolio. The RCMI program, along with other new and existing initiatives, will bolster NIH's efforts to improve the recruitment and retention of a diverse workforce. Recently, NIH launched three inter-related initiatives to address this issue. These are (1) NIH Building Infrastructure Leading to Diversity (BUILD), (2) the National Research Mentoring Network (NRMN), and (3) the Coordinating and Evaluation Center (CEC). In addition, a search is currently underway to recruit a Chief Officer for Scientific Workforce Diversity. This individual will be responsible for enhancing the diversity of the NIH extramural and intramural biomedical research workforce, by identifying new and effective, evidence-based strategies to enhance diversity, and promoting synergy among existing programs.

Programs such as BUILD, NRMN, CEC, RCMI, and other existing NIH programs will complement one another and support NIH's efforts to enhance the diversity of the biomedical research workforce. By utilizing the synergy between these programs, NIH can move forward in enhancing the diversity of the biomedical workforce, and maximize the return on investment from the available resources.

- The BUILD initiative intends to test new, innovative approaches to recruitment and training of scientists from diverse backgrounds. The emphasis is on development of culture-changing methods to motivate young scientists for careers in biomedical research and to enable them to thrive in the NIH-funded environment. It will support research training at multiple career stages and promote faculty development at comparatively under-resourced institutions with a concentration of students who receive Pell Grants. This initiative recognizes the critical role that the faculty-student relationship plays and intends to provide salary offset and other mentor-promoting activities to enable outstanding mentors to work with students and train new mentors.
- The NRMN is intended to augment local mentoring efforts for undergraduate students through junior faculty members by creating a national group of scientific leaders who are willing to serve as external mentors. The NIH intends to identify an entity that will engage and assemble multiple persons and/or professional organizations into a single, nationwide, consortium of mentors. The NRMN intends to develop contemporary methods to facilitate networking between mentors and mentees and also intends to promote face-to-face experiences as needed. This initiative will address the standard wisdom that says that success depends on "who you know," by ensuring that contacts are

made between mentees and mentors with shared interests and by facilitating subsequent interactions.

- The goal of the CEC is to assess efficacy of the new approaches being developed via BUILD and the NRMN and to disseminate lessons learned across the community at large. It will help ensure optimal coordination of the BUILD and NRMN activities, minimize redundancy, and facilitate data tracking and analysis.

The RCMI program provides resources for several critical areas of support for biomedical, clinical, behavioral, and social sciences research. Infrastructure development creates a foundation for the research enterprise through renovation/alteration of new research facilities and the development of specialized research support capabilities such as biomedical informatics and research design/biostatistics expertise. Instructive training and mentored research training experiences for early-stage investigators interested in health disparities research facilitate career advancement for junior faculty members. Together these activities address many of the challenges faced in promoting diversity in the biomedical, clinical, behavioral, and social sciences research workforce. RCMI institutions as well as other institutions supported through ongoing NIH-funded activities are expected to benefit from the innovative approaches being tested through BUILD, the NRMN, and the CEC.

NIH anticipates greater collaboration, partnership and networking among its various programs aimed at contributing to the diversity of the workforce, including but not limited to these programs.

5. In regards to molecular pathology services in Medicare, CMS eliminated stacking payment codes last year in favor of a re-pricing process called "gap-fill" to establish pricing for these services. While these molecular tests provide the foundation for personalized medicine, the gap-fill process has resulted in a lack of transparency, prices below the cost of providing some tests, and unnecessary delays in payments from the MAC's to clinical labs.

Would you please provide the Committee with a status report on the gap-fill process to date, in addition to what steps CMS plans to take to improve the gap-fill process in the near future to ensure adequate Medicare beneficiary access to molecular pathology services?

Answer: As you know, CMS regularly uses Current Procedural Terminology (CPT) codes developed by the AMA in establishing payment rates for Medicare services. The AMA CPT Panel developed 114 new CPT codes for CY2012 and CY2013 to replace multiple “stacking codes” (based on component steps) that were previously used to bill for molecular pathology tests. The old “stacking codes” were deleted at the end of 2012 and are no longer available.

The majority of the new codes were issued for CY 2012, but CMS decided to delay their use for a year to carefully consider whether they should be paid under the physician fee schedule (as physicians preferred) or the clinical laboratory fee schedule (as preferred by laboratories). After

requesting comments as part of the CY 2013 physician fee schedule proposed rule, we finalized a policy to pay for these codes under the clinical laboratory fee schedule, with an additional payment available for interpretation by a physician under the physician fee schedule.

New rates for these tests are being established through the “gapfilling” process, which enables the local Medicare contractors to use a wide range of relevant data to determine payment amounts for these tests. CMS will then use the contractors’ gapfill prices to set “national limitation amounts” for these tests. The contractors’ prices were submitted to CMS in April and will be posted on the CMS website in May and open for public comment for a 60-day period.³ CMS will post final payment amounts in September, at which point stakeholders have 30 days to request reconsideration. The 2014 clinical laboratory fee schedule, including national limitation amounts for the new test codes, will be issued in November.

While this process is underway, these molecular pathology tests are being paid at interim rates set by the contractors, which may reflect invoice amounts, the previous price amounts known as “stacking codes,” or case-by-case determinations by the contractor medical directors. CMS has asked laboratories to bring to our attention any areas where the Medicare contractors have not taken action on submitted claims. As indicated above, a 60-day public comment process is currently underway on the prices proposed by the contractors. We urge laboratories to bring cost information to our attention to assist with final pricing of these services over the next several months. As we obtain more information on the costs of these services from laboratories, we are optimistic that we will be able to establish prices satisfactory to both Medicare and the laboratory industry.

The Honorable Phil Gingrey

1. Why does the budget propose excluding certain services from the in-office ancillary services exemption (IOASE) when both the GAO and MedPAC reviewed the exception and did not recommend closing it?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer for services to be performed by their group practices for patient convenience. While there are many appropriate uses for this exception, there is evidence that suggests this exception may have resulted in overutilization and rapid growth of certain services. In a report released last September, GAO found that in that in 2010, providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. GAO found that these additional referrals cost Medicare about \$109 million.

³ Information on the current 60-day public comment process is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html>.

- 2. Recent MedPAC data suggests that the growth of advanced diagnostic imaging services has slowed in recent years. If this is the case, why does this budget include provisions to eliminate imaging services from the in-office ancillary services exception?**

Answer: It is true that MedPAC's March 2013 report stated that utilization rates for imaging services slightly declined in 2010 and 2011. However, the report also stated that despite the decrease in 2010 and 2011, the use of imaging services has remained much higher than it was a decade ago. The cumulative decrease in imaging volume in 2010 and 2011 was less than 4 percent, while the cumulative increase that occurred from 2000 to 2009 was 85 percent. According to MedPAC, the growth in imaging volume last decade was more than double the cumulative growth rates for evaluation and management (E&M) services and major procedures respectively. During this period, many physicians have been outspoken about the overuse and duplication of these services. Other studies have supported this assertion. From this strong evidence, the Administration feels that it is appropriate to include advanced imaging in the list of services that should be excluded from the in-office ancillary services exception.

- 3. How are the "accountability standards" defined that would allow providers to continue providing services under the IOASE?**

Answer: This proposal allows the Secretary flexibility to determine these standards, which would be done through a rulemaking process. Factors to be considered could include quality, value, efficiency, utilization, and access.

- 4. The ability for physicians to provide ancillary services in the office setting achieves both lower cost treatment and increased care coordination. Are you concerned that closing the IOASE will result in higher costs and fragmented patient care?**

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer quick turnaround services. While there are many appropriate uses for this exception, the services covered under this proposal are rarely performed on the same day as the related office visit. Additionally, there is reason to believe this exception has resulted in the overutilization and the inappropriate use of certain services. Receiving unnecessary tests, such as additional CTs, can actually pose risks to beneficiaries. This proposal is designed to encourage appropriate use of services while providing exceptions (to be specified by the Secretary) that would ensure beneficiaries continue to have access to appropriate, medically necessary care.

- 5. As an obstetrician and gynecologist, I know how important it is for OBGYNs to have up-to-date nutrition advice based on the latest science, and doctors look to FDA for that advice. Unfortunately, FDA's advice to pregnant women on seafood consumption is far outdated, leaving expectant mothers with old information that has resulted in a decline in seafood consumption to the detriment of fetal development. You've been saying for over two years that the advisory to pregnant women on seafood consumption will be updated. As FDA continues to miss deadlines for releasing the advice, it is time that you**

personally engage in the finalization process to get this advice out. Would you provide an update on the seafood advisory's status and commit to completing the final advice by this summer?

Answer: The Food and Drug Administration (FDA or the Agency) first issued fish consumption advice relating to methylmercury in 1994. The advice was updated in 2001 and again in 2004. The 2004 advice was issued jointly by FDA and the Environmental Protection Agency (EPA). Its purpose was to protect against the possibility of neurodevelopmental harm to the fetus and to infants from methylmercury as a result of their mother's consumption of fish in excess of recommended amounts and to protect young children from the possibility of neurodevelopmental harm from methylmercury as a result of their own consumption of fish. Since then, studies published in the scientific literature indicate that, under certain circumstances, fish consumption by pregnant women and young children may actually improve neurodevelopment. The Dietary Guidelines for Americans 2010, the government's nutritional recommendations issued every five years by the Departments of Health and Human Services and Agriculture, have already taken this development into account by recommending that pregnant and nursing women eat at least 8 and as much as 12 ounces per week of fish lower in mercury. The 2004 FDA/EPA advice does not contain this consumption target nor does it mention a potential neurodevelopmental benefit from fish since the evidence for it did not exist in 2004. We have devoted a significant effort to update the advice and to complete a quantitative assessment of the net effects of fish consumption during pregnancy on neurodevelopment in order to have a sound analytical underpinning for that advice. We are making every effort to complete that process as soon as possible and please be assured that your concerns are being taken into account.

The Honorable Cathy McMorris Rodgers

- 1. This Committee has spent a great deal of time reforming the way pharmacies are paid for generic drugs in the Medicaid program.**

The Deficit Reduction Act, and later the Affordable Care Act, established that Average Manufacturer Price (AMP) would be used to set Medicaid Federal Upper Limits (FULs) for pharmacy reimbursement. Because AMP has never been used in this manner, Congress gave CMS flexibility to increase the multiplier to calculate FULs, should they prove to provide insufficient payment to retail pharmacies.

As you know, CMS has been publishing AMP—based FULs in draft form on a monthly basis, and the pharmacies in my district/state tell me that the FULs change dramatically in value from month to month, and that in many cases they are below pharmacy's cost to purchase these medications.

Given this is a new reimbursement model that has yet to be fully tested in the marketplace; it seems premature to make any changes.

- (a) Consequently, I was surprised to see the provision in the president’s budget, “Lower Drug Costs” that alters the way FULs are to be calculated. I am also surprised that CMS has chosen to ignore the authority granted by Congress to increase the multiplier to calculate FULs if necessary. Why has the Administration proposed this change to the calculation of FULs?**

Answer: The Medicaid Federal Upper Limit (FUL) is used to limit reimbursement for certain multiple source drugs, and is currently calculated based on the weighted average price of all brand-name, authorized generic, and other multiple source generic drugs for each product. This proposal removes brand and authorized generic prices from the FUL calculation. Currently, the inclusion of both brand and authorized generic drugs in the calculation of the FUL unduly inflates the FUL. Removing both categories of drugs ensures that the government remains a prudent purchaser of prescription drugs.

- (b) What portion of the \$8.8 billion in savings from this budget provision is attributed to reduced pharmacy payments?**

Answer: The Medicaid prescription drug proposals in the President’s FY 2014 Budget strengthen the fiscal management of the Medicaid program. If enacted, we estimate the proposals will save money by bringing down FULs that are inflated by generic prices. To the extent that pharmacy payments may be reduced, the reduced payment will more accurately reflect the price of the generic drugs for which Medicaid pays.

- (c) Why has CMS chosen to disregard the authority provided by Congress to increase the multiplier to set Federal Upper Limits, even on a case by case basis?**

Answer: CMS has issued monthly draft AMP-based FULs and three-month rolling average FULs. The draft three-month rolling average FULs were developed in response to comments that the draft AMP-based FULs fluctuated from month to month. States can use the draft monthly AMP-based FUL, or the draft three-month rolling average FUL, once they are finalized, depending on the approved state plan, to develop a pharmacy reimbursement methodology that will allow their pharmacy payments to remain within the FUL in the aggregate. CMS is continuing to accept comments on these methodologies and will consider those comments when we finalize the FULs. Based on recent work by the OIG and the GAO, we continue to believe the FULs will provide sufficient payment to retail pharmacies.

- 2. Under the mandate requiring all insurance plans cover sterilization and contraception including the morning-after and week-after pills, many non-profits and family owned businesses will no longer be able to operate in keeping with their principles and values, while also offering health insurance to their employees. Because you have not provided an exemption that fully respects religious freedom, over 160 plaintiffs have filed suit against this mandate—seeking the courts grant them relief from the mandate that**

infringes of their fundamental Constitutional rights. The family owned business' cases are moving forward, but the non-profits' cases are delayed until a final rule is issued. Since both the advance notice of proposed rulemaking and the proposed rule have been similarly rejected by religious objectors, they have little hope that the final rule will address their concerns. Therefore, they expect to be forced to rely on relief in court. However, their cases cannot move forward until the rule is finalized.

(a) Faith-based charities, hospitals and schools are still waiting for their day in court, waiting for a final rule, and time is running out for them—they must comply starting August 1st of this year with the mandate or face ruinous fines. When will HHS issue the final rule, so that these faith-based charities, hospitals and schools who want to provide good health care to their employees and continue to keep that health care in line with their deeply held beliefs can go to court and protect their religious liberty?

Answer: This rule was published in the Federal Register for public comment on February 6, 2013. The deadline for comment submissions was April 8, 2013. HHS is still examining comments and expects to issue a final rule when we have completed our analysis and response to comments.

(b) As I mentioned previously, Americans have been seeking redress through the courts because the administration continues to push forward a rule that violates deeply held moral and religious beliefs. In issuing a final rule, will you seek to protect the First Amendment rights of all Americans?

Answer: HHS cannot comment on the contents of any final rule before it is released to the public.

The Honorable Leonard Lance

1. Much has been made about the issue of drug rebates to the Medicare program. This committee has done much work in exploring the ways in which Medicare Part D drugs have kept down costs in the Medicare program. In proposing to apply Medicare drug rebates to the Medicare program, did your office conduct an analysis to ascertain what impact on innovation or access these rebates might have?

Answer: The Medicare Part D program is working well and providing valuable savings to seniors and people with disabilities with their prescription drug costs, particularly for dually eligible Medicare-Medicaid beneficiaries who automatically receive Extra Help from the government with their premiums and copayments. Given the fiscal challenges our country faces, however, Medicare must continue to find ways to ensure the program is providing the best value to beneficiaries and taxpayers.

The FY 2014 budget proposal would obtain price concessions from pharmaceutical manufacturers for individuals who are dually eligible and for the poorest Medicare beneficiaries, who receive the Part D Low Income subsidy. The Part D Low Income Subsidy (LIS) is the largest component of Part D spending, totaling \$22.8 billion in 2012. These price concessions, or rebates, are the same rebates that the Medicaid program currently receives from manufacturers. This proposal stems from a recommendation by the bipartisan National Commission on Fiscal Responsibility and Reform and reinstates savings that taxpayers previously received when dually eligible individuals received their drug benefit through the Medicaid program.

2. The proposed budget would seek to expand Medicare claims data sharing with qualified entities for such purposes as fraud prevention. Would you explain how this policy would work?

Answer: The Affordable Care Act includes a provision that allows CMS to make Medicare Part A, B, or D claims data available to qualified entities for the purpose of publishing reports evaluating the performance of providers and suppliers. The budget proposal would expand the scope of how qualified entities can use Medicare data beyond simply performance measurement. For example, entities would be allowed to use the data for fraud prevention activities and value-added analysis for physicians. In addition, qualified entities would be able to release raw claims data, instead of simply summary reports, to interested Medicare providers for care coordination and practice improvement.

Qualified entities (QEs) offer a unique mechanism for CMS to share data with providers. Many of the organizations that have been approved as QEs were already doing provider performance measurement, so have established relationships with providers in their region. In many cases, these organizations already share claims data from other payers with providers, offering not only access to the data, but also value-added analytics. Many QEs charge for their value-added analytics; however, this offers an important service to providers, who don't necessarily have the infrastructure to store and analyze raw claims data, which allows them to gather further information on the quality of care they deliver.

3. Citing concerns with the way CMS has handled fraud prevention to date, and alarmed by the tens of billions CMS loses to waste, fraud and abuse each year, this committee recently put out a proposal on its intention to identify and reform the ways in which CMS manages fraud prevention. Yet the President's budget would request that fraud prevention funding in 2015 be mandatory and fall outside of Congressional oversight. Would you explain how giving CMS more autonomy with regards to fraud funding will help address concerns on capitol hill that CMS is not properly conducting fraud prevention in the Medicare and Medicaid programs?

Answer: CMS launched the Fraud Prevention System (FPS) as part of a broad effort to shift the agency beyond a "pay and chase" approach to preventing fraud before it happens. Created under the Small Business Jobs Act of 2010, the FPS analyzes all Medicare fee-for-service claims using risk-based algorithms developed by CMS and the private sector, prior to payment, allowing CMS

to take prompt action where appropriate. CMS uses the FPS to target investigative resources to suspect claims, providers, and suppliers, and swiftly impose administrative action when warranted. Early results from the FPS show significant promise and CMS expects results to increase as the system matures over time. As reported in our Report to Congress in its first year of implementation, the FPS:

- Prevented or identified an estimated \$115.4 million in improper payments;
- Achieved a positive return on investment, saving an estimated \$3 for every \$1 spent in the first year;
- Generated leads for 536 new fraud investigations;
- Provided new information for 511 existing investigations; and
- Triggered 617 provider interviews and 1,642 beneficiary interviews regarding suspect claims or provider activity.

In addition to CMS' fraud prevention work, HHS and DOJ continue to coordinate investigations and prosecutions of health care fraud, waste, and abuse under the Health Care Fraud and Abuse Control Program (HCFAC). As reported in the 2012 HCFAC Report to Congress, these activities returned \$4.2 billion dollars to the Department of Treasury and Medicare Trust Funds in 2012. The HCFAC account has returned over \$23 billion to the Medicare Trust Funds since the inception of the program.

The Budget Control Act of 2011 recognized that a multi-year strategy permitting agencies to pay closer attention to the risk of improper payments, commensurate with the large and growing costs of the programs administered by that agency, is a laudable goal. Despite enactment of these multi-year discretionary cap adjustments, annual appropriations bills have not provided the full amount of program integrity funding authorized in BCA. Billions of dollars in savings over the next ten years from curtailing improper payments will not be realized if consistent, additional funding for program integrity is not provided. The President's Budget proposes to provide a dedicated, dependable source of additional mandatory funding beginning in FY 2013 that will ensure HHS and the Department of Justice (DOJ) have the resources that they need to conduct necessary program integrity activities and make certain that only the right people receive the right payment for the right reason at the right time. CMS will continue to report to Congress on program integrity efforts.

The Honorable Bill Cassidy

- 1. In 2006, government-funded patient advocates coached schizophrenic William Bruce to say the right things in order to be released from a psychiatric facility- despite his doctor's recommendation. Two months later, he murdered his mother with a hatchet. Today, he is receiving effective treatment (including medication) and lives in a state psychiatric facility. (See "A Death in the Family" in the WSJ). He is quoted as saying of the advocates, "They helped me immensely with getting out of the hospital, so I was very happy (but) the advocates didn't protect me from myself." It seems the patient advocates (who are funded to protect against patient abuse and neglect) do a better job**

advocating for the irrational and often dangerous voices of the disease than advocating what is in the best interest of the individual. I see the budget will again allocate 36 million to this program. What has been done since the 2006 death of this boy's mother to prevent government funded patient advocates from coaching seriously mentally ill individuals, who are clearly in need of treatment, to forego it to their detriment, their families and their communities?

Answer: Protection and Advocacy for Individuals with Mental Illness (PAIMI) project officers and grants management staff provide routine fiscal, programmatic and monitoring oversight of all aspects of the PAIMI formula grants within states. In this capacity, the project officer and monitors work to ensure that the federal PAIMI funds are being utilized consistent with the statutory authority and in compliance with the PAIMI applications' requirements and annual program priorities that are established by the respective PAIMI Advisory Councils.

SAMHSA receives allegations and complaints relating to health and safety concerns from both the HHS Office of Inspector General Hotline and directly from the general public. Upon receipt, SAMHSA's allegations point of contact convenes a meeting with appropriate program officials who communicate with and gather information from the grantee in question and take appropriate actions, which may include a site visit and corrective action plan depending on the circumstances.

2. Assisted Outpatient Treatment (AOT, also known as outpatient commitment or "OPC") allows a judge to order an individual with serious mental illness, who is unable to live safely without supervision and treatment, to follow a treatment plan while living in the community. In 2010, NIMH director Thomas Insel wrote, "One of the challenges we face in correcting (the problem of SMI individuals ending up in jail) is the absence of an institution for longer-term, evidence-based care for people with severe mental illness." With state psychiatric hospital beds being closed every day, AOT not only provides what Insel was describing, but also provides it in a way that allows an individual to remain in the less restrictive setting of his/her community. Unfortunately, lawyers paid by SAMHSA's PAIMI program actively advocate against programs like AOT despite the fact that the DOJ rates the program as a cost-saver and crime-preventer. While a small subset of people with severe mental illness are at significant risk of committing violent acts (including homicide and suicide) at far higher rates than national averages, research has shown that those with schizophrenia and other severe psychiatric diseases are no more violent than those without SMI if their psychosis is controlled. What is SAMHSA doing to address the needs of seriously mentally ill individuals whose brain disease prevents the person from voluntarily seeking treatment before they end up in the criminal justice system? Please provide a detailed list of SAMHSA funding that has supported implementation of evidence-based AOT/OPC programs over the last ten years. If no funding or limited funding has gone to these programs, please explain why.

Answer: AOT/OPC is a form of leveraged, court ordered treatment. Since 2002, SAMHSA has supported court-ordered treatment through the Grants for Jail Diversion Program. Jail diversion

programs are aimed at persons who have mental illness, who have violated a law, and who can improve with treatment and support. In alignment with the authorizing language (Section 520G of the Public Health Service Act), Requests for Applications have announced funding opportunities to states, municipalities and tribes to divert individuals from incarcerated settings to comprehensive community based mental health and recovery oriented services. Communities proposed and implemented grants to support screening and community treatment for individuals with mental illness and co-occurring substance use disorders who were diverted at police encounter, after arrest and booking, in pre-screening, at first appearance in court, in mental health courts and at violation of probation and parole. Mental health courts issue court-ordered treatment to individuals with mental illnesses and monitor progress at regular hearings, offering rewards or sanctions depending on whether or not participants are adhering to their treatment plans and other conditions.

Based on funding appropriated by Congress for the SAMHSA Center for Mental Health Services Criminal and Juvenile Justice Program Summary Listing of Activities line, during FYs 2003 – 2012, a total of \$56.4 million was spent on the Grants for Jail Diversion Program.

- 3. The President's budget requests \$1.5 billion in new funding for federal fallback exchanges (FFE's). This includes \$554 million in "education and outreach." Congress denied the request for \$1 billion additional funding for FFEs in last year's continuing resolution. Without congress providing these funds, how are you funding federal exchanges? Please provide a detailed accounting chart of what internal accounts the money is coming from.**

Answer: The President's Budget requests \$1.5 billion for the Federal Marketplace. CMS is committed to carrying out the Secretary's ongoing statutory responsibility to establish and operate a Federally-Facilitated Marketplace in states that do not elect to establish and operate their own Marketplaces, or that the Secretary determines will not have any required Marketplace operational by January 1, 2014 or that have not taken the actions she determines necessary to implement the requirements for operating a State-Based Marketplace.

- 4. In August 2012, CDC found that three-fourths of all persons infected with Hepatitis-C are among the baby boom birth cohorts, with the vast majority unaware of their infection, and recommended that every boomer get screened once in their life regardless of risk factors (risk based screening was deemed of "limited success.") Meanwhile a sister agency, the U.S. Preventive Services Task Force (USPSTF), issued its draft guidelines for HCV screening that wants to continue on using risk-based screening and ignores the high density of HCV positive people in the baby boom generation. The ACA requires health plans to follow the USPSTF guidelines. HCV costs are about to explode on Medicare—even though it's easy to test and then treat these populations, with upcoming treatments literally curing people of the disease while safety and efficacy increase. What is the Secretary office doing to navigate and head off this looming medical and fiscal crisis?**

Answer: In regard to Medicare coverage of screening for Hepatitis C Virus amongst the baby boom birth cohort, CMS has limited authority to consider coverage of new preventive and screening services. Specifically, the Medicare statute authorizes the Secretary to add coverage of “additional preventive services” – that is, preventive services not already covered under specific statutory provisions – if the service is recommended at the “A” or “B” level by the U.S. Preventive Services Task Force (USPSTF), and the service is determined through the Medicare national coverage determination (NCD) process to be appropriate for Medicare beneficiaries.

As you noted, the USPSTF recently initiated a reconsideration of their 2004 recommendation on routine screening for Hepatitis C Virus and issued a draft updated recommendation for public comment in November 2012. Until the USPSTF issues a final recommendation, Medicare lacks authority to consider coverage of this service. When a final recommendation is available, we will consider whether it warrants the opening of a national coverage analysis (the first step in the NCD process). The status of the Task Force’s work on this subject can be monitored at <http://www.uspreventiveservicestaskforce.org/uspstf/uspshcpc.htm>.

In regard to the Affordable Care Act provision for private insurance coverage of preventive services recommended by the USPSTF, the law requires that non-grandfathered plans cover services with an A or B recommendation without cost-sharing. Screening for Hepatitis C does not currently have an A or B Recommendation from USPSTF, and it is therefore not required to be covered.

5. The President's Budget demonstrates that the ACA will take over much of the medical services of HIV patients, currently provided by Ryan White funded programs. From current levels, by what amount are Ryan White expenditures expected to decline, and how does the Administration intend to devote those 'surplus' dollars to achieve the stated goals of the national HIV strategy, advance public health and reach an AIDs-free generation? If there are 'surplus' funds, are those funds not best deployed on core medical services and infrastructure strengthening in areas where there are growing populations of HIV patients or continued implementation challenges due to resource-poor setting? The Ryan White Treatment Act calls for 75 percent of funds to be devoted to core medical services. Is it the Administration position that this threshold is no longer prudent or necessary?

Answer: The FY 2014 Budget request reflects continued support for the Ryan White HIV/AIDS Program (RWHAP) while HHS conducts an in-depth assessment of the interaction between the Affordable Care Act and RWHAP’s continued provision of HIV services, and the potential for achieving one of the key goals of the National HIV/AIDS Strategy (NHAS): improving health outcomes for people living with HIV/AIDS.

While HHS does not expect a significant shift in the demand for clinical services in FY 2014, nonetheless, HHS does expect that in FY 2014 the number of insured Ryan White clients is expected to increase to some extent. The FY 2014 Budget also supports investments in Ryan White funded services not covered by public or private insurance, but which are essential to linking people living with HIV into care and maintaining them on drug regimens. These

“continuum of care” services are critical to preventing the spread of the domestic HIV epidemic as recent studies have found that anti-retroviral (ARV) treatment reduces HIV transmission by 96 percent. Examples of these services include case management, transportation assistance, and treatment adherence, which are critical to keeping people in care and on drug regimens that decrease viral load and prevent the spread of the virus. Ryan White dollars are also used to support cost sharing, which leads to more consistent access to ARV drugs and increased adherence to treatment. Ryan white grants are also used by clinics to fund several core medical services not consistently covered by insurance, including comprehensive substance use treatment, mental health services, and care coordination services

The Ryan White Program plays an essential role in meeting the goals of the NHAS and supporting its objective to reach an AIDS-free generation through the Program’s critical role in filling gaps in the health system and its unique capacity, experience, and expertise in meeting the diverse and challenging health care needs of PLWH. If the NHAS goals are to be met, Ryan White Program funds must continue to be used to support care completion services (core medical and continuum of care services) for both newly diagnosed individuals and current clients who will be enrolled in Medicaid or private insurance options beginning in January 2014. The Ryan White Program not only works to ensure that individuals living with HIV gain access to care and life-saving anti-retroviral (ARV) drug treatment, it also works to ensure that people remain in care and adhere to their ARV drug regimens. Because ARV treatment suppresses the virus thereby reducing its transmission by 96 percent, the Ryan White program also plays a critical role in preventing the spread of the HIV epidemic.

By statute, the majority of Ryan White Program funds are distributed by formula with smaller amounts distributed as supplemental awards based on demonstrated needs in resource-poor settings. As noted earlier, based on what the Department learns from its assessment of the impact of the Affordable Care Act on the Ryan White Program, we will be better able to address challenges and future opportunities for changes.

The Ryan White HIV/AIDS Program legislation (title XXVI of the Public Health Service Act), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the statute. The statute grants the Secretary authority to waive this requirement if there are no waiting lists for the AIDS Drug Assistance Program and core medical services are available to all individuals identified and eligible an applicant’s service area. A Federal Register Notice (FRN) was published on May 24, 2013, that offered a proposed revision to the waiver policy for public comment. The FRN supports the Ryan White Program grantees’ request for additional flexibility in the timing of waiver applications by providing grantees additional options for making waiver requests. HRSA will review the information from the comments to inform future action on the waiver.

6. As you know GAO and MedPAC have examined the in-office ancillary Service Exception in depth and neither group has recommended repealing IOASE. I am concerned that the Administration proposal would result in more patients receiving care in the more expensive hospital setting, undermining the integrated delivery of care

and leading to more hospital acquisitions of physician practices. Would you provide the quantitative analysis that supports the \$6 billion score for the proposal? How much is attributable to each service?

Answer: The estimate of \$6 billion in savings was developed by the independent CMS Office of the Actuary based on its assumptions about predicted reductions in spending on services and behavioral changes related to the policy.

7. With regard to radiation, are you aware that radiation utilization from 2007-2011 has been flat at the precise time physician offices have acquired the IMRT technology? Doesn't that suggest that there would be no savings from prohibiting physician ownership of radiation?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer quick turnaround services. While there are many appropriate uses for this exception, certain services, such as advanced imaging and outpatient therapy, are rarely performed on the same day as the related physician office visit. Additionally, evidence suggests that this exception may have resulted in overutilization and rapid growth of certain services over time, including radiation therapy. Effective calendar year 2015, this proposal would seek to encourage more appropriate use of select services by amending the in-office ancillary services exception to prohibit certain referrals for radiation therapy, therapy services, and advanced imaging except in cases where a practice meets certain accountability standards, as defined by the Secretary.

The Honorable H. Morgan Griffith

1. Back in 2011, I asked your former colleague in the Cabinet, EPA Administrator Lisa Jackson, about the impacts of the administration's burdensome regulations would have on my poor and elderly constituents in Southwest Virginia by raising their heating prices. She responded along the lines of that there are programs to help those people. The President proposed to slash the Low Income Home Energy Assistance Program (LIHEAP) by \$650 million from FY12 levels. I cannot fathom how this administration can push through policies that raise energy costs while suggesting that programs like LIHEAP be cut. How will people needing this assistance that have had their energy costs exacerbated by other policies from this administration survive without these LIHEAP funds?

Answer: While the Low Income Home Energy Assistance Program (LIHEAP) remains an important program to the Administration, difficult budgetary choices need to be made across the board and new approaches have to be used to more strategically target resources where they are most needed. The Administration recognizes the importance of ensuring that grantees (States, Tribes, and Territories) retain as much flexibility as possible with their budget decisions for LIHEAP in terms of setting benefit levels and eligibility criteria.

For FY 2014, the Administration proposed a new funding stream of \$50 million to assist LIHEAP grantees with repairing and replacing inefficient heating systems to help enable households to reduce their home energy burden and maximize the impact of their LIHEAP benefits. This pilot program will provide evidence of the effectiveness of different strategies to improve home energy efficiency and reduce home energy burden for low-income households.

The Honorable Gus Bilirakis

- 1. First, in CMS's 45-day notice were changes made to the Medicare Advantage (MA) risk adjustment methodology? Do those changes in effect reward private plans for delaying patients' access to disease management programs and do you believe that this payment policy aligns with the President's stated priority, published in his own budget, to implement payment innovations that reward high quality care?**

Answer: CMS understands the clinical value of disease and care management programs in targeting conditions early and preventing or slowing the progression of disease, improving the health of beneficiaries, and potentially saving health care costs. The goal of risk-adjusted payments is to pay accurately using the appropriate relative risk for a beneficiary. Therefore, a key objective when we develop or update a risk adjustment model is to measure risk in the best way possible.

CMS balanced several goals when updating the CMS-HCC model for the Medicare Advantage program. One significant goal of the revised model was to conduct a fresh model build in order to clinically revise the model. Though CMS annually maps new ICD-9 codes into the existing HCCs, the base groupings in the CMS-HCC model are still based on ICD-9 codes from the late 1990s. CMS has not conducted a fresh model build since the model was created. Thus, a key feature of the proposed restructuring of the condition categories proposed for CY 2014 was achieved by taking into account ICD-9 codes that have been created in the decade since the original model was created. We also considered whether the condition categories predict expenditures, whether the diagnostic classifications measure disease burden, and whether diagnosis codes subject to discretionary or inappropriate coding should be excluded.

The risk adjustment model proposed for 2014 includes important clinical updates, as well changes to address differences in coding between MA plans and fee-for-service Medicare. Because of the concern regarding these risk adjustment changes being implemented at the same time as other program changes, the Final Rate Announcement substantially modified how we will implement the new risk model.

In the Final Rate Announcement, we announced that we will implement the updated, clinically revised CMS-HCC risk adjustment model proposed in the Advance Notice with the following differences: (1) we will not apply a budget neutrality adjustment to the denominator and (2) we will blend the risk scores calculated using this model with the risk scores calculated using the 2013 CMS-HCC model, weighting the risk scores from the 2013 CMS-HCC model by 25

percent and the risk scores from the 2014 CMS-HCC model by 75 percent. We finalized this approach to mitigate the changes in risk scores faced by individual MA organizations.

- 2. Second, I am concerned about further changes to the MA program. Your colleague Ms. Tavenner stated at her Senate confirmation hearing that MA provides high quality coverage to beneficiaries who are satisfied with their coverage. I can say first hand that MA enrollees in Florida, with a penetration rate of 34%, would agree with that statement and truly value their ability to access private plans.**

HHS's FY2014 budget proposed severe changes to the coding intensity adjustment for MA, raising it from 0.25 percentage points to 0.67 percentage points until the minimum adjustment plateaus at 7.59% in 2018. This is significantly higher than current law; under ATRA the adjustment plateaus at 5.9%. The ATRA increased the 2018 adjustment level over time from what was established under the ACA at a 5.7% adjustment in 2018 and beyond.

In light of ACA's deep funding cuts to the program (most of which have yet to take effect) and the way the proposed cuts included in CMS's draft 45-day notice were found to jeopardize stability within the program (and since have been reevaluated), why does the agency find it prudent to increase the coding intensity adjustment at such an accelerated rate from what we have seen in the past?

Answer: The legislative proposals in the President's FY2014 Budget related to coding intensity adjustments and MA employer group waiver plans (EGWPs) are designed to improve the accuracy of MA payments.

The proposal to increase the MA minimum coding intensity adjustment would improve the accuracy of statutorily required risk adjustment of MA payments that accounts for the health status of each MA-enrolled beneficiary. MA plans tend to submit both more diagnosis codes and higher levels of diagnosis codes for beneficiaries with similar underlying health status than providers in FFS (and this difference between MA and FFS diagnosis codes increases over time). Beginning in 2010, the ACA requires CMS institute a minimum coding intensity payment adjustment for MA plans. The coding intensity adjustment is applied as a downward adjustment to beneficiaries' risk scores in each MA plan. In a March 2013 report the Government Accountability Office estimates that the coding intensity adjustment has been insufficient to account for the differences in coding between MA plans and fee-for-service Medicare⁴. This budget proposal is consistent with the GAO recommendation and reduces overpayments to plans resulting from coding pattern differences between MA and Medicare FFS providers.

- 3. The Agency's budget also reduces funding to MA employer plans in which about 1 million beneficiaries are currently enrolled. Employers are already stretched thin by strict cost sharing mandates under ACA for their active workforce and the potential**

⁴ <http://www.gao.gov/assets/590/587637.pdf>

buy-up in coverage to meet the EHB requirements in 2014 under the President’s health law. What kind of impact could this funding reduction have on employers? Will it result in reduced benefits or potentially impact wages or job creation? Would you agree that this policy does not fulfill the “fundamental compact” the President’s rhetoric would indicate he is committed to defend?

Answer: The President’s FY2014 budget also proposes to set the base Part C payment amount for EGWPs in each county using the average standardized bid for individual plans in the county. EGWPs contract directly with employers and therefore have different bidding incentives from individual MA plans. CMS has found in recent years that the projected average risk scores for EGWP members were lower than for individual MA plan enrollees. However, the average EGWP bids were higher than those for individual MA plans. MedPAC also believes that payments for EGWPs could be made more accurate. The proposal would align MA payment policy for EGWPs more closely with Part D payment policy, which sets Part D payments to EGWPs based on the national average Part D bid amount and the national base beneficiary premium, not on Part D bids submitted by EGWPs. EGWP payments in both Parts C and D will be established on a set, prospective basis rather than letting EGWPs bid for their Part C payment level.

4. Do you believe you have such authority to shift funds between HHS accounts to cover expenses related to implementation of the health care law? If so, would you please provide a list of the authorized accounts you believe you have the ability to make such transfers for implementation purposes? Would you provide an accounting of what funds have been transferred or used for such purposes? Please provide a legal analysis for such authority.

Answer: HHS has used the following authorities to transfer funds between HHS appropriations in FY 2013, which includes monies from the Nonrecurring Expenses Fund (NEF), the PPHF, and amounts transferred under the HHS Secretary’s transfer authority. Some, but not all, of these transferred funds are being used in accordance with their relevant statutes and to support the implementation of the new Health Insurance Marketplaces. These authorities are also being used to support other important public health priorities, improve the Medicare appeals process, and make improvements to HHS’s financial management systems.

Nonrecurring Expenses Fund

The NEF was established by Section 223 of Division G of the Consolidated Appropriations Act of 2008 (42 U.S.C. 3514a; P.L. 110-161). This Act provides HHS with the authority to transfer unobligated, expired discretionary funds into a no-year NEF account to spend on specific purposes as authorized by Congress. Monies from the NEF can be used for purposes including capital acquisitions necessary for the operation of the Department, including information technology infrastructure and facility infrastructure. Consistent with the requirements of the law, HHS has notified the Appropriations Committees in the House and Senate of its plans to obligate up to \$600 million from the NEF at this time. The notification includes a plan for CMS to

receive \$200 million to assist with implementing the Marketplaces and \$250 million to carry out other CMS activities.

Prevention and Public Health Fund

The PPHF is an annual account that received an initial appropriation of \$1 billion for FY 2013, which was reduced to \$949 million after the sequester. In FY 2013, funds were allocated to HHS operating divisions, including the Administration for Community Living, the Agency for Healthcare Research and Quality, the CDC, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and CMS.

The PPHF was established by Section 4002 of the Affordable Care Act and may be used to support prevention and public health activities, including activities related to implementing the Marketplaces created by the Affordable Care Act. The PPHF may be used for both programs authorized by the Public Health Service Act, and prevention, wellness, and public health activities. Assisting Americans in gaining affordable health care aligns with the purpose and authority of the PPHF which is to support prevention, wellness, and public health. The implementation of the Marketplaces is a top health care priority for the Department and the nation. New coverage options available in the Marketplaces will increase access to preventive care and improve health outcomes for millions of individuals who will be able to enroll in affordable private health plans. Ensuring Americans have access to affordable, quality care will help further the Department's objective of improving public health.

Secretary's Transfer Authority

Section 206 of Division F—titled “Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2012”—of the Consolidated Appropriations Act, 2012 (P.L. 112-74), as continued under the Consolidated and Further Continuing Appropriations Act, 2013, authorizes the Secretary of HHS to transfer 1 percent of any discretionary funds which are appropriated for the current fiscal year for HHS in the Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act between appropriations within HHS. Section 206 further specifies that no appropriation can be increased by more than 3 percent and requires that HHS notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days in advance of any transfer. Consistent with the requirements of the law, HHS has notified the Appropriations Committees in the House and Senate of its plans to transfer \$114 million under this authority to CMS to implement the Marketplaces.

5. Would the Department share a written timeline of what we can expect with respect to upcoming ACA implementation?

Answer:

June 2013:

Web Re-Launch & Call Center Launch

- In late June, CMS will re-launch healthcare.gov, which will be the consumer destination for the Federally-facilitated and State Partnership Marketplaces and consumers will be able to access educational information. The site will add functionality over the summer before the October 1, 2013 open enrollment.
- At the same time, CMS' Federally-facilitated Marketplace consumer call center will begin taking calls from consumers, beginning with educational information and then assisting with enrollment and plan selection on October 1.

July 2013:

Final Qualified Health Plan (QHP) Evaluation Results Received & Data Finalized

- This refers to the period in which CMS conducts the final QHP review and quality assessment in advance of the plan preview period for QHPs in the Federally-facilitated Marketplaces.
- States send final QHP data and approval recommendations to CMS for State Partnership Marketplaces.

State Department of Insurance Approval of QHPs, State Partnership Review of QHPs Complete

- This refers to the time during which State Departments of Insurance (DOIs) will review QHPs.

August 2013

Navigator/ Agent/Broker Training Complete

- Consumer assisters, including Navigators, Non-Navigator Assistance Personnel, Certified Application Counselors, and Agents & Brokers will be available to help consumers with analyzing the coverage available in their state, selecting the coverage that is right for them, and completing eligibility applications. CMS will provide training to these consumer assisters in Federally-facilitated and State Partnership Marketplaces to ensure they are knowledgeable about the Marketplaces and the coverage that is available through them. CMS expects to have training modules available no later than August so that various types of assisters will be prepared when enrollment begins in October. Trainings will be ongoing.

QHP Plan Preview for Federally-facilitated & State Partnership Marketplaces

- This refers to a process by which issuers will be able to view their QHP offerings loaded onto the Marketplace website the way consumers will see them, identify any inaccuracies, and request corrections to the information before the plan offerings are made public.

September 2013

IT Development & Integration Testing Complete

- This refers to the date by which systems development will be complete for open enrollment, beginning on October 1, 2013.

October 1, 2013

Enrollment Begins

- This refers to the first day (10/1/2013) of the initial open enrollment period for the Marketplaces.

6. A number of news articles have noted higher premiums under the ACA. Would you provide your analysis on why this will or will not be the case?

Answer: In an effort to slow health care spending and give all Americans more value for their health care dollars, the Affordable Care Act has brought an unprecedented level of scrutiny and transparency to health insurance rate increases by requiring insurance companies to justify rate increase, which has discouraged them from raising monthly premiums for unreasonable or unnecessary costs. Insurers must provide clear information so consumers can understand their reasons for significant rate increases. We know this is making a difference, and that the Affordable Care Act is driving down health insurance premium costs in the private market by holding insurers accountable.

A February 2013 report, *Health Insurance Premium Increases in the Individual Market since the Passage of the Affordable Care Act*,⁵ shows that since the rule on rate review was implemented, the number of requests for insurance premium increases of 10% or more plummeted from 75% to an estimated 14% in 2013 as of the date of the report. The average premium increase for all rates in 2012 was 30% below what it was in 2010.

Even when an insurer decides to increase rates, consumers are seeing lower rate increases than what the insurers had initially requested the states to approve. As of the date of the study, more than half of the rate requests for 10% or more ultimately resulted in customers receiving either a lower rate increase than requested or no hike at all.

Furthermore, the rate review program works in conjunction with the 80/20 rule, which generally requires insurance companies to spend at least 80% (85% in the large group market) of premiums on health care, rather than administrative costs (such as executive salaries and marketing) and profits; otherwise, insurance companies must provide rebates to their customers. Insurers that did not meet the 80/20 rule have already provided \$1.1 billion in rebates that benefited nearly 13 million Americans, at an average of \$151 per family.

Insurance benefits and costs also will become easier to understand for millions of Americans and small businesses starting on October 1, 2013, when they will have the opportunity to shop in a Health Insurance Marketplace in their state. Consumers will be able to find information to make apples-to-apples comparisons of health plans by quality and price and buy the one that best fits their needs and budget.

Delivering smarter health care includes holding insurers accountable, and that is helping to hold down costs. In the past three years, we've seen the slowest growth in overall health care spending since the government started keeping records more than 50 years ago. The new Marketplaces will increase competition between issuers in the individual market. Whether individuals are uninsured, or just want to explore new options, the Marketplace will provide more choice and control over health insurance options. CBO projects that lower administrative costs, greater economies of scale, and increased competition will decrease premiums 7 percent to 10 percent in the non-group market.

⁵ <http://aspe.hhs.gov/health/reports/2013/rateincreaseindvmt/rb.cfm>

The Honorable Phil Gingrey

- 1. During the hearing, Dr. Gingrey asked about your comments you made in March during a speech in Philadelphia. During that speech, you stated that “...some men are going to see some higher costs. It’s sort of a one to one shift...some of the older customers may see a slight decline, and some of the younger ones are going to see a slight increase. These folks will be moving into a really fully insured product for the first times, so there may be a higher cost associated with getting into that market.” You did not address his question about whether you think it is fair that young people will pay higher insurance rates because of this law. Has your department created contingency plans in the event that young people choose to pay the penalty instead of purchasing the insurance that they cannot afford?**

Answer: The individual and small group markets—the markets that much of the Affordable Care Act is designed to improve in particular—are broken. People are currently locked out of these markets because of their pre-existing conditions, or if they are able to buy insurance, they may find out their coverage will not extend to the care they need when they get sick. Young women who currently pay for their own insurance plan may discover that, simply on account of their gender, they are sometimes charged 50 percent more than young men are for the same plan. This fall, people are going to be able to buy comprehensive insurance without discrimination based on gender or pre-existing conditions. Also, low- and middle-income people may qualify for premium tax credits to help them buy insurance.

Starting in 2014, people in the individual and small group market will be able to choose new health plans based on the actuarial value they think fits their needs and their budget. Actuarial value means the percentage paid by a health plan of the total allowed costs of benefits. For example, if a plan has an actuarial value of 70 percent, the average consumer would be responsible for 30 percent of the costs of the essential health benefits the plan covers. Plans will range from 60 to 90 percent of actuarial value.

Additionally, the Marketplace will increase competition between issuers on the individual market. CBO projects that lower administrative costs, greater economies of scale, and increased competition will decrease premiums 7 percent to 10 percent in the non-group market.

Also, young adults and certain other people for whom coverage would otherwise be unaffordable may enroll in catastrophic plans, which have lower premiums, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing. Young people under the age of 26 are also generally allowed to stay on their parents’ insurance, helping make insurance more affordable for that group.

There are also many provisions in the law to slow health care cost growth and create competition in the insurance marketplace. For example, the reinsurance and risk adjustment programs will help stabilize premiums.

Our outreach efforts will help ensure that young people across the country learn about the benefits of obtaining health coverage through the Marketplaces. We hope to reach this

population through both traditional and social media campaigns that highlight the importance of health insurance. Consumers can sign up for updates about the marketplace through a mailing list on HealthCare.gov,⁶ by “liking” the Health Insurance Marketplace on Facebook,⁷ or by following @MarketplaceGov on Twitter⁸. On HealthCare.gov⁹ and on the HealthCare.gov YouTube channel¹⁰ there are several short videos explaining how shopping for qualified health plans in the marketplace will work.

The Honorable Bill Cassidy

1. Dr. Cassidy asked if you could accept a 2 percent reduction in your HHS request. Due to time constraints you could not elaborate on your answer that you would not be able to accept a 2 percent reduction. Please explain why you could not accept a 2 percent reduction in your HHS request.

Answer: My FY 2014 request includes investments needed to support the middle class, grow the economy, and create jobs. A two percent cut to this request—a reduction of \$1.6 billion—would limit the Department’s ability to protect the nation’s public health and national security, focus on responsible stewardship of taxpayer dollars, promote science and innovation, protect vulnerable populations, create opportunity and give kids the chance to succeed, and improve health care and expand coverage. Further, a two percent cut would result in fewer resources for proven program integrity initiatives that reduce the deficit in the long term and ensure that the programs millions of American rely on will be there for generations to come.

⁶ <https://signup.healthcare.gov/?x=135&y=17>

⁷ <https://www.facebook.com/HealthInsuranceMarketplace>

⁸ <https://twitter.com/MarketplaceGov>

⁹ <http://www.healthcare.gov/marketplace/index.html>

¹⁰ <http://www.youtube.com/user/HealthCareGov>