**Secretary Burwell's Hearing on**
**"The President's Fiscal Year 2017 Budget"**
**E&C Health Subcommittee**
**February 24, 2016**

**Attachment — Additional Questions for the Record**

*Note: All responses are accurate as of February 24th, 2016.*

**The Honorable Joseph R. Pitts**

1. **Are you or anyone at HHS, working on an executive order with the White House to repeal the non-interference provision in Part D? If so, please expand.**

**Answer:** To my knowledge, we are not working with the White House on an Executive Order that would allow the government to negotiate prices.

Having said that, drug costs are not just the state and Federal governments' fastest growing cost, but are a real kitchen table issue for working families and retirees. Per capita Part D costs increased by 11 percent in 2014, driven primarily by increased spending on high cost drugs in the catastrophic phase of the benefit, which grew much faster than any other part of the program.[1] The extremely high cost of certain specialty drugs raises issues about whether beneficiaries have access to the drugs that they need most. The President's FY2017 Budget proposes one potential solution for this issue: allowing the Secretary to negotiate prices for high-cost drugs.

Over the past several months, HHS has engaged with consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from state and Federal government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients.

We welcome continued engagement and feedback as we work together to address this rapidly growing cost center, while continuing to support innovation and access.

2. **As you may be aware Chairman Upton, Brady, Hatch and Alexander wrote to CMS concerning the "Medicare Drug Spending Dashboard" launched on December 21, 2015. In that letter, the Chairmen expressed concerns about the selective nature of the data presented and if it would be helpful without context. It is my understanding that CMS intends to add a hyperlink on Medicare Plan Finder to the Medicare Drug Spending Dashboard, estimating implementation for 2017 Open Enrollment in Fall 2016. What do you plan to do to ensure that data related to the dashboard is presented in the appropriate context?**

[1] https://blog.cms.gov/2015/11/20/remarks-of-cms-acting-administrator-andy-slavitt-at-the-hhs-pharmaceutical-forum-innovation-access-affordability-and-better-health/

**Answer:** As you noted, CMS intends to add a hyperlink to the Medicare Drug Spending Dashboard on the Medicare Plan Finder on Medicare.gov, which estimates implementation for 2017 Open Enrollment in Fall 2016. The CMS webpage that includes the dashboard[2] provides detailed information on the methodology[3] underlying the data presented as well as background information providing the context for this data release. CMS is committed to increasing the transparency of our programs by making more data available to the public. The release of the Medicare Drug Spending Dashboard is another step CMS is taking to further transparency. Our goal is that more information sharing will inform health care decisions, policy considerations and encourage collective problem solving around the important issues of providing more affordable and accessible medications to beneficiaries.

The Medicare Dashboard is an important part of a larger story. By sharing this information and allowing people to analyze the data, we can increase the knowledge around drug spending and support efforts that to evaluate whether public dollars are being spent most effectively. While data on all Part B and Part D drugs are made available through our other annual public transparency releases, the Medicare Dashboard provides additional information and trends on a subset of significant drugs. Drugs are included in the dashboard if they are likely to have an impact on spending, noted by the highest total Medicare program spending, high spending per user, or large and impactful increases in their cost per unit. Thus, these drugs are likely to have an impact on spending and should spur public discussion of how these products are affecting the Medicare program.

We also seek to stimulate the release of additional data that will promote a more complete understanding of value and patient affordability. For example, the Agency for Healthcare Research and Quality's Evidence-based Practice Center reports are linked with the Medicare Dashboard, and synthesize the evidence regarding the effectiveness of some of these drugs when used by certain populations for specific conditions. We believe that there is complementary data now available from other entities on rebates, clinical effectiveness, pharmacoeconomics, comparative effectiveness, safety, formulary placement and discounts on these drugs. Our hope is that over time outside parties will release this type of information in order to broaden the understanding of these drugs.

At CMS, we are committed, as we always are when we publish data, to receiving input to make sure the data are accurate, fairly presented, constructive, and shown in a way that protects the identity of beneficiaries. Physicians, pharmacists, patients, manufacturers, researchers, and others are encouraged to provide us with feedback to inform our understanding of these data and ensure they are presented appropriately. We welcome your input; please do not hesitate to have your staff reach out to my team to discuss this issue further.

**3. On Friday, October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) released 2016 Medicare Physician Fee Schedule Final Rule. Within this rule were provisions relating to mandating the consultation of appropriate use criteria for select advanced imaging services under PAMA. This policy was scheduled to go into effect**

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Downloads/Drug_Spending_Methods.pdf

**January 2017. CMS has announced that they will not be able to meet the January 2017 implementation deadline and in fact, stated that they will not commit to any date-certain for implementation. Please explain to the Committee why the Agency will not meet the implementation deadline of January 2017 and please tell the Committee a date certain as to when this program will be implemented.**

**Answer:** We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. The number of clinicians impacted by the scope of this program is significant, as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) rulemaking process, we will begin to identify priority clinical areas and expand them over time. We anticipate including further discussions and adopting polices regarding claims-based reporting requirements in the CY 2017 and CY 2018 PFS rulemaking cycles. Also, in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals. We recognize the importance of moving expeditiously as well as ensuring transparency and working with stakeholders to accomplish a fully implemented program.

**The Affordable Care Act established the Independent Payment Advisory Board (IPAB), a board of unelected bureaucrats that are to reduce Medicare spending once certain spending triggers are hit. The President and Congress have not nominated any members to the Board and thus IPAB's authority falls to you.**

4. **Based on current forecasting, when do you expect the IPAB trigger will be hit?**

**Answer*:*** The Chief Actuary of the Centers for Medicare and Medicaid Services (OACT) determines in the annual Medicare Trustees' Report when IPAB is triggered. According to the 2015 Trustee's Report, IPAB will not be triggered for an implementation year before 2019.

**As you know, the Patient Access and Medicare Protection Act of 2015 (PAMPA), P.L. 114-115, should have prevented cuts in the Medicare payment rate for about 170 complex rehabilitation technology (CRT) codes. Unfortunately, CMS has delayed action, as directed by this law, until July 1. As a "fix", CMS has suggested that CRT providers "rebill" for the difference in payment <u>after</u> July 1.**

5. **What assurances do providers have from CMS that they will be able to recoup full payment as required by PAMPA? And how long will providers have to wait to receive that full payment from CMS?**

**Answer:** We appreciate your concerns regarding this issue. CMS began working on implementation of the Patient Access and Medicare Protection Act of 2015 (PAMPA) when it first passed Congress in late December. Since PAMPA was signed into law at the end of

December, it would not have been feasible for us to implement it on January 1, 2016. Given the amount of system changes required and the testing involved, the soonest we are able to implement this change is July 1, 2016. Until these changes are implemented, payments for these items will be based on the adjusted Durable Medical Equipment (DME) fee schedule amounts. The DME adjusted fee schedule rates are currently in a 50/50 blend during this six month transition period. The average reductions for these Group 3 complex rehabilitative wheelchair accessories are about 10 percent. On or after July 1, 2016, suppliers can adjust previously paid claims to receive the full fee schedule amount.

Because the changes to the Medicare claims processing system cannot be implemented any sooner than July 1, the Part B Medicare contractors are unable to process claims within established time limits and an advance payment may be available. Suppliers are able to submit a single advance payment request for multiple claims for an eligible period of time. To apply for an advance payment, the Medicare supplier is required to submit the request to their appropriate Medicare Administrative Contractor. If a provider in your district has concerns or needs additional assistance they should contact their appropriate Medicare Administrative Contractor.

CMS will be monitoring beneficiary access closely during this time to ensure that beneficiaries receive the wheelchairs and accessories that they need.

6. **For over half of the reimbursement codes, the "rebill" amount will be less than $20. It is important to bear in mind that the CRT provider's administrative cost for billing is at least $20. Therefore, won't these providers end up losing money when they rebill Medicare? I do not understand how CMS can say this is a "fix," especially when providers end up losing money.**

**Answer:** CMS wanted suppliers to receive some payment for their claims on a timely basis rather than holding claims until July 1, 2016, when the Medicare claims processing system could be updated to reflect this change given the amount of system changes and testing required. In addition, because the changes to the Medicare claims processing system cannot be implemented any sooner than that date and the Part B Medicare contractors are unable to process claims within established time limits; an advanced payment maybe available for suppliers. To minimize burden, suppliers may submit a single advance payment request for multiple claims during an eligible period of time, consolidating their administrative efforts, until system changes can be implemented.

On or after July 1, 2016, suppliers can adjust previously paid claims with dates of service on or after January 1, 2016, to receive the full fee schedule amount. Since these Group 3 complex rehabilitative wheelchair accessories are also used on other types of wheelchairs, suppliers would have to identify and submit previously submitted claims that would need to be adjusted on or after July 1, 2016. For these items, the average adjustment to the 2016 rates in the transition period is a reduction of about10 percent.

7. **Has CMS provided any information to beneficiaries, providers, or other payers to let them know that Medicare is underpaying for certain CRT equipment until July 1? And, has CMS offered any guidance on what the actual payment rates should be for CRT equipment?**

**Answer:** CMS has posted information regarding the delayed implementation of the PAMPA provision on the DME Spotlight web page, including a message to suppliers on how to receive advance payments until the system changes could be implemented. In addition to the DME Spotlight web page, CMS also alerted suppliers to the delayed implementation of PAMPA via two messages in newsletters in late January and earlier this month[4].

CMS will be releasing the list of HCPCS codes for wheelchair accessories affected by PAMPA soon. Once the HCPCS codes are identified, suppliers can calculate the payment rates using the 2015 DMEPOS fee schedule amounts multiplied by the 2016 DMEPOS fee schedule update factor available in the January 2016 DMEPOS Fee Schedule Update Change Request. The unadjusted 2016 fee schedule amounts for these wheelchair accessories will be posted as part of the July update to the DMEPOS fee schedule file. The July update files are typically posted in early June.

**8. Shouldn't CMS, instead, be developing a process where CMS' contractors *automatically* reprocess these types of claims? That way, the provider would not have to rebill. Since this system would need to be operational by July 1, that gives CMS plenty of time to implement such a system. Do you agree?**

**Answer:** CMS wanted suppliers to receive some payment for their claims on a timely basis rather than holding claims until the systems could be updated to reflect this change. Because the changes to the Medicare claims processing system cannot be implemented any sooner than July 1, the Part B Medicare contractors are unable to process claims within established time limits and an advance payment may be available. Suppliers are able to submit a single advance payment request for multiple claims for an eligible period of time.

On or after July 1, 2016, suppliers can adjust previously paid claims with dates of service on or after January 1, 2016, to receive the full fee schedule amount. Since these Group 3 complex rehabilitative wheelchair accessories are also used on other types of wheelchairs, suppliers would have to identify and submit previously submitted claims that would need to be adjusted on or after July 1, 2016. For these items, the average adjustment to the 2016 rates in the transition period is about a reduction of 10 percent.

**Regarding reform of the Clinical Laboratory Fee Schedule (CLFS), as required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), statute required CMS to issue final rulemaking on CLFS reform by June 30, 2015, providing both laboratories and the agency with sufficient time to create the necessary systems to collect, certify, report, and calculate data, with new reimbursement rates going into effect January 1, 2017. CMS has failed to meet this schedule. A proposed rule was not issued until October 1, 2015, and there still is no final rule. A January 1, 2017 effective date seems unlikely.**

**9. What is the status of the final rule and what are CMS' plans to provide laboratories with sufficient time and guidance to comply with reporting requirements?**

**Answer:** On October 1, 2015, CMS published a proposed rule to implement section 216 of the

[4] All responses are accurate as of February 24, 2016

Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare payment rates. In the proposed rule, CMS proposed to define the term "laboratory" according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. CMS also addressed how to meet the statutory requirement that an "applicable laboratory" receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, CMS proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

CMS is currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an "applicable laboratory". We will carefully consider those comments in developing a final rule implementing PAMA section 216.

**The House of Representatives has demonstrated a strong commitment to precision medicine through our 21st Century Cures initiative, and we remain committed to working with the Administration to enact comprehensive precision medicine legislation. One issue providers have brought to our attention is the complex set of Medicare billing rules, specifically the CMS 14-day Rule, for molecular and advanced diagnostic laboratory tests performed on specimens collected from hospital outpatients. As you know, specialty care is increasingly moving towards the hospital outpatient department, however, many of these advanced diagnostic laboratory tests are performed by independent laboratories separate from the hospital. Under this complex set of rules, the hospital where the specimen was collected is required to bill for the test in most cases even though the hospital did not actually perform the laboratory test. We have heard from cancer centers and others that they do not want to bill for a test that the institution did not perform. Congress previously required CMS to conduct a demonstration project on this issue and CMS issued a report in December 2015 that failed to provide recommendations.**

**10. Would CMS be willing to address this issue as part of the annual rulemaking process this summer to modernize the rule so that the laboratory that performs the test bills Medicare for the test, which is consistent with how other diagnostic tests are billed when performed outside of the hospital?**

**Answer:** Thank you for your leadership on 21st Century Cures and your commitment to advancing scientific innovation. In general, Medicare makes only a single bundled payment to the hospital for all services furnished to inpatients and outpatients, including laboratory tests on specimens stored for up to 30 days. The "date of service" rule limits this policy to tests ordered not more than 14 days after the patient's discharge from the hospital.

We are aware of challenges this policy may pose for laboratories performing certain advanced diagnostic tests on stored specimens. This was addressed through a two-year demonstration required by the Affordable Care Act, allowing separate direct payment to laboratories under certain circumstances. As you noted, CMS issued a report to Congress on this demonstration in 2015, which noted extremely low participation in the demonstration. Given such low participation, we were unable to conduct a thorough assessment of the demonstration's effects or make meaningful recommendations on changes to the policy.

**Last fall, the Office for Civil Rights at HHS published a proposed regulation that is intended to implement section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Although the statute itself refers to any health program or activity that receives federal financial assistance, the proposed regulation goes much, much further by also, apparently, applying the new rules to employer-sponsored health plans that utilize the services of a third-party administrator.**

**11. This overreach of regulatory authority is striking. How do you justify this inappropriate new and costly burden on plans that do not actually receive any form of federal financial assistance and that already comply with a fully articulated set of rules in many of these areas, especially those with respect to individuals with limited proficiency in English?**

**Those employers sponsoring group health plans that utilize the services of a third-party administrator will most likely be forced to comply with the regulatory oversight of the proposed HHS nondiscrimination regulations under section 1557 of the Affordable Care Act. This will add significantly to the regulatory and compliance burden of these plans, from both an administrative and financial standpoint. Moreover, employer-sponsored plans in the future will likely try to avoid using the TPA services of insurers who offer plans through the Exchanges. If not concerned with the additional burden forced on plans, are you at least concerned with the potential impact on the Exchanges if more insurers were to exit as a result of this regulation?**

**Answer:** While I appreciate your concern, the proposed rule to implement Section 1557 of the Affordable Care Act is consistent with the underlying statutory provision. It incorporates the long-standing civil rights principles under the four civil rights laws that Congress referenced in Section 1557. Accordingly, the proposed rule interprets the obligations under Section 1557 consistent with the Civil Rights Restoration Act of 1987 (CRRA), which establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. Therefore, it is consistent with existing civil rights laws and principles to hold a covered entity principally engaged in a health program or activity liable for all of its operations, as we do in the proposed rule.

The proposed rule also reflects careful consideration of input from a variety of stakeholders in response to OCR's Request for Information. It also reflects feedback provided during listening sessions, including input on application of the rule to employers who provide employer-sponsored group health plans that utilize the services of a third-party administrator. As a result of OCR's consultations with HHS components, other Federal agencies, and stakeholders to develop the proposed rule, we do not believe it will result in issuers exiting the Exchanges or employers using third-party administrators who offer plans offered through the Exchanges. In addition, as set forth in the Regulatory Impact Analysis to the proposed rule, the cost to covered entities is limited because most obligations already exist under other civil rights laws and OCR is minimizing costs to the extent possible by developing training and material that covered entities

can use to meet their obligations. For the latest information on Section 1557 please see http://www.hhs.gov/civil-rights/for-individuals/section-1557/.[5]

**In your 2011 regulations regarding the enforcement of federal health care provider conscience protection laws, you stated that the Department of Human Services (HHS) sought to strengthen longstanding protection statutes by ensuring there is a clear process for enforcement. The Office for Civil Rights (OCR) of HHS is the designated department to receive and address complaints of discrimination and coercion in violation of statutory protections. I would like to ask you about the adequacy of this enforcement process.**

12. **How many complaints have been filed since 2011 when the enforcement regulations were finalized?**

13. **How many of those complaints have been resolved? How many remain outstanding?**

14. **On average, how long does it take to resolve a complaint under these regulations? On average, how long does it take to resolve a complaint filed under all other areas of OCR jurisdiction (Disability, Age, Religion, etc.)?**

15. **Is it acceptable if a complaint is never resolved?**

16. **Please provide a list of all actions taken by your department to notify the public and particularly health care providers of their rights under the abortion conscience laws covered in the 2011 regulation.**

17. **As a general matter, not specific to complaints regarding abortion conscience protections, please explain how complaints filed with OCR are handled. Specifically,**

    - **What happens when a complaint is filed?**
    - **How are cases assigned?**
    - **On average how many people serve on a typical team assigned to investigate an OCR complaint?**
    - **What is the average length of time it takes to resolve a complaint filed with OCR?**
    - **Does OCR have the authority to stop an alleged violation while the complaint is being investigated?**

18. **Please provide information about abortion conscience complaints received and processed by OCR since 2011. Specifically,**

    - **How many abortion conscience complaints have been filed since 2011 when the enforcement regulations were finalized?**

[5] All responses are accurate as of February 24, 2016.

- **Is there a particular team assigned to these complaints?**

- **How many people serve on the team(s) assigned to investigate abortion conscience complaints?**

- **How many of those complaints have been resolved?**

- **How many remain outstanding?**

- **On average, how long does it take to resolve a complaint under these regulations?**

- **Is it acceptable if a complaint is never resolved?**

**In 2014 you opened an investigation into complaints that California violated the Weldon abortion conscience protection when it required all insurance plans under the authority of the CA Department of Managed Care to cover abortion. With regard to the complaints filed in response to the abortion coverage mandate in California:**

**19. How many people are assigned to investigate and resolve this issue? Please provide the names of the members of the team investigating and the amount of time each has spent on the investigation since it was opened. [alternatively if asking for names is risky: How many people are assigned to investigate and resolve this issue? Please indicate the cumulative amount of time that the team has spent on the investigation since it was opened.]**

**20. How many meetings has OCR held on the issue internally?**

**21. How many interviews or meetings have been conducted with the parties who have filed complaints (or their representatives) or California officials (or their representatives)?**

**22. Has OCR discussed this case with any person or group other than those who filed complaints (or their representatives) or California officials (or their representatives)? If so, please list the parties consulted.**

**23. How many times have you personally spoken with OCR staff regarding this complaint?**

**Answer:** The HHS Office for Civil Rights (OCR) ensures that individuals receiving services from HHS-funded programs are not subject to unlawful discrimination and that the privacy and security of individuals' health information is protected. OCR engages in investigations, technical assistance, voluntary compliance efforts, enforcement, policy development, and education to ensure that all people have access to health care and health services. As you are aware, OCR also enforces the Federal Health Care Conscience Protection Statutes, including the Church Amendments, the Weldon Amendment, the Public Health Service Act, and the Affordable Care Act.

If an individual feels they have been discriminated against because of their race, color, national origin, disability, age, sex, or religion in programs or activities that HHS operates or to which

HHS provides federal financial assistance, they can file a complaint with OCR. OCR receives more than 20,000 complaints per year; the length and scope of a particular investigation varies based on a number of factors, including the allegations of discrimination, the number of individuals or entities involved, and the types of legal issues that are raised by the complaint.

Once a complaint is received, OCR determines if it has the legal authority to review and investigate the complaint. When it becomes clear that OCR can accept the complaint, an investigation is opened and the complainant is notified. OCR has a variety of investigative tools that it can use, depending on the statute under which a complaint alleges discrimination. During the course of the investigation, OCR may interview the complainant, the covered entity, and any other parties that may have information relevant to the case. OCR may also obtain additional documentation through data requests and, if needed, can complete an on-site visit to the entity's location. Importantly, where areas of concern arise during an investigation, OCR may work with an entity to reach voluntary compliance.

When the investigation is completed, OCR may take several actions, which are tailored depending on the type of relief necessary and remedies available under the law. If OCR determines that no violation has taken place, OCR sends a letter to the complainant and the covered entity providing the results of the investigation and closes the case. If a violation has occurred, OCR may work with an entity to provide corrective action, including updating policies and procedures, training staff members, requiring a service to be provided, or restoring lost benefits. In the rare case where an entity is unwilling to take corrective action, OCR may recommend the initiation of enforcement proceedings, which are carried out by the Office for General Counsel or the Department of Justice. A final decision upholding a violation finding could result in the termination of Federal financial assistance to the recipient.

HHS supports clear and strong conscience protections for health care providers and entities that are opposed to performing abortions and is committed to enforcing these laws. Since January 2011, OCR has received eight complaints alleging discrimination under the provider conscience protection statutes, six of which are currently open and undergoing investigation. Among those filed, OCR received three complaints alleging that the California Department of Managed Health Care directive violates the conscience clause protections of the Weldon Amendment. OCR has an open investigation to examine the allegations in these complaints. Because these are open cases, we cannot comment on the status of the review.

Lastly, OCR includes information about its authority to enforce conscience protections in its overview of OCR's authorities when it does general outreach presentations. Notably, OCR has an entire section of its website dedicated to the provider conscience protection statutes. The website includes references to the laws it enforces, how to file a complaint, and detailed information about OCR's enforcement of these laws (including a PowerPoint presentation and a fact sheet).[6]

**24. SAMHSA administers the Now is the Time Project AWARE program which gives out grants to Local Educational Agencies (LEAs) to support training of school personnel to detect and respond to mental illness in our youth. However, these federal dollars have been interpreted to narrowly only apply to one specific type of mental health awareness**

[6] All responses are accurate as February 24, 2016.

**program, in lieu of other ones listed in their National Registry of Evidence-Based Programs and Practices (NREPP). Can you state the reasons why SAMHSA currently restricts the eligibility for Project AWARE dollars to only one program administered by one organization in lieu of others listed in their Registry? Do you believe it would be better if state and local agencies would be able to choose the evidence-based and proven program that works best suit the needs of their schools and communities?**

**Answer:** SAMHSA administers the Project AWARE Local Educational Agencies (LEA) programs in a manner that is consistent with Congressional direction. In the Consolidated Appropriations Act, 2014, Congress appropriated $15 million to SAMHSA for "Mental Health First Aid" and final Conference Report language directed SAMHSA "to focus on a broad public health safety approach when implementing the Mental Health First Aid program that offers training for both school officials and the range of actors in the public sphere that interact with youth." Consistent with Congressional direction, SAMHSA implements Mental Health First Aid training. This training is for teachers and other adults who interact with youth to detect and respond to mental illness in children and young adults, including how to encourage adolescents and families experiencing these problems to seek treatment.

**25. CMS told GAO it expects to issue guidance outlining how the Marketplace will determine whether an applicant has demonstrated a good faith effort to obtain the required documentation, and expects good faith extensions for applications for 2016 coverage to be very limited. So, what *precisely* is CMS's policy for resolving inconsistencies now? And, based on past problems identified, are you confident CMS's actions will *eliminate* the problems GAO identified with CMS protocols and processes for 2014 and 2015?**

**Answer:** The FFM takes action on a monthly basis for consumers with unresolved data matching issues who have not provided adequate documentation within 95 days for citizenship or immigration status data matching issues and within 90 days for household income inconsistencies. Consumers who do not submit sufficient documentation to resolve their annual household income data matching issue will have a recalculation of their APTC and/or CSRs based on available tax data. Individuals who have not provided the necessary documentation for their citizenship or immigration status will have their enrollment through the Marketplace terminated. As discussed in the response to the GAO, decisions to grant an extension under 45 CFR 155.315(e) have been made on a case by case basis for a small number of applicants.

CMS learned from the first year of implementation and made improvements in advance of and during the second and third open enrollments. CMS is continually improving its policies and procedures in order to fulfill its responsibility to protect taxpayer funds, while providing coverage to eligible consumers. Since May 2015, consumers have been able to call the Marketplace call center and representatives have access to near real-time data on the documents consumers have submitted to address their inconsistency. These program improvements will help address the issues raised by the GAO.

**26. The committee has been told that if a consumer who has exchange coverage wants to make a simple change to their coverage, say for example, to update their address, they must go through the entire exchange enrollment/eligibility process again. How long is**

**the average call or time online for consumers wanting to make a simple change like this? Why is CMS's process so difficult for consumers?**

**Answer:** CMS continually works to improve the customer experience including making it simple for consumers to keep their Marketplace information up to date. Consumers can report changes to their Marketplace coverage in three ways: online, by phone, or in-person. Consumers are not required to go through the entire enrollment process again for a simple change in contact information such as an email address or phone number. If a consumer's address change involves a change in ZIP code or county that results in access to different qualified health plans, the consumer may qualify for a Special Enrollment Period, in which case a new eligibility determination is required. Other changes that may impact eligibility and therefore require a new application include change in income or eligibility for other forms of health coverage. We encourage consumers to report income or household changes as soon as possible, since it may affect the coverage or savings for which they are eligible. We have also made an online tool available to give consumers a better sense of how changes will impact their premium tax credit amount.

**27. Next year, States that have expanded Medicaid to childless adults will start paying 5% of the costs for that population, as the full federal financing for this population declines. Your predecessor made headlines in recent months, criticizing one state's decision not to expand Medicaid under the ACA as "morally repugnant and economically stupid." I appreciate that you've often had a better tone than your predecessor. Isn't the budget proposal to extend to states that have not expanded Medicaid the full federal financing for newly eligible adults –isn't that proposal an implicit omission that State governors and legislators are not "economically stupid" but are actually making decisions based in part on their own economic interest?**

**Answer:** State decisions to extend Medicaid coverage to low-income adults have been proven to expand insurance coverage, reduce the uncompensated care burden on health care providers, and save states money. As of January 2016, 30 states and the District of Columbia have elected to expand Medicaid, and more states are actively discussing expansion (Louisiana will make the 31st state). Through November 2015, an additional 14.1 million individuals have gained Medicaid or CHIP coverage, including over 335,000 Pennsylvanians; many of whom would not have been eligible for coverage absent Medicaid expansion[7].

Research shows that expansion makes good fiscal sense for states and their residents. Medicaid coverage offers low-income families a set of affordable and comprehensive health benefits from preventive screening to prescription drug benefits. Adults with Medicaid report that they are able to access care and can afford the services they need. People with Medicaid coverage report also very high satisfaction, even higher than those who receive health insurance through their place of employment. Medicaid expansion has not only increased access to quality care, but it has also reduced costs for hospitals and other medical providers that may otherwise have burdened providers or be passed on to taxpayers and already insured individuals. According to the Council of Economic Advisers, if all states fully expanded Medicaid, uncompensated care costs would be about $8.9 billion lower in 2016 than they would be if no states expanded Medicaid. In

[7] https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/november-2015-enrollment-report.pdf

Kentucky, for example, expansion has been projected to add 40,000 jobs and $30 billion to state economy through 2021.

As you say, the President's Budget includes a proposal to provide all states, regardless of when they choose to expand Medicaid, the same federal share as states that expanded right away by providing three years of full Federal funding for newly eligible adults. We believe that continuing to incentivize states to expand Medicaid coverage will benefit millions of people across the country, reduce the uncompensated care burden on urban and rural providers, and stimulate state economies. As you know, I am personally committed to working with states to find solutions that work best for their residents, while protecting certain fundamentals of the program.

**28. Today, under Medicaid expansion, it's a fact that many medical and law students in states that expanded Medicaid are enrolled in the program. That's in part because universities have dialed back their private coverage programs, due to Medicaid expansion. I worry this is just one more example of how the ACA's Medicaid expansion can often crowd out private coverage. Would CMS survey newly-eligible Medicaid beneficiaries to see what coverage they had before their current coverage?**

**Answer:** Research shows Medicaid expansion does not "crowd out" private coverage. While some colleges and universities may have dialed back their private coverage, much of this is attributable to the Affordable Care Act extending coverage under parents' health plans up to age 26 and to elimination of low-benefit plans that once provided many students with subpar coverage. Not only does Medicaid expansion not "crowd out" other coverage, but it also increases the number of low-income Americans receive coverage through private insurers. Many of these individuals would otherwise have been unable to afford private insurance. Research from Oregon showed that an expansion of Medicaid coverage was associated with a 25 percentage point increase in the probability of having insurance during the study period. This net increase in insurance appears to come entirely through a gross increase in Medicaid coverage, with little evidence of crowd-out of private insurance.

In most of the states that have expanded Medicaid, newly eligible adults are enrolled in private managed care plans that contract with state Medicaid agencies to serve this population. And in states like Arkansas that have expanded using a premium assistance approach, some of the newly eligible adults receive coverage through private insurers through the Marketplaces; their premiums are paid by the state Medicaid program, with a contribution from the individual.

As reflected in the President's FY 2017 Budget proposal to provide all states, regardless of when they choose to expand Medicaid, the same federal share as states that expanded right away, the agency is focused on decreasing the number of low-income Americans who are still without insurance coverage in states that have not yet decided to expand their Medicaid programs.

**29. The Committee has been very interested in CMS's vague criteria for approving 1115 waivers. In responses to the Committee, CMS admitted "we do not apply a standard federal definition of 'low-income.'" In fact, CMS went on to say that "in some cases, we have approved state requests for demonstrations involving populations at higher incomes levels when we determine that the program furthers the objectives of title XIX**

**in that state." CMS went on to explain that "approving a program that serves individuals with income above 250 percent FPL can further the objectives of title XIX, if the program helps keep individuals healthy, especially those who may be at risk of developing medical conditions that could cause them to lose income, which may cause the individuals to become Medicaid eligible." Given the positive correlations between participation in the labor force and health outcomes, why is CMS so ideologically opposed to states testing the utility of work requirements for the non-disabled population?**

**Answer:** Section 1115 of the Act authorizes the Secretary to waive provisions of section 1902 of the Act to enable states to conduct demonstrations that would, in her judgment, be likely to assist in promoting the objectives of Title XIX. We have used this authority to enable states to conduct demonstrations that promote the objectives of the Medicaid program. Since 2009, we have approved new demonstrations in 29 states[8] and approved 86 renewal actions.[9] However, the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work or receive job training because that is not an objective of Title XIX.

We are committed to working with states interested in pursuing new and innovative policy approaches in their Medicaid program. We do consider encouraging work an important state objective, and to that end we have worked with states to develop approaches that encourage work and job training participation. However, the structure of the ACA is built on every American having a guarantee of access to affordable health insurance. We cannot condition that access on any requirement, including work. It is also notable that nearly three out of four (72%) of the uninsured adults who could gain Medicaid coverage in non-expansion states live in a family with at least one full-time or part time worker and more than half (57%) are working full or part-time themselves.

**30. I have a question about Medicaid's approval of funding for designated state health programs through 1115 waivers. I know CMS has explained that States deduct from their waiver requests any existing federal funding the state may have. But why is it appropriate for CMS to approve Medicaid federal financing of state-based healthcare workforce training and loan repayment programs, when there are already federally-funded programs to do the same thing through HRSA? This is clearly duplicative of the existing federal funding stream—just within HHS.**

**Answer:** CMS and HRSA work together on the 1115 waiver approval process to ensure that appropriate review to prevent duplication occurs. The 1115 waiver program is a research and demonstration mechanism for states to improve Medicaid and CHIP programs. These 1115 waivers may include components related to workforce with the purpose of stabilizing and strengthening access to care for Medicaid and low-income populations in the state.

HRSA workforce and loan repayment programs are statutorily defined programs through separate authorities and for a different purpose than 1115 waivers HRSA provides grants to academic institutions and other entities to train the health care workforce across the entire

[8] AL, AR, AZ, CO, DC, GA, IA, ID, IL, IN, KS, LA, MI, MN, MO, MT, ND, NH, NJ, NM, NV, OH, PA, RI, TX, VA, WA, WI, & WV

[9] All responses accurate as of February 24, 2016.

training continuum. States are not eligible to compete for all HRSA-administered programs. . These programs provide separate but complementary efforts, which both work to address the Nation's healthcare workforce shortages.

**31. To help ensure the accuracy of eligibility determinations for the aged and disabled population in Medicaid, in 2008, Congress passed legislation that required States to implement electronic asset verification systems to verify the assets of aged, blind, or disabled applicants for Medicaid. The law provided for States' implementation of these systems to occur on a rolling basis, with all states required to have systems in place by the end of fiscal year 2013. The law also specifies that federal matching payments for expenditures for the populations subject to asset verification must be withheld should states fail to implement the required asset verification system, unless the State demonstrates a good faith effort to comply, submits a corrective action plan to remedy such noncompliance, and fulfills the terms of the corrective action plan within 12 months. It is now fiscal year 2016, yet CMS does not even know which states have implemented these statutorily required systems intended to ensure the accuracy of Medicaid eligibility determinations. Does HHS or CMS not believe that the accuracy of Medicaid eligibility determinations is a high priority? Why hasn't CMS required states to submit corrective action plans within the time frames outlined in the law?**

**Answer:** The accuracy of Medicaid eligibility decisions is a high priority and CMS has implemented a number of strategies to ensure program integrity. Pursuant to CMS regulations, states have implemented strategies to electronically verify a number of factors of eligibility, including income, citizenship, and eligible immigration status.

Since 2011, all states have either built new eligibility systems or have dramatically re-engineered legacy systems to implement new Medicaid eligibility rules. These new systems present an opportunity to automate the asset verification systems (AVS). However, states have faced a number of obstacles in the implementation of AVS. These include the cost of the product and availability of state funds, a limited number of vendors with an appropriate product, and, in some states, a reluctance/refusal of financial institutions to participate and provide data.

CMS has been working to promote faster progress across states. In order to help states move toward full implementation of an AVS, CMS has issued guidance on AVS and provided extensive technical assistance to states. They have, for example, facilitated state-to-state discussions of ways to overcome implementation obstacles. Additionally, CMS is evaluating states' Advanced Planning Documents to ensure that plans for electronic asset verification are integrated into current and future system development/build schedules.

CMS has approved Medicaid state plan amendments (SPA) to implement asset verification systems in 31 states[10]. To date, 7 of these states have fully implemented an AVS and another 13 expect to be live before the end of 2016. CMS requested that each of the remaining 20 states

[10] These 31 states are Alabama, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Kentucky, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, Utah, Vermont, Virginia, Washington, Wisconsin and Wyoming.

submit a SPA to CMS for approval, along with a detailed work plan and timeline for full implementation. CMS is evaluating whether each state that has not yet implemented an AVS is making a good faith effort to comply with the statutory requirements. Any state determined not to be making a good faith effort will be required to submit a corrective action plan.

As more states re-engineer their eligibility systems for the aged, blind, and disabled populations, CMS expects that more will commit resources to complying with asset verification

**32. According to GAO, State Medicaid Directors raised concerns that Medicaid eligibility determinations made by the federal exchange were incorrect. Despite these concerns, at the time of their work, GAO noted that CMS was not assessing the accuracy of federal eligibility determinations, but that CMS officials indicated that the agency was planning to begin looking at such determinations in August 2015. What is CMS doing to examine the accuracy of federal eligibility determinations and what has CMS found?**

**Answer:** CMS agrees that it is important that determinations made by the FFM are accurate, and has a number of processes in place to support this goal. First, all business requirements for the FFM's systems were developed by federal subject matter experts who were involved in drafting the guiding regulations, particularly those pertaining to eligibility requirements. Second, as part of the normal CMS systems development lifecycle, FFM code goes through developer and independent testing, including regression testing as changes are introduced. Third, CMS routinely engages with a number of issuers who are able to do end-to-end testing of the eligibility and enrollment process to ensure accurate eligibility determinations and correct enrollment information. In this vein, CMS is leveraging this process to also ensure that Medicaid eligibility determinations are accurate by implementing a pilot program to test complex eligibility scenarios in three states. CMS will use this pilot program to refine the eligibility testing process and will gradually add more FFM states with routine, scheduled testing windows throughout the year. Lastly, CMS is constantly reviewing issues reported to our help desk and through other channels to determine whether improvements are required, and also receives continual feedback from state Medicaid and CHIP agency staff on any potential concerns.

**33. According to GAO, Medicaid quarterly expenditure reviews only assess whether expenditures for an enrollee that a State claims to be newly eligible is submitted under the newly eligible expenditure category. It does not whether the enrollee is *truly* newly eligible. Given the 100 percent federal funding for the newly eligible, States obviously have a financial incentive to increase the proportion of applicants and expenditures for that population. As such, what is CMS doing to ensure that expenditures claimed under the higher federal matching rate are indeed for individuals that are newly eligible? Can you also speak to CMS's oversight of matching rates with respect to CHIP, since many states have a very high CHIP matching rate?**

**Answer:** CMS is committed to ensuring that federal financial participation (FFP) paid to states for Medicaid and CHIP expenditures is accurate and appropriate. To ensure federal funding is provided at the appropriate Federal Medical Assistance Percentage (FMAP) and expenditures were for covered services CMS conducts expenditure reviews that contain a series of management controls and validation activities as oversight of states. These expenditure reviews do not include eligibility reviews which are handled by a separate process. However, the two

complementary processes collectively serve to provide appropriate oversight of the FFP paid for state expenditures. The reviews for CHIP reported expenditures follow the same quarterly review and oversight process that is conducted for all claims for Federal matching funds.

To specifically address oversight needs for the newly eligible expenditure category, CMS implemented new quarterly CMS-64 expenditure reporting and review procedures for the new adult group. CMS developed new financial reporting forms where states must separately report expenditures for newly eligible individuals and also provided significant training and guidance to states about how to accurately track and report these expenditures. CMS is also conducting rigorous financial management reviews of these expenditures. CMS samples claims and generalizes the results obtained from the sample review for purposes of deferring federal funding, as necessary, to ensure appropriate claiming and proper state corrective action. The deferral process allows CMS to withhold federal funding from a state while obtaining additional documentation from a state or requesting state corrective action, including the return of FFP when appropriate. CMS is also exploring additional ways to reinforce for Medicaid and CHIP enrolled consumers the need to report application changes to the applicable state agency.

**34. Last year CMS did not check for Medicaid coverage for the 1.96 million individuals who the agency auto-enrolled in qualified health plan for plan year 2015. This likely resulted in duplicate coverage and inaccurate federal payments. With open enrollment for plan year 2016 having just ended, what, if anything, did CMS do this year to check for Medicaid coverage before automatically enroll people?**

**Answer:** The Marketplace checked whether enrollees were dually enrolled in Marketplace coverage with APTC and Medicaid or CHIP prior to Open Enrollment for 2016. Consumers who were identified as dually enrolled were notified that they should end their Marketplace coverage with APTC. In spring 2016, we will check again whether Marketplace enrollees with APTC are also enrolled in Medicaid or CHIP. Notices will be sent in May to consumers who were enrolled in both.

**36. Medicare expenditures this year will total nearly $570 billion, and are expected to roughly double over the coming decade.[1] The budget includes very modest structural changes to Medicare, but they would not be sufficient to make Medicare solvent. In fact, according to CBO, the Medicare Hospital Insurance Trust Fund will be insolvent in 2026—meaning the next president will inherit a program rapidly hurtling toward going belly up and jeopardizing care for millions of Americans. [2] As a former budget official, are you content with this Administration's record on shoring up the Medicare program to protect it for current and future beneficiaries?**

**37. I know we all agree Medicare is a critical program for Americans. There have been bipartisan proposals in the last eight years that would make needed changes to help save Medicare—plans like those from the president's fiscal commission; Rivlin-Domenici; Wyden-Ryan, and Lieberman-Coburn. Unfortunately, the Administration largely ignored these plans and used Medicare savings to make Obamacare look like it**

[1] https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf
[2] https://www.cbo.gov/about/products/budget_economic_data#5

**reduced the deficit. Yet, the insolvency of the Medicare hospital trust fund is within sight, and Medicare continues to consume more general revenue. In addition to a few of the bipartisan proposals in the president's budget, do you acknowledge more needs to be done to help save Medicare?**

**38. Each day about 10,000 baby boomers age into the Medicare program. The present value of Medicare taxes for a married couple earning the average wage and retiring at 65 is approximately $140,000 in payroll taxes but the lifetime average benefit is $422,000 roughly 3 times what is paid in payroll taxes. Can the current financial condition of the Medicare program sustain this growth?**

**39. One could argue that the most serious threat to the nation's long-term prosperity is the rapid and unfinanced growth of entitlement spending. Left unchecked, spending commitments for these programs will consume future revenue. According to CBO, Medicare spending in 2015 "rose by $34 billion, or nearly 7 percent—the fastest rate of growth recorded for the program since 2009." This spending growth is expected to continue at roughly the same level over the next 10 years. Does the Administration believe that the current Medicare program is sufficiently financed to be able to handle this growth without significant cuts to providers or decreases in benefits?**

**40. The first Baby Boomers aged into the Medicare program 5 years ago with 10,000 more joining every day. By 2030 75 million seniors will be in the program, living longer than ever before while retirement age has stayed constant. While the budget proposes savings it is near silent on large structural reform designed to protect future benefits, why hasn't the Administration supported structural reforms such as raising the retirement age to correspond with Social Security?**

**Answer:** This Administration has taken historic steps to help change the trajectory of health care spending. The Affordable Care Act is contributing to the recent slow growth in health care costs, while expanding coverage and improving the quality of care for millions of people across the country – including through the provisions that reduce Medicare excessive payments and shift toward payment models that promote high-quality, efficient care. The continuation of slow growth for years after the recession and slow growth in Medicare, which is insulated from broader economic trends, both point to a major role for structural changes in the health care system in explaining recent slow health care cost growth. Work by outside researchers has reached similar conclusions.

Since August 2010, the Congressional Budget Office's projection of Medicare spending under current policy in 2020 has fallen by $123 billion. This decline represents a 15 percent reduction in projected spending and primarily reflects the recent slow growth in health care spending. Medicare spending per beneficiary rose just 1 percent in nominal terms in 2015, according to projections from the Centers for Medicare and Medicaid Services. This would make 2015 the sixth consecutive year in which per-enrollee Medicare spending was near or below economy-wide inflation. From 2000 to 2010, per-enrollee Medicare spending exceeded overall inflation by an average of 3.6 percent per year, even after adjusting for the introduction of Medicare Part D.

Since the enactment of the Affordable Care Act nearly 10.7 million Medicare beneficiaries have received discounts over $20.8 billion on prescription drugs – an average of $1,945 per beneficiary. In 2015 alone, nearly 5.2 million seniors and people with disabilities received

discounts of over $5.4 billion, for an average of $1,054 per beneficiary. This is an increase in savings compared to 2014, when 5.1 million Medicare beneficiaries received discounts of $4.8 billion, for an average of $941 per beneficiary.

That said, we know we still have important work ahead. The Budget presents a balanced set of proposals aimed at creating a health care system that spends money in a smarter way, provides better care, and leads to healthier people. Specifically the Budget proposals promote high-quality, efficient care, improve beneficiary access to care, address the rising cost of pharmaceuticals, align payments more closely with costs of care, and create incentives for beneficiaries to seek high-value services.

The Budget also includes some structural reforms to Medicare, including increasing income-related premiums under Medicare Parts B and D, modifying the Part B deductible for new beneficiaries, introducing home health copayments for new beneficiaries, and encouraging the use of generic drugs by low-income beneficiaries.

Together, the Medicare budget proposals would save a net $419 billion over ten years, slowing down the average annual growth in Medicare spending by approximately one percent. These proposals, plus additional tax proposals included in the Budget, would extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years. I believe that the proposals in the Budget represent progress toward curbing Medicare spending, but I recognize that there is more that can be done. For instance, in January 2015, the Administration set a goal of tying 30 percent of traditional Medicare payments to quality or value through alternative payment models by the end of 2016 – a goal which HHS estimates it has already met ahead of schedule, and tying 50 percent of payments to these models by the end of 2018. I believe that the enactment of the Medicare Access and CHIP Reauthorization Act will help us achieve our goal by promoting participation in alternative payment models. I look forward to working with Congress on more bipartisan efforts to help ensure that the Medicare program is sustainable for current and future generations.

**The Honorable Marsha Blackburn**

1. **In a report issued last October, the Congressional Budget Office stated that the growth of obesity in the US since 1980 poses "a significant public health challenge." CBO further stated that "obesity is associated with numerous diseases and higher than average health care spending."**

2. **Is the department taking specific steps to address the impact of obesity on health care spending? Do you believe legislative proposals to address the obesity crisis might be useful in impacting incidence of obesity and the growing impact of obesity on other chronic conditions, and spending associated with obesity?**

**Answer**: The Department shares your concern about obesity. Currently, the Office of the Assistant Secretary for Health convenes a monthly HHS inter-agency workgroup on Healthy Weight, Nutrition and Physical Activity (HWNPA). Representatives from across HHS share information on their agencies' HWNPA activities, which range from school nutrition, childhood obesity, and healthy weight measures to walking and walkability. CMS is part of this workgroup.

In partnership with National League of Cities, HHS's Let's Move: Cities, Towns and Counties Initiative has engaged over 500 local municipalities. These cities have committed to improving nutrition standards and increasing physical activity, with a goal to reverse the tide of childhood obesity in a generation. Over 80 Million Americans now live in a city, town or county that have logged over 3000 local, voluntary policies ("promising practices") committed to this action. This includes a goal focused on increasing access to healthy nutrition programs in schools.

Additionally, The Dietary Guidelines for Americans (DGAs), issued jointly by HHS and USDA every five years and most recently in January 2016, are the cornerstone of Federal nutrition policy and nutrition program activities. DGAs inform USDA and HHS food programs, from the National School Lunch Program to nutrition programs for older adults. Other departments, including the Departments of Defense and the Department of Veterans Affairs, also use the DGAs to inform things like menu standards in military dining facilities.

Medicare covers diabetes self-management training for diagnosed diabetics, as well as diabetes screening tests for those with risk factors for diabetes (including obesity). Medicare also covers medical nutrition therapy for persons diagnosed with diabetes or renal disease. In addition, Medicare covers intensive behavioral therapy for obesity in primary care settings. The availability and importance of these services would also be highlighted, as appropriate, in the one-time "Welcome to Medicare" visit and the Annual Wellness Visit.

Medicare also covers several types of bariatric surgery for beneficiaries with a Body Mass Index (BMI) of 35 or greater and at least one co-morbidity related to obesity who have previously been unsuccessful with medical treatment for obesity. Medicare also covers intensive behavioral counseling for obesity for individuals with a BMI of 30 or greater.

Beyond these activities, proposals to ensure funding to scale up key proven obesity prevention initiatives are important to maintain the declines that are being observed in children aged 2-5 years and to stabilize the obesity growth observed in older youth and adults which is diminishing worker productivity and leading to health care spending on obesity and its related health conditions.

CDC has promising strategies to address obesity. Although multiple individual factors can influence obesity, strategies have primarily focused on changing the energy balance opportunities including caloric reduction and increased physical activity.

The scientific literature shows us that we need a variety of approaches, not one single approach, to reduce obesity. These include behavioral changes and changes in the food and physical activity environment. Reports by a number of experts and expert bodies including CDC, the Institute of Medicine, the Surgeon General and the National Resource Center for Health and Safety in Child Care and Early Education have identified strategies based on the best available evidence combined with expert opinion.

- Overall, these experts support a multi-component approach to addressing key behaviors that impact weight gain and healthy growth. These include the need to address both physical activity and diet, and the need to strengthen supports for

making healthy choices in the multiple places where people eat and have the potential to be active.

In addition to these population level reports, the Clinical Preventive Services Task Force, as well as other expert medical groups, has recommended screening for obesity for all aged 6 years and older combined with referrals to intensive family-based pediatric weight management programs with nutrition and physical activity behavioral interventions for those at risk. CDC is working to promote adoption of these recommendations to promote reductions in BMI.

CDC conducted the Childhood Obesity Research and Demonstration (CORD) project (2011-2016) that focused on linking low-income children who have obesity to integrated primary care and community weight management initiatives. Early results show BMI reductions for children 6–12 years of age. CDC is supporting these obesity prevention strategies, in part, through our Division of Nutrition, Physical Activity and Obesity which includes work with national partners, states, communities, and land grant universities to increase access to and consumption of healthy foods and beverages and promotion physical activity, particularly walking and the creation of walkable communities.

**On November 13, 2013 the FDA released a proposed rule on labeling changes for ANDA holders titled Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500. The proposed rule mandates that generic drug firms unilaterally change their labels for drugs under approved ANDAs by submission of a Changes Being Effected Supplement – 0 days (CBE-0) to add warnings, precautions, adverse reactions, contraindications and certain other information [hereafter collectively referred to as "warning(s)" even if the corresponding branded company has not implemented the same labeling change.**

3. **Secretary Burwell, your Administration and many of my colleagues on this Committee, have pointed out that more and more Americans are concerned with the rising cost of prescription drugs. In fact, the President's FY17 budget proposes a number of solutions for Congress to consider as solutions to the problem. However, I'm concerned the Administration is talking out of both sides of their mouth on this issue. Since 2013, the FDA has considered finalizing a proposed rule on labeling changes for approved medicines. The rule takes an unprecedented approach to long standing laws and regulations requiring generics to have the same label as the brand. By some estimates, this change would increase the costs on the generic pharmaceutical industry by as much as $4 billion annually. And your Agency, in spite of receiving more than 23,000 comments on the proposed rule, has never met with industry representatives to discuss it, nor have you made any effort to make a realistic estimate the rule would have on prescription drug costs and access. How can you tell me you're concerned about the rising cost of prescription drugs on one day, and then turn around and tell patients that you're going to finalize a rule that could add another $4 billion to the cost of their prescription drugs tomorrow?**

**Answer:** I share your concern regarding the rising cost of drugs, and like you believe that drug costs are not just the state and Federal governments' fastest growing cost, but also a real kitchen

table issue for working families and retirees. Per capita Part D costs increased by 11 percent in 2014, driven primarily by increased spending on high cost drugs in the catastrophic phase of the benefit, which grew much faster than any other part of the program. The extremely high cost of certain specialty drugs raises issues about whether beneficiaries have access to the drugs that they need most.

Our goal is to protect consumers' access to important drugs while encouraging research and innovation, and we have taken several steps to address this. The Affordable Care Act took steps to make Medicare drug coverage more affordable by closing the coverage gap – and 9.4 million seniors and people with disabilities saved over $15 billion on prescription drugs as a result. This year's the President's Budget also proposes to give the Secretary the authority to negotiate prices under the Part D program for biologics and high-cost drugs.

Over the past several months, HHS has engaged with consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from state and Federal government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients. This included a forum that brought together key stakeholders to share information focused on how to meet the overall goals of encouraging pharmaceutical innovation, assuring access to medications, and managing costs for Federal, state, and private health care purchasers. We welcome continued engagement and feedback as we work together to address this rapidly growing cost center, while continuing to support innovation and access.

At the same time, we are focused on bringing new drugs to the market and encouraging competition – and FDA is an important part of that work. FDA programs such as fast track and priority review help expedite getting new drugs and biologics into the hands of patients. The role of FDA is to ensure the safety and effectiveness of prescription drugs, both branded and generic. The proposed rule you reference is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), health care associations, drug and pharmacy associations, brand and generic drug companies, law firms, state governments, and Congress. These comments include proposals of alternative approaches to communicating newly acquired safety-related information in a multi-source environment. FDA received approximately 200 comments; along with the one comment with over 23,000 signatures that you mention. These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association on September 8, 2014, to listen to their comments and views regarding the proposed rule.

In addition, in March 2015, FDA held a public meeting at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve communication of important, newly acquired drug safety information to health care professionals and the public. In the February 2015 notice announcing the public meeting, FDA reopened the comment period for the proposed rule until April 27, 2015, to allow the submissions of written comments concerning proposals advanced during the public meeting.

FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting. Any final rule will reflect FDA's consideration of public comments and be accompanied by an updated analysis of the economic impact of the regulatory change.

4. **During Dr. Robert Califf's confirmation hearing in the Senate HELP Committee he was asked about the status of finalizing the Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products labeling rule currently pending at FDA. In response to that question he said finalizing the rule was a "top priority" and added that "[FDA needs] to make sure that if there are problems with generic drugs that come up later, and they do, with better surveillance systems, that there's a way of making sure the labels are up-to-date and *consistent across similar products."* [emphasis added.] I believe the pending rule would require the generic company that identified the adverse event to unilaterally change their drug labeling information prior to the review and approval of the FDA, but would NOT require the remaining generic companies or the brand to change their labeling; thus, continuing to allow for all labels of similar products to not be consistent – and conflicting directly with the Hatch-Waxman statute requiring "sameness", thwarting the law's objectives, and imposing significant confusion and costs on patients. In light of your desire to assure consistency and timely updates of information across similar products – a goal I share with you – why do you believe this proposed rule is necessary?**

**Answer:** The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

Under current regulations, there is a difference between the brand and generic drug labeling during the period when FDA is reviewing a brand drug manufacturer's "changes being effected" or "CBE" supplement. Once FDA approves a change to the brand drug labeling, the generic drug manufacturer is required to revise its product labeling to conform to the approved labeling of the corresponding brand drug. FDA advises that this update should occur at the very earliest time possible; however, there may be a delay of varying lengths. The proposed rule, if finalized, would generally reduce the time in which all generic drug manufacturers make safety-related labeling changes by requiring conforming labeling changes within a 30-day timeframe.

5. **I am aware this proposed rule has been delayed 3 times. While I welcome those delays, the pharmaceutical industry deserves clarity on the Agency's intentions, especially in the closing months of this Administration. When will you make a final determination on whether to move forward with this rule?**

**Answer**: The Unified Agenda[11] currently lists an anticipated publication date of July 2016 for the final rule on "Supplemental Applications Proposing Labeling Changes for Approved Drugs

[11] Available at *http://www.reginfo.gov/public/do/eAgendaViewRule? pubId=201604&RIN=0910-AG94*

and Biological Products."[12] The dates for rules in the Unified Agenda are projected dates that may be adjusted to reflect ongoing work on specific rules.

6. **On January 22, 2014 Chairman Alexander and Chairman Upton lead a letter signed by twenty-eight House and Senate lawmakers noting grave concerns regarding the FDA's proposed rule on generic drug labeling, which would depart from more than two decades of established Hatch-Waxman "sameness standard" by allowing generic companies to unilaterally change their drug labeling information – conflicting directly with the Hatch-Waxman statute, thwarting the law's objectives, and imposing significant costs on health care consumers. Both in the proposed rule, and in the agency's response to this letter, the claim is made that the U.S. Supreme Court's 2011 decision in Pliva v. Mensing somehow "alters the incentives for generic drug manufacturers to comply with current requirements to conduct robust post-marketing surveillance" – but the agency's response letter contradicts that statement by noting that the proposed rule "neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive." It seems to me that the proposed rule is a solution in search of a problem. Does the FDA have any evidence or data to suggest that generic drug manufacturers are not complying with current reporting requirements? Has there been any reduction in adverse event reporting since the 2011 Supreme Court decision?**

**Answer:** The proposed rule focuses on the obligation to update labeling to reflect newly acquired information, not on the legal duties to report adverse drug events to FDA or more generally to meet postmarket surveillance requirements associated with adverse event reporting obligations. As the Agency has explained, the proposed rule neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive. FDA has received a great deal of public input from stakeholders during the comment period on this proposed rule.

- **In the agency's response to this letter signed by twenty-eight Senate and House lawmakers outlining our concerns with the FDA's misguided proposed rule on generic drug labeling, the claim is made that during its review of a generic manufacturer's labeling changes in a CBE-0 supplement, the FDA "would make an approval decision on proposed labeling changes for the generic drug and the corresponding brand drug at the same time" to ensure the sameness of the labels, but labels could potentially be different for an indeterminate period of time. I am concerned that this explanation assumes that the FDA would receive only a single labeling change, from a single generic manufacturer, at a time. But we could easily imagine a scenario where multiple generic manufacturers – out of an overabundance of caution under the uncertain and unpredictable regulatory and legal environment created by this rule – submit multiple, potentially contradictory labeling changes to FDA at different times. How would the agency handle multiple labeling changes, received from multiple different generic manufacturers? And wouldn't this scenario result in multiple, different labels for identical products over an extended period?**

[12] All responses are accurate as of February 24, 2016.

**Answer:** In the proposed rule, FDA considered the scenario in which generic drug manufacturers submit CBE-0 supplements with labeling changes that differ from each other and from the corresponding brand drug. FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment.

7. **In a Senate HELP letter to the FDA regarding the agency's generic drug labeling rule, the Committee raised concerns with the provision in the rule that creates a public website where proposed label changes would be published before FDA consideration, since it would undermine the FDA's current role as the gatekeeper and deciding authority for changes to a drug's label. I remain concerned that by publishing this information prematurely, without FDA approval, the rule could provide the public and health care providers with potentially inaccurate and misleading information. How can health care providers, and the public, have confidence in the accuracy of this information?**

**Answer:** FDA's current regulations permit certain labeling changes based on newly acquired information about an approved drug to be implemented upon receipt by FDA of a supplemental application that includes the change. These supplements are commonly referred to as "changes being effected" or "CBE" supplements. FDA allows drug manufacturers to communicate certain safety-related labeling changes upon receipt by FDA of a CBE supplement -- and prior to FDA approval of the proposed labeling change -- in the interest of public health. FDA carefully reviews any labeling change proposed in a CBE supplement, as well as the underlying information or data supporting the change, and FDA has the authority to accept, reject, or request modifications to the proposed changes as the Agency deems appropriate.

**<u>The Honorable Tim Murphy</u>**

1. **Section 223 of the Protecting Access to Medicare Act of 2014 creates a demonstration project for new Certified Community Behavioral Health Clinics and one of the requirements for these new outpatient mental health clinics is that they "improve availability of, access to, and participation in assisted outpatient mental health treatment in the State." Now that the planning grants have gone out, can you please detail how this their criteria was in the decision making process for awarding the grants under Section 223 of the Protecting Access to Medicare Act of 2014?**

**Answer:** Award of the planning grants was based on the requirements in the statute. As you know, Pennsylvania was one of the funded states. Planning grant requirements are to solicit input with respect to the development of such a demonstration program from patients, providers, and other stakeholders; certify clinics as certified community behavioral health clinics (CCBHC) for purposes of participating in a demonstration program; and establish a prospective payment system for mental health services furnished by a certified community behavioral health clinic participating in a demonstration program. Selection of states participating in the demonstration program will be prioritized based on State plans that best meet the requirements in the law.

2. **Section 224 of the Protecting Access to Medicare Act of 2014 establishes an Assisted Outpatient Treatment Grant Program For Individuals With Serious Mental Illness which was funded at the end of last year. Can you please provide an update on where the grants established under the stand in terms of being able to award the funds?**

**Answer:** The funding opportunity announcement will be issued this Spring, with an anticipated award date before the end of the fiscal year.

3. **When and how was the Common Data Platform (CDP) developed for the Substance Abuse and Mental Health Services Administration (SAMHSA)?**

**Answer:** Throughout the life of the contract, the CDP had several Contracting Officer Representatives (CORs) and Alternate CORs overseeing the contract implementation. These individuals were part of CBHSQ and reported up the chain of command to the CBHSQ Deputy and Center Director, who reported to the Office of the Administrator.

The oversight of the CDP project was done by SAMHSA personnel; however, as the CDP's technical difficulties became increasingly evident, aspects of the approach to rectify the situation, including the decision to shut down the system and procure a new contract, were overseen and monitored by personnel from the Department. In addition, staff from the Department provided assistance and oversight in developing the next procurement.

SAMHSA has taken steps to ensure a more comprehensive management approach. The new effort involves leadership across SAMHSA and is managed by a cross-Agency Governance Council comprising Deputies from all four Centers as well as the Office of Financial Resources.

4. **What was its intended purpose within the grants management system?**

**Answer:** The intended purpose of the Common Data Platform (CDP) was to enable SAMHSA to collect and report data uniformly across its non-formula-based grantees. The intention was to provide SAMHSA staff access to uniform reports by which to manage its grant programs as well as to provide staff and leadership access to aggregate information across SAMHSA's grant programs. The effort was also intended to ease grantee burden for those who had grants from multiple SAMHSA Centers.

**Please describe:**

5. **Under which legislative or regulatory authority were CDP-related funds allocated?**

**Answer:** CDP funding was appropriated under the statutory authorities Sections 501 and 505 of the Public Health Service Act, 42 U.S.C. 290aa and 42 U.S.C. 290aa-4. This funding is part of the Performance and Quality Information Systems funding line of Health Surveillance and Program Support.

6. **When and why the solicitation notice for CDP was developed and published?**

**Answer:** The CDP solicitation was published to procure a system for SAMHSA to provide access to uniform information, management reports, and data as described above. The solicitation, via a Request for Task Order Proposal, was issued on May 3, 2013.

**7. Which grant program(s) is/was CDP intended to support?**

**Answer:** CDP was intended to support SAMHSA's non formula-based grant portfolio across its three programmatic Centers.

**8. What were the specific deliverables and tasks required of the contractor in the CDP contract?**

**Answer:** The primary tasks and deliverables of the contract were the development and implementation of a real-time data entry and reporting system for the collection and reporting of SAMHSA discretionary grant data. Specific tasks included: management, reporting, existing data management and archival database work, development and implementation of common data collection and reporting system, training and TA, and transition services.

**9. What procedure(s) were used to develop and award this contract?**

**Answer**: SAMHSA issued the Request for Task Order Proposal using the NIH NITAAC CIO-SP3 Small Business vehicle. NITAAC is an OMB-authorized government-wide acquisition contract (GWAC) for IT acquisitions. Once proposals were received, offerors' proposals were rated using an objective Technical Evaluation Panel (TEP) of federal employees. The contract was awarded to the offeror with the highest technical score and the lowest bid.

**10. Which contractor won the bid and is/has administered CDP for SAMHSA grantees?**

**Answer:** ACE Info was the contractor who won the bid and administered SAMHSA's CDP.

**11. Have additional contracts or contractors been engaged to supplement the original process? If so, why?**

**Answer:** Other contracts were not engaged to supplement the original CDP. A corresponding contract to provide training and technical assistance was released at the time of the CDP and was part of the original process. No additional contracts were used to supplement the CDP during the system's operation.

**12. Who at SAMHSA is/was responsible for overseeing the CDP contract? Was there oversight by the HHS Secretary or other authorities other than SAMHSA personnel?**

**Answer:** Throughout the life of the contract, the CDP had several Contracting Officer Representatives (CORs) and Alternate CORs overseeing the contract implementation. These individuals were all part of CBHSQ and reported up the chain of command to the CBHSQ Deputy and Center Director, who reported to the Office of the Administrator.

In order to ensure a more comprehensive management approach, the new effort involves leadership across SAMHSA. The new effort is managed by a cross-Agency Governance Council comprising Deputies from all four Centers as well as the Office of Financial Resources.

The oversight of the CDP project was only done by SAMHSA personnel; however, as the CDP's technical difficulties became increasingly evident, all aspects of the approach to rectify the situation, including the decision to shut down the system and procure a new contract, were overseen and monitored by personnel from the Department. In addition, staff from the Department provided assistance and oversight in developing the next procurement.

**13. How many grantees (actual number and percentage of total) had significant problems using CDP to enter consumer data that they are legally required to collect and submit to SAMHSA during FY2015? How many phone calls, emails and letters were received by SAMHSA from grantees that were unable to use CDP to report required information?**

**Answer:** SAMHSA received over 450 grantee notifications of technical difficulties to a central SAMHSA mailbox. In addition to these contacts, GPOs across SAMHSA received numerous phone and email contacts for all grant portfolios reporting issues. Some grant portfolios, e.g. Addiction Technology Transfer Centers and Access to Recovery, opted to utilize a single point of contact to relay concerns directly to SAMHSA leadership on behalf of the entire grant program.

**14. Has SAMHSA communicated with grantees in a prompt and clear manner about resolving any data collection problems involving CDP and/or to provide alternative reporting methods?**

**Answer:** Yes, SAMHSA Project Officers were communicating regularly with grantees regarding CDP and issues grantees were having. SAMHSA leadership communicated formally with grantees in May, July, and October of 2015 alerting them to the status of the CDP and the plan to revert to legacy systems for reporting. All SAMHSA grantees are currently using legacy systems for reporting. SAMHSA has received no inquiries or concerns from grantees on these systems.

**15. After months of advising grantees to retrain their staff to use a previous "Legacy" data collection tools (in lieu of the CDP-compatible tool), why did SAMHSA wait until the day after SAMHSA's own deadline (wasting precious grantee resources) to rescind this instruction?**

**Answer:** SAMHSA has not rescinded its instruction for grantees to use a previous legacy data collection tool; SAMHSA grantees are currently using legacy tools on which they have all been trained.

**16. Were General Project Officers (GPOs) given sufficient information and support to assist Grantees who were unable to use CDP to report data that they are legally required to report?**

**Answer:** Project Officers were given initial training on the CDP; however, technical difficulties proved too great to enable GPOs to use the system effectively.

**17. Were GPOs or their supervisors admonished to limit communications with grantees complaining about CDP for extended periods of time? Why was a GPO or their supervisor criticized for thoughtfully writing to (assigned) grantees to mitigate confusion about the contingency plans and data collection tools SAMHSA suggested (and then reversed) when CDP became unusable?**

**Answer:** SAMHSA leadership was never made aware of any admonishment of GPOs for communicating about CDP. No guidance was ever given to supervisors or Center leadership to deliver such admonishment.

**18. Did SAMHSA relieve grantees of their legal reporting burden?**

**Answer:** Grantees were not relieved of any statutory or legal reporting burden. Grantees were required to continue official reporting such as continuation application, financial reports, and progress reports. Grantees were directed to continue to collect performance data for future submission once system issues were resolved.

**19. What specific outcome data has been developed from SAMHSA grantee data collected through CDP during FY 2015? How does the quantity and quality of SAMHSA's outcome data differ from the quantity and quantity of outcome data that was expected from grants? How much money has SAMHSA expended on CDP to date?**

**Answer:** FY 2015 outcome data were not available through the CDP. The data collected through the CDP were not usable for outcomes reporting. The quality of the data collected through the CDP differed greatly from the quality collected through previous legacy systems which contained automated validation and verification checks on the data. The CDP did not contain these automated checks. The total spent on the CDP from the inception of the contract through its completion was $10,558,388.

**20. How much money did SAMHSA spend in FY2015 trying to resolve CDP problems or (in efforts) to replace the CDP system? Did this money come from administrative or service program allocations? How were funds to fix or replace CDP identified, by whom, and were these approved by appropriate oversight authorities?**

**Answer:** SAMHSA spent an additional $1.8M for a modification to the ACE Info contract to attempt to resolve issues with the development and implementation of the CDP. In addition, SAMHSA spent $7.6M to restore the legacy systems to cover a critical gap and assure continued compliance with reporting. Funding for these activities was primarily generated from delayed implementation of various initiatives within the CBHSQ portfolio.

**21. Is each state that receives a Projects for Assistance in Transition from Homelessness (PATH) grants required to document what they had spent on services for their homeless citizens (with behavioral health problems) and submit documentation that the state had continued its spending level at the same or greater level that it had prior to**

**receiving this federal money, or in other words required to show a "maintenance of effort (MOE)"?**

**Answer:** Yes, states that receive a PATH grant are required to document what is spent on services, and submit an assurance that they are meeting the maintenance of effort requirement.

**22. How has SAMHSA instructed states to establish and submit documentation of their baseline spending levels and compliance with the PATH MOE?**

**Answer:** Since FY 2012, SAMHSA has been assessing state MOE compliance during the fiscal and programmatic site monitoring visits. If it is determined that a state has not adequately met the requirement, SAMHSA issues a required follow-up action statement in the site visit report. States who have received these statements are addressing the required corrective actions. Further guidance has been developed and will be issued to all states in summer 2016.

**23. How many states that received PATH funding submitted their baseline and yearly MOE documentation to SAMHSA? How many were required to do so by law? Has SAMHSA received requests from states for help in fulfilling this reporting obligation?**

**Answer:** There is no specific statutory requirement for states to provide baseline data. The submission of baseline data will be requested through the SAMHSA-developed MOE guidance once we share it with states. All states submitted signed assurances regarding MOE compliance. SAMHSA has received requests for technical support, and as indicated above, guidance is forthcoming.

**The Honorable Michael C. Burgess**

**The Office of Refugee Resettlement (ORR) is responsible for taking temporary custody of unaccompanied children crossing the border, and for placing them with a custodian capable of caring for them while immigration proceedings are underway. ORR officials have acknowledged that, in recent years, their office relaxed standards for background checks of potential sponsors. ORR only checks on children after they are placed with sponsors in a small number of cases. There have been reports of these children becoming victims of human trafficking, being neglected and abused, and being lost in the system forever. Over the course of several years I have had several meetings and asked very specific questions, but been unable to gain specific information from this Administration about the processes and policies in place to ensure it is not prioritizing volume over integrity in dealing with these children. In multiple meetings with ORR, and in a briefing to Committee staff, ORR has claimed that HHS has no statutory authority to take action to ensure the safety and wellbeing of a child post-placement, but ORR has failed to cite any statute limiting such authority. A February 11, 2016, letter sent by members of the Energy and Commerce Committee to the Secretary requested specific information to explain the Department's legal position by February 25, 2016—HHS has failed to provide such information. Please provide a response to the following questions:**

1. **On what grounds does HHS claim the Department has no statutory authority to ensure for the well-being of children after they are placed with sponsors? Please explain HHS's legal position. How is this position consistent with the Department's policy to follow up**

**with some unaccompanied children after they are placed with sponsors in limited cases? If HHS has no authority, which agency does? Has HHS discussed this issue with other agencies such as the Department of Justice or the Department of Homeland Security? Explain.**

**Answer**: HHS's longstanding view across administrations is that, under the authorities governing the Unaccompanied Children Program, once a child is released to a sponsor, ORR's legal and physical custody terminates. ORR's Unaccompanied Children Program is authorized by and operated in accordance with the Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) The program is also operated consistent with the *Flores Settlement Agreement*. The authorities and the resources given to the Unaccompanied Children Program in ORR establish a system that is intended to temporarily care for children while in our physical custody, and releasing children to appropriate sponsors as expeditiously as is safely possible.

But the fact that ORR's custody ends upon release does not mean that its commitment to providing resources, connecting children and sponsors to services, and protecting vulnerable children from abuse or exploitation ends. HHS has authorities that permit it to provide a range of services and resources after a child is released from the agency's custody, and it makes use of that authorization to establish policies and procedures that, among other things, are intended to protect those children that may be vulnerable to abuse or exploitation. ORR's ability to provide these services is hindered by the uncertainty of the total program needs compared to resources available. Budgeting for the unaccompanied children's program is particularly challenging for HHS because funding for the program is set at the beginning of the fiscal year, when the number of children who will require services and the timing of their referral to HHS is unknown. For these reasons, the President's FY 2017 Budget again proposes a contingency fund that would provide additional resources to serve unaccompanied children, if referrals exceeded what could be accommodated within existing resources. If enacted, the contingency fund would help ensure ORR had sufficient capacity to adjust to large and unpredictable fluctuations in need and more deliberately plan for all components of the program including post-release services.

Within its current authorities, ORR deploys its resources in order to provide post-release services as effectively as possible. ORR provides post release services for any child who received a home study on a case-by-case basis if it is determined the child has mental health or other needs.

In July 2015, ORR began a pilot project to provide post-release services to all unaccompanied children released to a non-relative or distant relative sponsor, as well as children whose placement has been disrupted or is at risk of disruption within 180 days of release and the child or sponsor has contacted ORR's hotline.

In May 2015, ORR expanded the capability of an existing telephone hotline, which had traditionally been used to help parents locate children in ORR custody. Now the hotline accepts calls from children with safety-related concerns, as well as from sponsors with concerns or who need assistance connecting to community resources. Every child released to a sponsor is given a card with the hotline's phone number on it (Spanish language access as well) and all providers and sponsors are also provided with the hotline phone number.

Starting last summer, care providers now call each household 30 days after the child is released from ORR care to check on the child's wellbeing and safety.

If any of ORR's provider grantees or staff has reason to believe that a child is unsafe, they comply with mandatory reporting laws, state licensing requirements, and federal laws and regulations for reporting to local child protective agencies and/or law enforcement.

2. **Section 218(b) of the Protecting Access to Medicare Act (PAMA) (PL-113-93) established criteria to mandate the consultation of appropriate use criteria (AUC) by ordering physicians prior to referring Medicare patients for select advanced diagnostic imaging services. This PAMA legislative policy, which passed the Congress with strong bipartisan and bicameral support, was scheduled to go into effect January 2017. This policy was intended to ensure proper utilization of advanced imaging studies based on clinical evidence, rather than merely burdening access with arbitrary restrictions. Despite the passage of PAMA AUC provisions, the Obama Administration's Fiscal Year 2017 Budget for the Department of Health and Human Services, once again, calls for the implementation of a Medicare prior authorization program. Can you please update the committee on the January 1, 2017 effective date for the PAMA imaging AUC policy? Will the agency meet the January 1, 2017 effective date by which ordering physicians must begin consulting imaging appropriateness criteria as a condition for Medicare payment? If the Agency will not be meeting the January 1, 2017 deadline, please explain why a delay is necessary, as well as when CMS expects to finalize implementing regulations?**

**Answer:** We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. The number of clinicians impacted by the scope of this program is significant, as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) rulemaking process, we will begin to identify priority clinical areas and expand them over time. We anticipate including further discussions and adopting polices regarding claims-based reporting requirements in the CY 2017 and CY 2018 PFS rulemaking cycles. Also, in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals. We recognize the importance of moving expeditiously as well as ensuring transparency and working with stakeholders to accomplish a fully implemented program.

**<u>The Honorable Leonard Lance</u>**

**Last August, the U.S. Court of Appeals for the D.C. Circuit issued a decision interpreting the Federal Vacancies Reform Act of 1998 that would prohibit various acting federal officers from serving in positions for which they have been nominated. The Department of Justice filed a petition seeking further review of the case by the entire D.C. Circuit, which**

**was subsequently denied. A *Washington Post* article covering this story quoted the Justice Department saying a recent D.C. Circuit court decision casts a "legal cloud" over a number of acting government officials. The Justice Department wrote "the service of approximately a dozen current acting officers would be subject to question under the panel's opinion, including senior officials in the Department … of Health and Human Services."**

1. **Have you been briefed, or have you asked for a briefing, about the impact of the court's decision on the Vacancies Reform Act on the actions of certain senior HHS acting officers? If not, will you ask for such a briefing? When?**

2. **Have you requested what changes will be made to be in compliance with the Vacancies Reform Act? If not, why not?**

**I'm particularly concerned about this as it relates to the Anti-deficiency Act. As you know, this Act prohibits federal employees from making or authorizing an expenditure from, or creating or authorizing an obligation under, any appropriation or fund in excess of the amount available in the appropriation or fund unless authorized by law.**

3. **According to a recent HHS financial audit "HHS's management determined that it may have potential violations of certain provisions of the Anti-Deficiency Act related to FY2014 and F2015 obligation of funds for conference spending and a potential violation related to the appointment of a presidentially-nominated official with the required information." Are you aware of these potential violations? Has any action been taken to address them?**

**Answer:** We are aware of both matters and I have discussed the Vacancies Reform Act with the Office of the General Counsel. On conference spending, the consolidated appropriations acts for each of FYs 2013- 2015 included a government-wide general provision that limited the availability of funds appropriated in those acts, or any other acts, for expenses of conference activities that are not in compliance with OMB's memorandum M-12-12, dated May 11, 2012; which requires that such expenses be approved by certain specified agency officials prior to use of funds for such purposes. HHS has worked intensively to assure compliance with those appropriations acts provisions that restrict the use of funds for conference expenses. Currently, the Department is reviewing the use of ACF's appropriations to award contracts for the performance of services in support of an ACF conference to determine if such obligations complied with the applicable appropriations acts provisions. With respect to the appointment of the agency official to which the audit referred, HHS is reviewing whether an HHS appropriation was used to pay for the services of an individual who was carrying out the responsibilities of a position that required Senate advice and consent after the second nomination for that individual was returned to the President in violation of a government-wide general provision that prohibits the use of appropriations for such purpose. We are committed to being responsible stewards of taxpayers' funds in these areas and across our programs.

**<u>The Honorable Brett Guthrie</u>**

**I am a cosponsor of Rep. Reichert's legislation, H.R. 2649, the Medicare Secondary Payer and Workers' Compensation Settlement agreements Act. This legislation includes**

**language to authorize payment of amounts for future medical in workers' compensation settlements to be paid directly to meet MSP future medical obligations. HHS included in its FY 2017 budget request a provision to enable CMS to accept sum certain payments to meet Medicare Secondary Payer obligations, which projects $63 million in savings over the budget period.**

1. **Would you please provide the data and assumptions used to determine the budget savings?**

2. **In addition, has CMS provided technical assistance regarding H.R. 2649 to Congressional supporters and stakeholders? If not, would you please work with Congressional supporters and stakeholders on this issue?**

**Answer:** CMS has received a request for technical assistance on this legislation, and would be happy to discuss further with your office.

**The Honorable Morgan Griffith**

**The Center for Medicare and Medicaid Innovation (CMMI) will be testing enhanced medication therapy management (MTM) models designed to find innovative approaches to MTM that will result in more efficient outreach and targeting of beneficiaries and create better alignment of program incentives.**

1. **Given the important role retail community pharmacies play in medication management, how does CMMI plan to ensure that there is robust community pharmacy participation in the enhance MTM models?**

**Answer:** CMS believes that pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use the prescription drugs upon which they rely. The Enhanced MTM model aligns financial incentives and grants flexibility for basic, stand-alone Prescription Drug Plans (PDPs) to test MTM interventions that could include increased reliance upon the pharmacist as a trusted community resource to ensure that targeted beneficiaries are taking their medications accurately and appropriately.

When announcing the model, CMS noted that it expects sponsors to rely more heavily on more personalized strategies, such as contacts from trusted community pharmacists or their medical providers, because in many cases these will be more effective than call-center or mail contacts from the PDP.

Moreover, CMS noted that it expects to see plan sponsors suggest protocols involving multi-pronged, proactive, and persistent efforts to make contact with Medicare beneficiaries and ensure their on-going participation and engagement, as well as use of diverse communication modalities such as person-to-person interactions, phone calls, and trusted community contacts and relationships (including community pharmacists and prescribers) to achieve significant engagement rates.

2. **Will the agency partner with Part D plans that propose to utilize retail pharmacies in their enhanced MTM model?**

**Answer:** CMS is granting basic, stand-alone PDPs the flexibility to design enhanced MTM programs that incorporate interventions beyond the standard MTM programs under Medicare. As a result, plans may propose an expanded range of MTM activities, including contracting with pharmacists to provide enhanced engagement or other services. Any financial compensation to pharmacists under this model would be provided by the participating PDP or contracted vendors, not CMS.

**3. Additionally, does CMS plan on using its authority to expand successful approaches to the entire Part D MTM program before the end of the five year testing period?**

**Answer:** Under statute, successful Innovation Center models can be expanded if they either reduce Medicare expenditures without reducing the quality of care or improve the quality of care without increasing expenditures. If the Enhanced MTM model proves successful and satisfies these criteria, it could potentially be expanded (including on a national basis) under this authority.

In addition to possible formal expansion, the results of this model could also be used to inform policy in other ways. Specifically, lessons from this model could inform potential changes to MTM policies and rules in integrated care models, or be adopted by other types of health plans, such as those in state Medicaid programs or exchange plans.

**In responses to Questions for the Record from testimony before the committee in July, Vikki Wachino, the head of the Centers for Medicaid and Chip Services (CMCS), claimed "the Secretary does not have the authority to permit a state to require Medicaid beneficiaries to work or receive job training because that is not an objective of Title 19." Yet, at the same time, CMS has approved federal funding under 1115 waivers for designated state health programs (DSHP) [or "DISH-pee"] that provide job training. For example, one funded DSHP provides pre-vocational services for individuals with disabilities to help prepare them for paid employment. CMS states that this promotes Medicaid program objectives because the services can lead to better outcomes for Medicaid and low-income individuals.**

**4. So, could you explain why you think CMS can fund pre-vocational services, but not approve required vocational engagement for the non-disabled population?**

**Answer:** Pre-vocational services for people with disabilities are a long-standing element of Medicaid's benefit package. They involve services supporting improved function, including both physical and cognitive therapies. Pre-vocational services are designed to facilitate the ability of individuals to attain and maintain competitive employment. As such, they should be provided for a time-limited period in which individuals with disabilities are given the skills necessary to seek employment according to their strengths and preferences, such as: effective communication with supervisors, colleagues and customers; workplace conduct; the ability to follow directions and complete tasks; and problem solving skills. Medicaid funds pre-vocational services primarily through the home and community-based waiver and state plan authorities. This is one example

of a way in which CMS promotes employment among Medicaid beneficiaries without requiring employment as a condition of Medicaid eligibility.

5. **Since CMS has denied several requests from governors to utilize work requirements for the non-disabled population, I assume CMS examined this issue in some legal depth. Can you share such analysis with the committee?**

**Answer:** In reviewing state proposals for section 1115 demonstration programs, CMS does consider encouraging work an important state objective and has worked with states to develop approaches that encourage work and job training participation. Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve demonstration projects only if they promote the objectives of the Medicaid and CHIP programs. However, requiring Medicaid beneficiaries to work or receive job training is not an objective of Title XIX. Consequently, 1115 demonstration programs may include services such as pre-vocational services that aim to promote the overall health of Medicaid beneficiaries involved, but Medicaid funding may not be used for work requirements or other work programs that have the primary goal of promoting work rather than promoting health. As noted earlier, the structure of the ACA is built on every American having a guarantee of access to affordable health insurance. We cannot condition that access on any requirement including work. I also noted earlier that we have approved demonstrations in which states promote employment through state programs outside of Medicaid.

6. **What do you make of the various studies that show how employment can help boost self-esteem, health, and lead to better outcomes for low-income individuals?**

**Answer:** Most Medicaid beneficiaries are employed or are in households where someone is working. In 2013, 79 percent of children who were Medicaid beneficiaries lived with at least one worker; 65 percent lived with at least one full-time worker. That year, 65 percent of adults with Medicaid were in a family with a worker; half were in a family with at least one full-time worker. Adults who qualify for Medicaid may be working but earning low wages and may not be able to afford private coverage. With Medicaid, such workers have health coverage and are likely to have a usual source of care, which helps them stay healthy and remain productive on the job. Such studies support section 1115 demonstrations including limited programs that help prepare beneficiaries for the workforce as a means of improving the health and wellbeing of those beneficiaries. This includes pro-vocational services for individuals with disabilities. The Medicaid program contains a number of incentives for beneficiaries to enter the workforce or to increase their hours.

Additionally, health coverage through Medicaid promotes individuals' health and ability to participate in the workforce. There are several examples of how Medicaid promotes employment: First, in the case of individuals with disabilities, Medicaid disregards a certain amount of earnings in determining their eligibility for benefits; this enables these individuals to retain their Medicaid coverage while working. Second, for individuals with serious mental illness, Medicaid can provide supportive employment services to help these individuals find and maintain employment. I also note that as a result of Congressional action on MACRA, Medicaid continues to provide up to one year of transitional coverage for individuals who lose cash assistance due to earnings from employment.

**The Honorable Gus Bilirakis**

**HHS's FY2015 financial audit noted that HHS management determined that it may have potential violations of certain provisions of the Anti-Deficiency Act related to Fiscal Year 2014 and Fiscal Year 2015 obligation of funds relating to conference spending, and a potential violation related to the appointment of a presidentially-nominated official without the required confirmation.**

**1. What conferences and what presidentially-nominated officials are in question?**

**Answer**: HHS is currently reviewing obligations incurred for expenses of the Administration for Children and Families' Community Economic Development Conferences. The appointment matter in question relates to payments that HHS made for services performed by the former Acting Director of the Indian Health Service that may have been in violation of section 749 of Pub. L. No. 111-8, div. D, title VII, 123 Stat. 680, 693 (2009).

**2. Has HHS actually determined if there was a violation?**

**Answer**: The Department is reviewing whether the obligations incurred for the ACF conferences violated provisions in the appropriations acts that restricted the use of appropriations for expenses of conference activities not in compliance with OMB M-12-12. The relevant appropriations act provisions require that the Deputy Secretary approve in advance any conference sponsored or hosted by the agency (or by other Federal or non-Federal entities) where the net conference expenses to be paid by agency will exceed $100,000. The Department plans to complete its review, and to the extent any violations are determined, it will issue the required reports. As to the appointment matter, the Department is in the process of finalizing its review.

**3. Can you provide more information about this potential violation?**

**Answer**: For the two conferences in question, HHS is investigating whether the amount of the obligations incurred or the amount of payments made exceed $100,000, and if so, whether ACF obtained the Deputy Secretary's approval prior to using its applicable appropriation for the conferences as required by the government-wide general provisions in the appropriations acts. For the appointment matter, section 749 of division D of Public Law 111-8 prohibits the use of appropriated funds to pay an individual to act in a position after that individual's nomination to that position had been withdrawn or returned twice. As soon as HHS learned there was a potential problem, the former Acting Director of the Indian Health Service was reassigned.

**The Honorable Renee Ellmers**

**1. As a nurse, I am committed to our seniors having a strong Medicare Advantage program. Today, encounter data by Medicare Advantage plans includes information on beneficiary diagnoses and medical services received, similar to fee-for-service claims data. These encounter data are reported to CMS, and beginning with CY 2016 are used to determine Medicare Advantage enrollee risk scores for the purpose of risk adjusting plan payments. Currently, CMS calculates risk scores using a blend that includes 10%**

**encounter data. However, in the 2017 Advanced Notice which came out Friday, CMS proposes to increase this amount to 50%. Although plans have been collecting and reporting encounter data to CMS since 2012, ongoing operational issues have prevented plans from submitting accurate data in a timely fashion to CMS and receiving data back from CMS necessary to understand how their enrollee risk scores will be impacted. How does CMS propose to implement such sweeping changes to the data sources used to calculate enrollee risk scores before resolving the slew of operational issues faced by the Agency in both data collection and reporting?**

**Answer:** I appreciate your feedback and know that CMS understands the challenges regarding the use of encounter data for risk adjustment. CMS has been and continues to work in good faith with plans and other stakeholders on technical and operational issues to address encounter data acceptance, completeness, and quality. CMS is also working closely with health plans to respond to their questions and make changes, where needed, to address the issues cited. CMS's goal is to transition entirely from using diagnoses submitted to Risk Adjustment Processing System (RAPS) to using diagnoses from encounter data, and CMS intends to continue transitioning away from a reliance on RAPS data for calculating risk scores

Encounter data submission rates have steadily increased while error rates have steadily decreased. CMS expects this trend to continue to improve as more experience is gained and for the data to stabilize by the time this blend would be in effect.

2. **The need for our country to be better prepared against biological threats is clear and has been recognized by this Committee and many policy experts, including the recent Blue Ribbon Study Panel on Biodefense. This need follows numerous failures to deal adequately with a series of recent global health threats: both naturally occurring, including the H1N1 and H5N1 influenza pandemics, SARS, Ebola and now Zika; and bioterrorist threats like anthrax and smallpox. There is no reason to expect these threats will subside. Each of these threats provoked emergency actions and an accelerated response from many stakeholders, often in an uncoordinated way. In all cases, the response required massive efforts from the private sector racing against the clock. This scramble was often highly disruptive, and required companies to stop ongoing research and development programs, as well as manufacturing. This situation is sub-optimal and unsustainable. An alternative platform-based approach could allow for more timely readiness when a threat arises. It is my understanding that vaccine platform technologies could now be called upon to quickly develop a Zika vaccine and in general respond more expeditiously to the next outbreak or threat. What is BARDA/HHS doing to support and facilitate platform-based technologies against known and emerging threats?**

**Answer:** ASPR/BARDA has made it a high priority to support advanced development and implementation of platform-based technologies to more rapidly and efficiently develop vaccines for existing and newly emerging threats. As part of its long-term strategy, ASPR has targeted investment in flexible and nimble capabilities designed to meet novel challenges like those posed by Ebola and now Zika. Specifically in response to current challenges, in October 2015, ASPR/BARDA issued a Board Agency Announcement in support of medical countermeasures platform development. ASPR/BARDA has engaged extensively with the private sector in the

area of platform-based technologies and is currently reviewing proposals that will utilize these approaches to develop Zika vaccine candidates as well as to make these platforms available to respond to other existing or emerging threats.

3. **One of the most urgent and predictable threats we face as a nation is pandemic influenza. As you know, the 2009 H1N1 pandemic, a relatively mild pandemic, killed 18,000 Americans and sickened 600,000 more. Pandemic influenza is not just a public health threat, it is indeed a national security threat. But unfortunately, preparedness against pandemic flu threats has been largely episodic since 2009. The vast majority of funding provided to HHS for pandemic flu was in emergency supplemental legislation during an outbreak. Since that time, sustained resources for HHS' pandemic flu readiness programs have dramatically declined. This has led to an aging stockpile that HHS has demonstrated doesn't match currently circulating strains, domestic manufacturing capabilities that must be sustained, and private sector partners who see waning a commitment and aren't sure if HHS is committed to this partnership that so critical to our readiness. We need to be prepared for the next pandemic BEFORE it happens. Do you believe HHS is ready to handle another outbreak like H1N1 despite dramatic decreases in pan flu preparedness budgets? What steps are you taking to improve HHS' pandemic influenza preparedness programs?**

**Answer:** HHS has made significant investments and progress toward pandemic preparedness, including the build out of critical infrastructure that will provide significant increases in the production capacity of influenza vaccine needed to respond to a pandemic outbreak. HHS has also supported the development and licensure of new influenza vaccines, including cell-based, recombinant and adjuvanted vaccines that will allow us to respond more quickly with a diversified portfolio of available vaccines in the event of a pandemic. HHS is continually exploring and implementing strategies to ensure that the USG will be able to respond to a pandemic outbreak. These strategies include the implementation of the established Centers for Innovation in Advanced Development and Manufacturing (CIADMs) as well as the Fill Finish Manufacturing Network (FFMN) as part of the National Medical Countermeasure Response Infrastructure (NMRI). These CIADMs and the FFMN offer flexible and nimble approaches that include surge capabilities to address urgent vaccine needs in the event of a pandemic.

ASPR/BARDA has a Broad Agency Announcement open solicitation for the advanced development of medical countermeasures for pandemic influenza. This solicitation supports the advanced development of pandemic influenza medical countermeasures including personal protective equipment and ventilators, influenza test systems and diagnostic tools, therapeutics and vaccines.

HHS is working closely with industry partners to develop and evaluate improved influenza vaccines with universal potential. These improved influenza vaccines will be broadly cross-protective and elicit longer, more durable immune responses as compared to existing influenza vaccines.

4. **HHS' efforts to prepare for and respond to pandemic flu are unclear, unorganized, and underfunded. I am disappointed that your 2017 budget request does not address these problems. Let me read you a quote from last year's budget where you said: "[The**

**current funding level of $72 million] impedes HHS' ability to maintain existing programs for pre-pandemic influenza vaccine stockpiling and development of influenza antiviral drugs and immunotherapeutics, which are central programs to address critical vulnerabilities for U.S. pandemic preparedness." Given that nothing has changed since last year, can you describe how our preparedness against pandemic influenza has suffered as a result? What are you doing to ensure HHS sustains readiness efforts against this threat?**

**Answer:** The FY17 Budget requests an increase of +53 million, for a total of $125 million to support activities to address pandemic influenza threats. These activities include the advanced development of new vaccines and therapeutics, international collaboration and capacity building, stockpiling of existing medical countermeasures, and vaccine manufacturing improvements. We appreciate the support that has been provided to develop new influenza vaccines, therapeutics, diagnostics and other medical countermeasures needed to address a pandemic influenza outbreak. We have made significant investments and progress toward pandemic preparedness, including the development of critical infrastructure that provides a significant increase in the production capacity of vaccine needed to respond to a pandemic outbreak. HHS has prioritized the development to licensure of new influenza vaccines, including cell-based, recombinant and adjuvanted vaccines that will allow us to respond more quickly with a diversified portfolio of available vaccines in the event of a pandemic. HHS has also supported the advanced development of new influenza diagnostics, antiviral drugs, ventilators and personal protective equipment.

HHS has expanded our stockpile program to include vaccines that will generate immunity to avian influenza viruses that are perceived to pose the greatest risk to humans. This is determined by a USG interagency review of emerging viruses with pandemic risk, through the implementation of the Influenza Risk Assessment Tool. In addition, to address the material in the stockpile that has been in long-term storage, HHS has and continues to conduct clinical studies to assess the safe and effective use of these vaccines should they be needed to respond to a pandemic outbreak. These clinical data are compiled with additional analytical data on the long-term stability of the stored vaccines. HHS has determined that influenza vaccines and adjuvants stored in the stockpile remain stable, safe and immunogenic beyond what was originally anticipated from prior limited data; therefore extra funding is not currently needed to replace these vaccines and adjuvants. We thank you for your interest in this critical issue, and recognizing we still have much work to do, look forward to working with you to build on this progress as we move forward.

5. **Larry Summers recently said that global security for infectious diseases outbreaks is an area where the "urgent has crowded out the profoundly important." By this he means that we shouldn't let the threat of the moment – whether it be Ebola or Zika – overshadow our efforts to prepare against more predictable threats like pandemic influenza. As you know, the 2009 H1N1 pandemic killed 18,000 Americans and sickened 600,000 more. Pandemic influenza is not just a public health threat, it is indeed a national security threat. What are you doing to ensure the threat of pandemic influenza continues to be addressed in the midst of the urgent demands of the Zika outbreak and ongoing Ebola and MERs outbreak efforts?**

**Answer:** HHS is committed and dedicated to sustaining the level of pandemic preparedness and readiness that has been built to respond quickly in the event of a pandemic influenza outbreak. This includes the sustainment of: critical infrastructure to produce and manufacture available influenza vaccines; a National Pre-pandemic Influenza Vaccine Stockpile that contains vaccine and adjuvant to meet requirements as set out in the HHS Pandemic Influenza Plan; the National Medical Countermeasure Response Infrastructure that includes flexible manufacturing capabilities; clinical, non-clinical, and regulatory support for rapid surge response capabilities; and other core capabilities needed to respond to a novel infectious disease. I am personally briefed on this topic, even as I continue my extensive involvement in our response to the Zika virus and other critical issues.

6. **Public Health England - England's Center for Disease Control and Prevention - is taking the assertive stance that e-cigarettes are hugely less harmful than combustible cigarettes. In fact, Public Health England estimates that e-cigarettes are 95% less risky than combustible cigarettes. Public Health England thinks that it is critical for adult smokers to know this and consider shifting away from burning cigarettes. Do you share Public Health England's view? Do you think it would be appropriate for FDA to prepare and implement a similar program to tell current adult smokers that the health risks associated with smoke-free tobacco products, specifically e-cigarettes or electronic nicotine delivery systems, are significantly lower than the risks associated with cigarette smoking? Broadly speaking, what is your agency doing to encourage smokers who will not quit to move to less harmful forms of nicotine?**

**Answer**: Much remains to be learned about the health risks or benefits of e-cigarettes. They could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. On the other hand, e-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective products (such as exploding batteries). Anecdotes illustrating both benefits and harms abound, but it is definitive scientific evidence that should drive the actions taken with respect to e-cigarettes.

It is important to be aware that there are notable differences between the U.K. and the U.S. e-cigarette marketplace. These include the sharp increase in youth usage of e-cigarettes in the United States.

The 2015 National Youth Tobacco Survey found that between 2011 and 2015, current e-cigarette use among high school students increased nearly 900 percent. This sharp increase in youth usage in the United States is of great concern. While youth usage in the U.K. has gone up, it hasn't gone up 900 percent.

FDA is tasked with understanding the population level impact of e-cigarettes, which includes an assessment of the potential benefits and potential harms of e-cigarettes. FDA is committed to using an evidence-based approach in applying the principles of harm reduction to tobacco

regulatory policy. Pre-market review of new tobacco products is one of FDA's core consumer protection responsibilities. Scientific evidence may demonstrate that certain products are less harmful than others at an individual level, but under the law FDA must also take into account the impact of the products on the health of the population as a whole, including both users and non-users of tobacco products, in making regulatory decisions about these products.

**The Honorable Susan Brooks**

**Secretary Burwell, as you know, Congress created Project BioShield's Special Reserve Fund (SRF) in 2004 for material threats and over the last decade, SRF funds have been used to stockpile millions of doses of drugs and vaccines against threats like anthrax, smallpox, nuclear radiation – and hopefully soon against Ebola and Zika.**

**HHS released a budget last year for the SRF where you planned to procure over $870 million in medical countermeasures in 2017. Yet this year's budget request only asks Congress for $350 million, about 40% of this amount. This request would decimate Project BioShield and our nation's preparedness against numerous biological threats and is actually in direct contradiction with your previous MCM plans.**

1. **Do you understand the tremendous uncertainty you've created for your private sector partners by asking Congress to gut Project BioShield?**

2. **Which MCM projects are you planning to scrap if Congress reduces funding for the SRF?**

3. **What threats will we fail to be prepared for as a result?**

**Answer:** Project BioShield represents the government's commitment to industry that a market will exist for medical countermeasures targeted against agents for which Material Threat Determinations (MTDs) have been issued. Because most of these agents do not produce disease in civilian populations under normal circumstances, many of the medical countermeasures directed against them have no or next to no commercial market. HHS understands the importance of the Project BioShield commitment and the uncertainty that may be caused by fluctuations in the annual appropriation provided by Congress.

The FY 2017 President's Budget will enable us to make meaningful progress on vital medical countermeasure procurements. Unlike a grant or research program that supports a steady and recurring level of effort, the Project BioShield budget is made up of a different set of discrete procurements in any given year when medical countermeasures are mature enough in development to meet FDA requirements for accessibility under Emergency Use Authorization. In FY 2017 the new resources will enable the Department to procure several new chemical, biological, radiological and nuclear medical countermeasures, including:

- New Ebola vaccines and immunotherapeutics for the prevention and treatment of Ebola infections;
- New high throughput biodosimetry devices to measure internal radiation exposure following a detonation;

- New antibiotics for the treatment of bacterial biothreats and high priority antimicrobial resistant bacteria;
- New diagnostics for the detection of anthrax in exposed persons; and
- Replenishment of anti-neutropenia cytokines for the treatment of radiation-induced blood illnesses.

At this time, ASPR is not planning to eliminate any medical countermeasure acquisition programs as a result of the reduced request. ASPR is currently working with the Department of Homeland Security to refresh the Material Threat Assessments (MTAs) and medical consequence modeling that inform HHS's medical countermeasure requirements and acquisition targets. The new requirements will incorporate: 1) updated threat information, including a range of plausible scenarios identified in the new Anthrax MTA, 2) revised public health and medical consequence assessments, 3) consideration of desired MCM product characteristics, and 4) assessment of the national ability to effectively use anthrax MCMs in an emergency. These updated requirements, and the acquisition targets stemming from them, will be incorporated into research and development funding priorities and procurement decisions, including the 2016 Strategic National Stockpile (SNS) Annual Review (which will inform sustainment and procurement decisions for the SNS as early as FY17). The revised MTA process underscores the fact that preparedness represents a spectrum; there are few threats for which we are fully prepared and none for which we are entirely unprepared. The challenge the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) faces, given the inevitable funding constraints, is to allocate resources in a way that provides the greatest degree of preparedness against the greatest range of threats.

ASPR and the PHEMCE are committed to maintaining our national preparedness and making sure that medical countermeasures are available when needed. Maintaining stockpiles of medical countermeasures typically entails large procurement costs and is associated with substantial carrying costs. In an era of constrained resources, BARDA and its PHEMCE partners are mindful of the need to meet established requirements, sustain preparedness, and be good stewards of the taxpayers' investments. To this end, the PHEMCE is currently working to refresh the material threat assessments that form the foundation for our requirements, many of which have not been reassessed in years. ASPR, for its part, emphasizes innovative approaches to total lifecycle cost-containment and strives to decrease the long-term costs of stockpiling medical countermeasures.

**Secretary Burwell, just last week our colleagues on the Appropriations Committee sent a letter to the Office of Management Budget in response to the Zika virus funding request for $1.8 billion. The letter specifically spells out the fact that $1.4 billion is unobligated at HHS and $1.031 billion is unobligated at CDC.**

**4. Can you please expand on what funds are currently available for the Zika response?**

**Answer:** The Administration is committed to taking necessary steps, as quickly as possible, to protect the American people from the Zika virus. On February 23, HHS notified Congress of our plans to transfer and reprogram a total of up to $50 million in Fiscal Year 2016 resources within the Centers for Disease Control and Prevention for immediate Zika response needs. This included up to $5.75 transferred from the Strategic National Stockpile (SNS) and up to $44.25

million re-programmed from the Public Health and Emergency Preparedness (PHEP) Cooperative Agreement.

Without reimbursement, the $5.75 million reduction of SNS will result in decreased acquisition of 20,000 vials of anthrax vaccine that would be used to treat or provide prophylaxis to 67,000 individuals exposed to anthrax. The $44.25 million reduction of PHEP will result in reduced preparedness awards to states and cities.

In addition, CDC is making available $18 million in unobligated balances from the Public Health Prevention Fund for Zika control efforts, primarily in Puerto Rico.

But, these repurposed funds are not enough. They only allow us to address the most immediate needs until Congress acts on the Administration's supplemental request. Emergency supplemental funding continues to be urgently needed for a robust and complete response to the Zika virus.[13]

**5. Do you need Congress to legislate to allow for the flexible use of these unobligated funds from HHS? Please elaborate on how these funds are currently being used.**

**Answer:** The repurposed funds referenced above are being used for initial activities in the areas of mosquito control, surveillance, lab capacity, development of diagnostics and vaccines, and time-sensitive research activities.

HHS currently has the flexibility needed to use these funds as indicated above. However, there are not sufficient funds to support the full range of activities needed to prevent, detect, and respond to further transmission of the Zika virus; and additional authorities requested in the Administration's supplemental request are needed to ensure the most effective response, including:

1) The ability to add products purchased with the supplemental funds to the Strategic National Stockpile;
2) Overseas auto purchase and insurance authority to allow supplemental funds to be used overseas for car purchase and usage;
3) Flexibility to avoid burdensome matching requirements on grantees related to mosquito control;
4) Construction authority for grantees to allow state and local health departments and other grantees to use funds for facilities that may be necessary to Zika response and prevention, such as laboratory facilities; and
5) Funding transfer authority to allow CDC to move supplemental funds across CDC accounts to be able to more quickly respond to health security issues.

In addition, several General Provisions also support CDC's response:

[13] All responses accurate as of February 24, 2016.

- **Expanded overseas facilities authority**: This proposal would allow CDC to "acquire, lease, construct, alter, renovate, equip, furnish, or manage facilities" overseas without having to send payments through the Department of State.
- **Hiring authorities**:
    a. Personal service contracts: This authority would authorize CDC to use personal service contracts for response staffing. Although this authority has already existed globally, it does not currently exist domestically. People working under personal service contracts would NOT be Federal Government workers.
    b. Direct hire authority: This authority would allow expedited hiring authority for emergency positions.
- **Reimbursement authority**: This authority will allow CDC to use emergency funds to backfill transfers and reprogramming used before supplemental funds were available.

**The FY17 budget request proposes to combat opioid abuse by providing significant new resources to the Substance Abuse and Mental Health Services Administration (SAMSHA) within HHS. However, the request includes a $16.9 million reduction to the Screening, Brief Intervention and Referral to Treatment (SBIRT) program – from $46.9 million in FY16 to $30 million in the FY17 request.**

**The SBIRT program helps reduce the number of individuals who misuse drugs and alcohol and intervenes early to ensure individuals improve their health and overall quality of life. The Indiana University School of Medicine (IUSM)'s SBIRT Medical Residency Program, funded by SAMHSA through its SBIRT program, plays a key role in educating future physicians about problematic substance abuse.**

**6. Why does your agency propose to cut the SBIRT program at a time when these funds are in such drastic need by medical schools throughout the nation?**

**Answer**: Programs of Regional and National Significance, which includes the Screening, Brief Intervention and Referral to Treatment (SBIRT) program, are intended to be test new and innovative approaches. The SBIRT program has been proven to be a successful model, and states therefore can use Substance Abuse and Prevention Block Grant funding to support these services. Lessons learned from these efforts will be used by SAMHSA to develop an implementation package for SBIRT to encourage its development and sustainability across healthcare settings.

**7. How will SAMSHA absorb the proposed reduction?**

**Answer**: The President's Budget request for the SBIRT program will serve 145,000 individuals in FY 2017, and continues support for all existing grants. Given SBIRT's proven success, SAMHSA will continue to encourage its implementation and sustainability across healthcare settings.

**The President's budget request includes a ten percent cut to Indirect Medical Education—amounting to $17.8 billion in cuts over the ten-year budget window. Many academic medical centers, like Indiana University Health in Indiana, already fund residency slots beyond the amounts reimbursed by Graduate Medical Education, and bear the additional**

**costs associated with educating the future doctors my state and our nation need to meet the growing demand for health care providers.**

8. **How can the ten percent cut to IME be anything but contradictory to the administrations stated goal to increase access to care?**

**Answer**: HHS recognizes the importance of graduate medical education and indirect medical education funding. Nonetheless, like any other category of Medicare spending, payments to teaching hospitals must be justified by incurred costs. This proposal in the President's Budget will help graduate medical education programs promote high quality primary care services that address relevant public health needs by allowing the Secretary to target funding to training activities most effectively. HHS believes this proposal brings these payments closer to the appropriate level and provides incentives for promoting high-quality primary care.

In addition, the Teaching Health Center Graduate Medical Education (THCGME) Program provides funding for residency training in primary care medicine and dentistry in community-based, ambulatory settings. The THCGME Program seeks to not only bolster the primary care workforce through support for new and expanded primary care and dental residency programs, but also to improve the distribution of this workforce into needed areas through emphasis on underserved communities and populations. The FY 2017 Budget includes $60 million in funding appropriated in MACRA, and an additional $527 million over FYs 2018-2020 to support up to 876 residents.

**The Honorable Chris Collins**

1. **With the recent release of the final rule on Medicaid Covered Outpatient Drugs, CMS has altered pharmacy reimbursement through newly formulated Federal Upper Limits and the use of Average Acquisition Cost-based reimbursement. How will CMS ensure that Medicaid patients continue to have access to their critical pharmacy services under the provisions of this final rule? I have heard concerns about how the President's budget proposal seeks to calculate Federal Upper Limits based only on generic drug prices, thereby jeopardizing fair and adequate pharmacy reimbursement. How will CMS address these concerns?**

**Answer:** We expect Medicaid beneficiaries will benefit from the finalized provisions of the Medicaid Covered Outpatient Drug regulations, which are designed to help control drug costs and ensure adequate pharmacy reimbursement through the transition to a pharmacy reimbursement system based on an actual acquisition cost (AAC) and a professional dispensing fee. These changes will provide adequate reimbursement to pharmacies, as states are required to calculate reimbursement prices based on the prices actually paid by pharmacy providers. Further, CMS affords the states the flexibility to adjust their professional dispensing fees, when necessary, to assure sufficient access.

When states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, they are required to ensure that total reimbursement to the pharmacy provider complies with the statute. They must provide adequate data such as a state or national survey of retail pharmacy providers, or other reliable data other than a survey, to

support any proposed changes to either or both of the components of the reimbursement methodology. Prior to the publication of the final rule with comment, many states were already basing their ingredient cost reimbursement on an AAC methodology without causing pharmacies to leave the Medicaid program or having other adverse effects on patient care.

With respect to the calculation of the Federal Upper Limits (FULs), CMS uses the most current monthly National Average Drug Acquisition Cost (NADAC) data that we collect, and compare this data to the FULs calculated at 175 percent of the weighted average of average manufacture prices. In situations where that FUL amount is less than the NADAC, CMS establishes the FUL using a higher multiplier so that the FUL amount equals the NADAC. This ensures that pharmacy providers have an upper limit reimbursement that is benchmarked to an acquisition cost.

The President's budget proposal would exclude innovator multiple source drugs from the calculation of the FUL. The FULs should only be calculated using non innovator multiple source drug prices. Including the brand name drug (innovator multiple source drug) in the weighted average unduly inflates the FUL since the brand name drug is usually significantly more expensive than the generic equivalents. The FUL price also does not apply to the brand name drug, as it is obtained through a brand medically necessary override, and then paid at the state payment rate for non-FUL drugs. Clarifying that only the non-innovator multiple source drugs will be used in the calculation of the FUL provides reasonable reimbursement to pharmacies while ensuring that the FUL remains cost efficient. In addition, to encourage the use of generic drugs, states can pay pharmacies a higher dispensing fee for generic drugs than for brand name drugs.

2. **The Center for Medicare and Medicaid Innovation (CMMI) will be testing enhanced medication therapy management (MTM) models designed to find innovative approaches to MTM that will result in more efficient outreach and targeting of beneficiaries and create better alignment of program incentives. Given the important role retail community pharmacies play in medication management, how does CMMI plan to ensure that there is robust community pharmacy participation in the enhance MTM models? Will the agency partner with Part D plans that propose to utilize retail pharmacies in their enhanced MTM model? Additionally, does CMS plan on using its authority to expand successful approaches to the entire Part D MTM program before the end of the five year testing period?**

**Answer:** CMS believes that pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use the prescription drugs upon which they rely. The Enhanced MTM model aligns financial incentives and grants flexibility for basic, stand-alone PDPs to test MTM interventions that could include increased reliance upon the pharmacist as a trusted community resource to ensure that targeted beneficiaries are taking their medications accurately and appropriately.

When announcing the model, CMS noted that it expects sponsors to rely more heavily on more personalized strategies, such as contacts from trusted community pharmacists or their medical providers, because in many cases these will be more effective than call-center or mail contacts from the PDP.

Moreover, CMS noted that it would expect to see plan sponsors suggest protocols involving multi-pronged, proactive, and persistent efforts to make contact with Medicare beneficiaries and ensure their on-going participation and engagement, as well as use of diverse communication modalities such as person-to-person interactions, phone calls, and trusted community contacts and relationships (including community pharmacists and prescribers) to achieve significant engagement rates.

CMS is granting basic, stand-alone PDPs the flexibility to design enhanced MTM programs that incorporate interventions beyond the standard MTM programs under Medicare. As a result, plans may propose an expanded range of MTM activities, including contracting with pharmacists to provide enhanced engagement or other services. Any financial compensation to pharmacists under this model would be provided by the participating PDP or contracted vendors, not CMS.

Under statute, successful Innovation Center models can be expanded if they either reduce Medicare expenditures without reducing the quality of care or improve the quality of care without increasing expenditures. If the Enhanced MTM model proves successful and satisfies these criteria, it could potentially be expanded (including on a national basis) under this authority.

In addition to possible formal expansion, the results of this model could also be used to inform policy in other ways. Specifically, lessons from this model could inform potential changes to MTM policies and rules in integrated care models, or be adopted by other types of health plans, such as those in state Medicaid programs or exchange plans.

**The Affordable Care Act provided for the establishment of CO-OPs, which were to be non-profit health insurers to compete with private insurers. At the beginning of the program, the federal government spent $2.4 billion on 23 CO-OPs. One of these CO-OPs was Health Republic in New York, which officially failed in November of last year, costing taxpayers over $265 million.**

**Immediately following the failure, the Oversight Subcommittee and I contacted the HHS Office of Inspector General as well as your office in order to obtain the documents your office used 1) to approve Health Republic as a CO-OP in the first place and 2) to approve an additional $91 million grant to Health Republic after it lost $35 million its first year. Your office has provided the first of these documents, but not the second.**

**3. When will you provide my office and the committee the report HHS used as a basis to grant Health Republic additional funds?**

**Answer:** My staff is happy to work with your staff on this request.

**4. Why was Health Republic not put on a corrective plan like other failing CO-OPs, even though it had wasted more taxpayer than other CO-OPs?**

**Answer:** CMS did not issue a corrective action plan to New York prior to the decision to wind down the CO-OP. However, CMS regularly uses enhanced oversight plans (EOPs) and

corrective action plans (CAPs) as part of our CO-OP monitoring and oversight process, as laid out in the CO-OP loan agreements and recommended by the HHS OIG. CMS places a CO-OP on an EOP or CAP when it identifies an issue that can be resolved through corrective action.

CMS ordered an independent audit of Health Republic in summer 2015 based on early warning signs about the CO-OP's finances. This independent auditor found higher losses than the CO-OP had expected or projected in its financial reporting to CMS. In this case, the financial problems confronting Health Republic appeared to be too severe to address or correct through a CAP. In the interests of consumers and taxpayers, CMS worked with the State Department of Financial Services, which is the primary insurance regulator, to wind down the CO-OP and to ensure that consumers would have coverage through the end of the year.

**Madam Secretary, I understand that on January 15, the World Health Organization (WHO) issued draft "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children." The guidance proposes to establish significant new restrictions and prohibitions on the promotion and marketing of milk products for young children up to three years of age without providing any evidence, scientific substantiation or an impact analysis to justify the measures. I don't understand the logic of these recommendations, as we continue to hear that milk and milk products are good for our health, most recently in HHS' own Dietary Guidelines which note that a healthy eating pattern includes fat-free or low free-free dairy, including milk, yogurt, cheese, and/or fortified soy beverages. The HHS guidelines apply to individuals age 2 and older. The WHO also appears to contradict the nutritious food provided to children under three in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).**

5. **Does HHS support these WHO draft guidelines? Why?**

6. **What is HHS's role in influencing WHO in this process?**

7. **How can we work together to ensure the WHO is developing science-based guidance to prevent unintended negative health consequences for young children and potentially violate World Trade Organization (WTO) trade rules, including imposing restrictions on the use of intellectual property by brand owners?**

**Answer:** As requested by Member States through a 2012 World Health Assembly (WHA) resolution, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children, and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting breastfeeding and supporting appropriate and timely complementary child feeding during the first three years of life, a critical window for health and nutrition outcomes. The voluntary guidance is a technical document, which is not subject to negotiation by Member States, and is not binding on Member States or on other actors.

The draft guidance does not seek to prohibit the marketing of all milk products consumed by young children or to limit product availability. The guidance aims to complement, not replace, domestic and global recommendations for feeding infants and young children, including the WHO Code of Marketing of Breast-milk Substitutes and current recommendations on feeding

breastfed and non-breastfed infants and young children. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comments.

HHS is leading a process to solicit input from relevant federal agencies and prepare a technical comment submission to WHO. HHS also met, individually and with other agencies, with multiple stakeholders on the matter. HHS will transmit comments and discuss them with WHO's Nutrition Department, conveying that revisions are needed to present countries with clear, evidence-based recommendations. We will continue to follow the issue closely as WHO revises the draft guidance for Member State consideration, and will discuss WHO's revised document, when available, with other agencies and with impacted stakeholders.[14]

**The Honorable Gene Green**

1. **Have the monies allocated by Congress in 2013 and in 2014 been fully released to the FDA when the BsUFA user fee trigger of $20 million was reached in 2015? I appreciate that the 2015 funding was released to the FDA, and also understand that the 2013 and 2014 allocations were carried over to the next budget when the trigger amount was not reached in those years. Please explain the current status of these funds.**

**Answer:** The BsUFA program has met its spending trigger for all three years. Any funds not expended remain available to FDA and have been rolled over into the new fiscal year as carryover. Those funds will be used to support the process for the review of biosimilar biological product applications in the current or a future fiscal year.

2. **How much money is currently allotted for vector control in the United States? Given the challenges with vector control, how much new money is needed for vector control? What percentage of this funding should be set aside innovative techniques, as opposed to older chemicals, which you have said are not very effective, to suppress the Aedes Aegypti mosquito?**

**Answer:** As many of these resources are from local and state sources, it is difficult to estimate the total funds available for vector control across the nation. CDC has issued Zika vector control guidelines based on the principle of Integrated Vector Management (IVM). IVM principles include approaching mosquito control through careful planning, using a variety of interventions targeting both larval and adult mosquito control, and including both chemical and non-chemical methods. Properly planned and executed, IVM ensures a more effective level of control than can be achieved by one single approach.

[14] All responses accurate as of February 24, 2016.

With supplemental funds, CDC-supported investments in mosquito control will help States and cities identify and address areas where mosquitoes breed in order to drive down mosquito populations. Continued CDC work on development of innovative mosquito control tools, such as promising new products that may be safer and more effective than today's methods, will help States reduce the population of mosquitoes that can spread Zika and other diseases. In February, the Administration submitted to Congress a request for $1.9 billion in emergency supplemental funding to support the full range of activities aimed at preventing, detecting, and responding to further transmission of the Zika virus to protect the American public.

**The Honorable Frank Pallone, Jr.**

**The Food Safety Modernization Act (FSMA) charged the FDA with transitioning our food safety system to one that was reactive, to one that is preventive. Despite receiving no additional funding as a part of this legislation, FDA has worked tirelessly to implement it, including finalizing five key rules related to Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Animal Food; standards for growing, harvesting, packing and holding produce; Foreign Supplier Verification Programs for Importers; and accreditation of third-parties to conduct food safety audits. The agency has also actively been working on guidance related to Voluntary Qualified Importer Program, and has conducted outreach to those impacted by FSMA's requirements.**

1. **The President's budget includes $1.5 billion for food safety activities and proposes user fees for food imports, food facility registration, and inspections. Will you please provide additional details regarding how this increased funding will assist the agency in implementation of FSMA? Further, will you please explain how the proposed user fees will be critical to the sustainability of FDA's food safety activities?**

**Answer**: The FY 2017 President's Budget includes two proposed user fees to support FSMA implementation. The first proposal, the import user fee, would enable FDA to modernize its import oversight program in ways that would facilitate the entry of safe food. These resources will benefit foreign food producers, U.S. food importers, and the general public. For importers in particular, the fee will result in an improved import program, and greater efficiency and predictability for their businesses. The improvements to the import process will not only facilitate the entry of safe products but also improve public health by enabling FDA to focus its attention on higher risk products. The ultimate result will be improved confidence in the safety of food from abroad, thus encouraging future trade opportunities in food.

The fee would support several key areas:

- Importer Support: To improve the safety of imported food, FDA will establish new systems to prevent the import of unsafe foods earlier in the process rather than detaining a product at the border. Additional funds will support the establishment of a "Help Desk" that would assure importers of an available, responsive communications system to help address their concerns and answer their questions about the status of their shipments.

- Port-of-Entry Streamlining: To help enhance food importers' ability to trade competitively, these funds will help develop and maintain improved risk analytics and IT systems that will allow FDA to target the highest risk imports, thus resulting in fewer detentions and less delay for lower-risk entries. This will include better integration with U.S. Customs and Border Protection (CBP) IT systems, and continuous improvement of FDA's import screening system. These systems will decrease reliance on paper notices and improve FDA's ability to exchange information electronically with industry during the import review process. These funds will also be used to expand the use of analytical tools deployed on-site for faster screening and better targeting of high-risk samples going to traditional laboratories for lengthy analysis. These tools will include technology such as hand-held scanners and small, portable on-site testing capability.

- Increased Border Staffing: Additionally, these funds will increase FDA border coverage and extend hours of operations at high-priority locations. The result will be fewer instances when FDA investigators are not available to process an entry and will help facilitate a timely response.

Second, the Food Facility Registration and Inspection user fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models, and information technology to improve targeting and risk-based efficiency of inspection. This investment will complement the investment in inspection modernization and training that can be achieved with the budget authority request and ensure that modernization is fully achieved on a timely basis.

The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide. With this investment, FDA will be better able to make sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply.

**2. What activities has FDA undertaken to work with the States in relation to an integrated national food safety system to enhance FSMA implementation?**

**Answer:** The National Integrated Food Safety System is crucial to successful implementation of FSMA because it will help ensure the quality, consistency, and effectiveness of local, state, and Federal efforts to protect the food supply. Funding in this area supports the goal of making state governments full partners in implementing the key preventive controls and producing safety components of FSMA.

The requested FY 2017 increase will be used primarily to enhance state capacity to support implementation of the produce safety rule through funding of state cooperative agreements and grants. Successful implementation of FSMA's new produce safety standards is especially dependent on partnerships between FDA and the states, both to deliver education and technical assistance and to provide on-going compliance support and oversight. Because of their relationships with and knowledge of local farming communities and practices, FDA believes the states can provide this oversight efficiently and effectively.

FDA has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan state support for implementation of the produce safety rule. Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation is actively participating in the development of these practices. NASDA will help facilitate industry training and will also play a role in delivering training to state regulators.

**3. Can you please provide additional detail regarding the activities the $20.2 million in new user fee will support? Further, will you provide additional information about the number of new full-time employees (FTEs) that the new user fee will support and the capabilities FDA will be hiring for?**

**Answer**: FDA would conduct Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA) activities with the new user fee resources. The fees provide $13 million and 42 FTE for CFSAN to establish and maintain a Mandatory Cosmetic Registration Program; acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards and review ingredient safety; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry and consumers. The fees provide $4.7 million and 18 FTE for ORA to refine inspection and sampling of imported products and apply risk-based approaches to postmarket monitoring of domestic and imported products, inspection, and other enforcement activities. Examples of skills and capabilities that FDA would target in recruiting additional staff include analytical chemists, toxicologists/pharmacologists, microbiologists, IT specialists, risk analysts, regulatory project managers, dermatologists, and consumer safety officers. The fee also includes $1.1 million and 3 FTE for program support activities and $1.5 million for rent activities.

**I know that there have been good and continuing discussions that FDA has had with the over-the-counter (OTC) medication industry. I understand that both the FDA and industry agree that the OTC Monograph system has slowed to an unworkable degree and that changes are necessary.**

**4. I encourage FDA and the OTC industry to continue those conversations and hope that Congress can be helpful in aiding a solution to these problems that benefits consumers.**

**Answer**: Thank you. Yes, FDA continues to discuss with industry and stakeholders ideas to reform the Over-the-Counter (OTC) review process. We appreciate Congress' interest in this important area.

**5. What funding is available to FDA currently to fulfill its mission for OTC drugs? How has funding levels for OTC drug activities changes over the past 5-10 years?**

**Answer**: For OTC Monograph review activities, FDA expended approximately $7.9 million in FY 2014, $7.4 million in FY 2015 and is on track to expend $8.2 million in FY 2016. None of these funds come from user fee programs, since the Agency is not permitted to expend user fees on OTC monograph work, and there are currently no user fees collected for OTC monograph work. These expenditures reflect non-user-fee work in the OTC monograph space, including the

work reported for sunscreens. The funding levels for OTC drug activities have remained relatively flat over the past 5-10 years.

**Many stakeholders have criticized FDA for not acting sooner to help address the opioid epidemic in this country. I was pleased when FDA released a multi-prong Opioids Action Plan. This plan is intended to take a number of steps towards addressing opioid abuse, such as: including additional warnings and safety information on labeling for immediate-release opioids, strengthening post-market requirements, providing guidance on the development of generic abuse-deterrent formulations, and reassessing the risk-benefit framework for approval of opioids. There is no one silver bullet for addressing opioid abuse and addiction, but it is clear that FDA has an important role to play as it weighs approval of new opioids.**

6. **Will you please elaborate on how the funding request included in the FY 2017 budget to address the opioid epidemic will help support implementation of FDA's Opioid Action Plan? Further, can you also comment on how you will encourage a collaborative and collective approach throughout HHS in addressing this epidemic?**

**Answer:** HHS, including the FDA, is deeply concerned about the growing epidemic of opioid abuse, dependence and overdose in the United States – and it is a personal priority for me as Secretary. In response to this crisis, at my direction the agency developed a comprehensive action plan to take concrete steps toward reducing the impact of opioid abuse on American families and communities. Our initiative aims to improve prescribing practices, expand the use of naloxone, and expand the use of Medication-assisted Treatment (MAT).

The President's FY17 Budget included critical investments to intensify efforts to reduce opioid abuse and overdose, including an increase of $1.1 billion in mandatory and discretionary funding to build on these and other investments proposed by the Administration and funded by the Congress in FY 2016. The prescribing aspect of the opioid epidemic is an important part of this complex public health issue, and using all of the tools available to us within HHS is a key part of our initiative to address opioid abuse and overdose.

The Initiative is a coordinated, multi-faceted approach across the Department that relies on education, prevention and treatment strategies with the strongest evidence base. Assisting health care professionals in making informed prescribing decisions, increasing the use of naloxone and expanding access to medication-assisted treatment for opioid use disorder are the key areas where we are focusing our efforts through the initiative, to deliver the greatest impact. At the same time, it is critical to balance combatting opioid misuse with the use of these drugs for legitimate purposes and supporting appropriate pain management. We are working to get all these tools into the hands of local health professionals and law enforcement officers through grants in CDC, SAMHSA, and by approving new formulations of naloxone at FDA.

As you note, FDA is taking steps to combat opioid abuse. The Agency has committed to work more closely with its advisory committees before making critical product and labeling decisions; enhancing safety labeling; requiring new data; and seeking to improve treatment of both addiction and pain. At the same time, the FDA will fundamentally re-examine the risk-benefit paradigm for opioids and ensure that the agency considers the wider public health effects. The

FDA is committed to taking all of these steps transparently and in close cooperation with its sister agencies and stakeholders. The FDA's actions include:

- Expanding the use of advisory committees;
- Developing warnings and safety information for immediate-release (IR) opioid labeling;
- Strengthening postmarket requirements;
- Updating the Risk Evaluation and Mitigation Strategy (REMS) Program;
- Expanding access to abuse-deterrent formulations (ADFs) to discourage abuse;
- Supporting better treatment; and
- Reassessing the risk-benefit approval framework for opioid use.

**The Vice President's Cancer Moonshot Initiative would direct FDA to develop a virtual Oncology Center of Excellence to help support the development of cancer diagnostics and therapies. This center would pull together the expertise of regulatory scientists and reviewers across the various programs at FDA – drugs, biologics, and devices – to encourage an integrated approach to the evaluation of next generation cancer treatments, such as combination products and immunotherapies. The Center will also serve as a resource to investigators at the National Cancer Institute offering advice and support in the development of new treatments.**

**7. Will you discuss how the proposed Oncology Center of Excellence and its integrated approach could help to expedite the development of novel cancer treatments?**

**Answer**: Increasingly, diagnostics and multiple therapeutic modalities, including drugs, biologics, and devices, are being used simultaneously or sequentially in the treatment of cancer. The optimal development and review of novel cancer therapies involves a thorough understanding of the overall disease context as well as the scientific basis of emerging diagnostics and therapeutic modalities. By integrating the perspective and expertise of the clinical reviewers from all of the medical product centers, teams from the Oncology Center of Excellence will readily be able to evaluate products in the context of existing diagnostic and therapeutic modalities, and be able to provide sponsors and other interested parties with the most informed advice regarding how to advance the development of novel products. This interaction will help to expedite the development and approval of important new cancer diagnostics and treatments. In addition, the Oncology Center of Excellence will serve as a single point of contact in the agency for all interested stakeholders, including patients, advocacy groups, medical societies, and industry.

**Cancer continues to effect far too many in this country with a more than 1.6 million people expected to be diagnosed with cancer in 2016, and more than 600,000 expected to succumb to this deadly disease. The cost of treating cancer is also continuing to rise predicted to reach $156 billion by 2020.**

**We know that there are promising new developments in the cancer treatment space – such as companion diagnostics, cancer immunotherapies and combination therapies, and new genetic tests. In order to further encourage the development of these treatments, and ensure future patient access, we must also ensure that FDA is able to utilize all the regulatory tools the agency needs to in order to keep pace with the science.**

**8. Will you please discuss how the FY2017 budget request for the National Cancer Moonshot initiative will help to improve the evaluation of these new products within FDA?**

**Answer**: FDA is committed to establishing a cross-center program with the overall goal of fostering innovation, improving the evaluation process, and enhancing regulatory research.

Funding in 2017 will enhance FDA's efforts to continue modernizing and integrating FDA's management and review of oncology-related activities and foster collaboration and transparency, both internally and externally.

**Advancing precision medicine is one goal I know that many members on this Committee support. I believe that moving away from a "one-size-fits-all" treatment model to getting the right treatment to the right patient at the right time will greatly help to improve the way we treat complex diseases and conditions, while also improving how we deliver care in this country.**

**Since the launch of the Precision Medicine Initiative last year, FDA has approved a number of new Precision Medicine-based therapies and has been working with industry to help encourage the development of targeted therapies. One such effort has been the launch of precisionFDA, a platform to help both the commercial and academic communities collaborate on testing and piloting new approaches to genetic tests to help inform treatment options. These are just a few of the ways the agency has played a role in advancing precision medicine.**

**9. Greater collaboration between the public and private sectors can play a critical role in improving how we discover and develop innovative treatments to treat disease in this country. Will you discuss how the FY 2017 budget request will help facilitate public-private collaboration in the area of precision medicine?**

**Answer**: The FY 2017 budget includes a request of $4.4 million, an increase of $2 million above FY 2016 for activities including supporting precisionFDA, working with the scientific community to develop new reference datasets for validating genetic tests, and developing a national device evaluation system.

In the last year, FDA has approved several new Precision Medicine-based therapies and launched precisionFDA, a platform for academic and commercial collaboration. These efforts directly support precision medicine activities across HHS.

FDA will use the requested FY17 increase to facilitate public-private partnerships through our continued work with the National Medical Device Evaluation System Planning Board to establish the National Medical Device Evaluation System. We envision that the proposed system would, among other attributes, help identify patients who would benefit from specific types of devices based on an evaluation of premarket and postmarket data, thereby advancing Precision Medicine. The device evaluation system will leverage real world data generated as a part of routine clinical practice to spur medical device innovation, allow for more timely patient access to safe and effective technologies, help identify medical devices associated with adverse events,

and reduce costs to the U.S. healthcare system. FDA will also continue to invest in precisionFDA, which provides a crowd-sourced, cloud-based platform to advance regulatory science around next generation sequencing based analytical tools and datasets.

**10. The President's FY2017 budget request proposes $18.4 million for compounding activities. Will you please provide additional details regarding how this proposed funding will assist with oversight of compounded drug products, including how such funding will be used to enforce the requirements outlined in DQSA?**

**Answer**: FDA will continue oversight of human drug compounding through inspections and enforcement, policy development and implementation, and state collaboration and coordination. Increased efforts in these areas will help to prevent patient injury and death associated with poor quality (e.g., contaminated) compounded drugs, and will provide clarity to compounders regarding FDA's expectations for compliance with the compounding provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the DQSA.

FDA continues to identify serious insanitary conditions at compounding facilities. For example, FDA recently recommended that a compounder cease operations and recall all sterile products within expiry when, during a surveillance inspection, FDA investigators identified the use of non-sterile drinking water for use in making injectable drug products; the use of non-sterile, non-pharmaceutical grade ingredients in making an injectable drug product; and the presence of dog beds and dog hairs within the facility, including in close proximity to the compounding room. To protect the public health, it is critical that FDA have sufficient resources to continue its inspection and enforcement efforts to address substandard practices and conditions for drug production that could compromise patient safety.

In addition to continuing its inspection and enforcement efforts, numerous policy issues must be addressed in implementing the provisions of the FD&C Act applicable to compounding. For example, FDA intends to use funds to promulgate specific current good manufacturing practice requirements for outsourcing facilities, promulgate regulations to implement the DQSA, and develop the list of bulk drug substances that may be used in compounding under section 503B.

Outsourcing facilities are also required to report adverse events associated with their products and FDA needs resources to review these reports and investigate the adverse events as appropriate.

**11. Office use compounding continues to be an area of debate related to implementation of DQSA. In response to inquiries from Congress, FDA has said that "to qualify for exemptions from certain requirements, such as having to submit a new drug application, a compounder must obtain a prescription for an individually identified patient." Will you please provide additional information regarding the Department's position on office use compounding?**

**Answer**: The Department shares your concern about the safety issues associated with compounded drug products. Since enactment of the DQSA in 2013, FDA has conducted over 250 inspections of compounders. During many of these inspections, FDA has identified serious

insanitary conditions that create a lack of sterility assurance of purportedly sterile drugs at the facility, prompting numerous pharmacies to recall purportedly sterile drug products and cease sterile drug production. FDA has also responded to serious adverse events associated with both sterile and non-sterile drugs compounded by state-licensed pharmacies that were as much as 1,000 times their labeled potency.

In April 2016, FDA issued for public comment a draft guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. As discussed in this draft guidance, compounding under section 503A of the FD&C Act must occur either after the receipt of a prescription for an identified individual patient (section 503A(a)(1)), or in limited quantities before the receipt of a prescription for an identified individual patient (section 503A(a)(2)). Section 503A does not provide for the distribution of a compounded drug without the compounder first receiving a prescription for an identified individual patient (e.g., for office use).

In contrast, entities that are registered with FDA as outsourcing facilities under section 503B of the FD&C Act can distribute compounded drugs to health care facilities without receiving patient-specific prescriptions for office use.

The prescription requirement in section 503A of the FD&C Act is critical to protecting patients. Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Because such compounders generally do not register their compounding facilities with FDA and are not under routine FDA surveillance, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination. As noted above, the limited number inspections that FDA has conducted of state-licensed pharmacies of which the Agency is aware have revealed serious deficiencies in drug production practices and conditions that could put patients at risk.

For these reasons, patients should only receive compounded drugs if their needs cannot be met by an FDA-approved drug product. The prescription requirement is critical to ensure that compounding by state-licensed pharmacies and physicians under section 503A is based on individual patient need, to differentiate such compounding from conventional manufacturing, and to differentiate compounding by pharmacists and physicians who are primarily subject to state regulation from compounding by outsourcing facilities, which are primarily subject to FDA regulation. Compounding for office stock by 503A facilities would undermine the incentive for compounders to become outsourcing facilities, removing a critical measure in place to prevent another outbreak on the scale of the 2012 fungal meningitis outbreak, which resulted in over 60 deaths and 750 cases of infection.

**In the Food and Drug Administration Safety and Innovation Act, FDA was directed to issue final regulations revising current medical gas regulations no later than July 9, 2016. If the agency does not act by the statutory deadline, FDA is directed to incorporate by**

**reference voluntary consensus safety and labeling standard developed by an accredited standard development organization until final regulations are issued.**

**12. FDA's recent report to Congress on the regulation review identified that regulation changes for warning label statements and adverse event reporting may be needed. Will you please provide an update regarding FDA's current progress in finalizing regulation changes for medical gas and identify what additional topics, if any, the agency is considering for regulation changes?**

**Answer**: In 2006, FDA proposed a rule to address medical gas mix-ups that included revisions to the medical gas labeling regulation. These revisions, once finalized, may largely satisfy a FDASIA provision indicating that "warning statement[s]" for designated medical gases are to be promulgated through regulation. FDA is working hard to publish this rule by the FDASIA-imposed deadline for rulemaking on medical gases (July 9, 2016). FDA is continuing to consider whether rulemaking is needed to address adverse event reporting for medical gases, and will continue to evaluate the need for targeted rulemaking in other areas, for medical gases as with other drug products, on an as-needed basis. However, as explained in our report to Congress[15], FDA generally thinks medical gases can be appropriately regulated under the existing regulatory framework. In addition to the applicable regulations, FDA will utilize guidance documents (to provide recommendations) and inspection practices, and will continue our productive working relationships with state regulators, industry, and other stakeholders. Given numerous competing agency priorities, we do not see a compelling need to undertake the sweeping regulatory overhaul requested by the medical gas industry.

FDA is working hard to ensure that medical gases continue to be appropriately regulated. In addition to our efforts to finalize the 2006 proposed rule, FDA has successfully implemented the key FDASIA medical gases provision - the new certification program for designated medical gases. Over 60 products have been certified. We are also actively revising, and will ultimately finalize, the existing draft guidance document on this topic – the 2003 draft guidance on current good manufacturing practices (CGMPs) for medical gases - to provide updated recommendations.

**The September 2012 report released by FDA, "Strengthening Our National System for Medical Device Postmarket Surveillance", proposed a National Medical Device Surveillance System for improving and addressing limitations in the agency's current system for monitoring device safety. In 2015, FDA took a number of steps to lay the groundwork for national system including implementation of the unique device identification rule for high-risk devices, building registry capabilities, and establishing a Medical Device Registry Task Force to develop new and more efficient methods to study medical devices.**

**13. Will you please provide additional information regarding the agency's progress in establishing a National Medical Device Surveillance System? What activities does the agency have planned for FY2017 to further facilitate the development of a national**

[15]Available at *http://www.fda.gov/downloads/regulatoryinformation/legislation/significantamendmentstothefdcact/fdasia/ucm453727.pdf.*

**system? Further, what additional resources, if any, will be needed to assist with the development and implementation of this system?**

**Answer**: The current medical device reporting system – which relies on an individual to detect an instance of actual or potential patient harm, then make the connection between the harm and a device, and report the event – is important, but also has important limitations.

FDA's Center for Devices and Radiological Health (CDRH), in collaboration with other stakeholders, is working to develop an *active* surveillance system, the National Evaluation System for Health Technology (NEST). This system would help generate evidence to enhance product development, innovation and safety; and support patient healthcare needs. Device manufacturers from across the spectrum – larger companies, and smaller manufacturers and startups – patients, and the entire ecosystem would benefit from the postmarket information provided by the system, as well as the premarket advantages it would provide, including potential reductions in manufacturers' evidence generation for device approval or clearance.

This system would not be owned or run by FDA, but rather would be operated by an independent public-private partnership, and governed by a board with representation from the primary medical device ecosystem communities, e.g., patients, providers, payers, industry, and government. Because the NEST is not an FDA-run system, we continue to work toward broad support in the medical device ecosystem, including from Congress, for this to be effective.

FDA has worked collaboratively with patient and consumer advocacy groups, health care providers, payers, and industry to lay the foundation for a national evaluation system for medical devices. Over the past five years, FDA has completed or engaged in approximately 50 projects and spent more than $10 million to help establish the national evaluation system.

In 2012 and 2013, CDRH set out a strategy and next steps toward creating the system; in 2015, two multi-stakeholder groups issued reports that endorsed the CDRH vision and made recommendations providing further direction for establishing the system; as part of its 2016-2017 goals, CDRH will build on its accomplishments to move closer to achieving the ultimate goal of a robust, fully functional system.

To accomplish these goals, CDRH will take several steps including:

- Resources permitting, establish an organizational structure and development of infrastructure for the NEST as envisioned in the report[16] of the Engelberg Center for Health Care Reform Medical Device Postmarket Surveillance Planning Board and the Medical Device Registry Task Force Report.[17]
- Develop a framework for the incorporation of real-world evidence into CDRH regulatory decision making.

[16] Available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf.*
[17] Available at *http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm459368.pdf.*

- Develop real-world evidence education and training for CDRH staff and industry.
- Develop metrics to track progress on building a national evaluation system.

The principal barrier to implementing the NEST is funding.

Congress and industry invested in the Sentinel system for drugs and biologics, but there has not been a similar investment in NEST for medical devices. For the national evaluation system to become operational and become a valuable resource for patients, providers, payers, government, and industry, funding is needed to continue the work FDA and others are already doing.

**14. When will pilots begin to explore the feasibility of including UDI on claims forms? What would pilots look like and when will they begin? What additional resources, if any, does the agency need to begin this process?**

**Answer**: We share the important goal of improving patient safety through post-market surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC's approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, incorporating UDIs into EHRs will allow the use of a device to be linked with a patient's experience with that device, thereby generating better information to enable patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

**15. Please explain how open enrollment has gone over this past year, including the volume of interest and timing of their health plan enrollment? What can Congress and HHS do going forward to make open enrollment even more successful? What, if any, additional resources would help with the ACA's success?**

**Answer**: HHS' priority is to provide Marketplace customers with access to quality, affordable coverage. CMS currently operates federal Marketplaces in 34 States and supports four State-based Marketplaces that use the HealthCare.gov platform. The Budget requests $535 million in budget authority, along with $1.6 billion in projected user fee collections, to maintain Marketplace operations in FY 2017 at approximately the same level as FY 2016. This funding supports oversight and operational activities for eligibility determination, enrollment, consumer outreach, quality improvement, and the supporting information technology.

At the end of open enrollment in January, about 12.7 million Americans selected or were automatically reenrolled in affordable, quality health plans for 2016 coverage through the Marketplaces.[18] Based on analysis through late December 2015, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit for the 2016 plan year.

4 million *new* people enrolled in coverage in HealthCare.gov states. Of the 9.6 million consumers who got coverage through HealthCare.gov, about 42 percent were new to the Marketplace in 2016.

More than ever, Marketplace consumers were engaged and satisfied with their coverage. About 60 percent (2.4 million) of new enrollees in HealthCare.gov states signed up for January 1 coverage compared to about 40 percent (1.9 million) of new enrollees last year. Instead of waiting until the last moment, as we saw in previous years, people signed up for coverage by the first deadline because they wanted coverage to start as soon as possible.

About 7 in 10 consumers with 2015 coverage came back to HealthCare.gov and actively selected a plan for 2016. Last year, about half of returning consumers actively selected a plan.

More than 3.6 million people used the total cost calculator, provider or drug look up tools – yet another sign of the seriousness and time they put into their decisions – and a sign that these tools were useful to them.

Finally, this year, 2.7 million people ages 18 to 34 are signed up for coverage in HealthCare.gov states, and the percentage of new customers in that age range is higher than last year. The overall percentage of plan selections for those ages remains stable.

**Secretary Burwell, we hear a lot on this Committee about controlling costs and ensuring our programs are available for future beneficiaries. However, the Medicaid program is among the most efficient programs we have. And, it must be said that the open-ended financing nature of the Medicaid program is critical to allowing it to expand and contract with need.**

**17. Secretary Burwell, isn't it true that over the past 30 years, Medicaid costs per beneficiary have tracked with costs in the health care system as a whole, public and private?**

**Answer:** From 1984-2014, Medicaid expenditures per enrollee increased at an average annual rate of 4.5 percent, which was slower than the rate of growth for Medicare enrollees (5.7 percent) and private health insurance (7.0 percent).

**18. And, isn't it true that Medicaid's costs per beneficiary are substantially lower than private insurance and Medicare, and in recent years these costs have grown far more slowly than per-beneficiary costs under both private employer coverage and Medicare?**

[18] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-04.html

**Answer:** Since 2008 per enrollee Medicaid spending has increased approximately 3 percent ($7,293 in 2008 to $7,523 in 2014). During the same time frame, Medicare per enrollee spending grew by about 11 percent ($10,520 in 2008 to $11,707 in 2014). Likewise, private health insurance expenditures per enrollee grew by about 27 percent ($4,108 in 2008 and $5,208 in 2014).[19]

**19. Ensuring Medicaid sustainability should mean promoting value-based care for beneficiaries, states and the federal government. Please describe CMS initiatives in the Medicaid program that promote value-based care for beneficiaries, states and the federal government.**

**Answer:** Medicaid is a payer with inherent flexibility and CMS has long supported states wanting to deliver services that improve the value of care. For decades, Medicaid has moved to change the delivery of long-term care from institutions to home and community based settings, highly valued by Medicaid beneficiaries for better meeting their long-term care needs in a more cost effective manner. Medicaid programs like the PACE program, Money follows the Person (MFP), Real Choice Systems Change Grant Program (RCSC), and the provision of telehealth services have all helped states and providers to transform the delivery of long-term care to locations that better serve the needs of beneficiaries. In fact, today more than half of Medicaid long-term services and supports are provided in home and community-based settings.

The Affordable Care Act, in addition to expanding coverage for more Americans, created additional opportunities for states to deliver value-based care. The law strengthened and expanded the MFP program allowing more states to apply and created the Medicaid "Health Homes" program. The Affordable Care Act created an optional Medicaid State Plan benefit for states to establish Health Homes to coordinate care for people with Medicaid who have chronic conditions. This new programs allows states health home providers to operate under a "whole-person" philosophy. Health Homes providers integrate and coordinate all primary, acute, behavioral health, and long-term services and supports to treat the whole person.

In 2012 CMS released a series of new guidance on how states could move from fee-for-service reimbursement to "Integrated Care Models" (ICM) under current Medicaid authorities – outlining pathways using both non-waiver authority (e.g., state plan authority) and waiver authority. ICMs are described as accountable care delivery and payment methodologies aligned across payers and providers to ensure effective, seamless, and coordinated care. CMS specifically provided guidance on how states could structure shared savings models, episode based models and primary care case management programs.

In addition to states providing care through established authority and state plan amendments (SPAs), Medicaid also supports innovative value-based care delivery models through a variety of 1115 waivers, too numerous to detail here.

The Medicaid Managed Care proposed rule further supports states provision of value-based care by encouraging managed care plans, through their contractual agreements, to develop and participate in broad-ranging delivery system reform or performance improvement initiatives.

[19] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html

This approach acknowledges the role of the managed care plan as an important partner in such initiatives and would provide the managed care plan the ability to participate as an equal collaborator with other payers and participants.

In addition to encouraging participation in VBP activities, the proposed managed care rule authorizes states to require the managed care plan to establish reimbursement standards or fee schedules for providers that deliver a particular covered service to support timely access to care. The regulation also proposes to clarify states' ability to use incentive arrangements for managed care plans that meet quality or performance targets established through the contract and use withhold arrangements to encourage managed care plans to meet quality or performance targets established through the contract.

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) created the State Innovation Models (SIM) initiative for states that are prepared for or committed to planning, designing, testing, and supporting evaluation of new payment and service delivery models in the context of larger health system transformation. The SIM is providing financial and technical support to states for the development and testing of state-led, multi-payer health care payment and service delivery models that will improve health system performance, increase quality of care, and decrease costs for Medicare, Medicaid and CHIP beneficiaries. In Round One of the SIM Initiative, nearly $300 million was awarded to 25 states to design or test innovative health care payment and service delivery models in the form of Model Design, Model Pre-Test, and Model Test awards. In Round Two, the SIM initiative is providing over $660 million to 32 awardees (including 28 states, three territories, and the District of Columbia).

To further spur innovation between CMS and the states, CMS created the Medicaid Innovation Accelerator Program (IAP) with the goal of improving health and health care for Medicaid beneficiaries by supporting states' ongoing payment and service delivery-reform efforts. Through the IAP, states can receive targeted program support designed around their ongoing delivery and payment system innovation efforts. To date, IAP is providing direct support to 28 state Medicaid programs through its four program areas, as well as its Medicare-Medicaid data integration support efforts. IAP will provide additional federal tools and resources to support states in advancing Medicaid-specific delivery system reform and by sharing lessons and best practices.

These are exciting times of forward movement for the Medicaid program as access to coverage is broadened, making the investment in delivery system and payment reform even more critical.

**20. Secretary Burwell, we have heard a great deal on this committee about the limitations of Medicaid data writ large. Please describe the work of CMS to transition to a more modernized Medicaid data structure, and any recommendations the Department has for future improvements in this area.**

**Answer:** CMS has been working actively to transition states to the Transformed-Medicaid Statistical Information System (T-MSIS) from the Medicaid Statistical Information System (MSIS). T-MSIS is a monthly, automated feed to CMS of states' beneficiary utilization and claims data as well as other key Medicaid and CHIP program information about providers and health plans. These data enable the agency to keep pace with the data needed to improve

beneficiary quality of care, assess beneficiary access to care and enrollment, improve program integrity, and support states, the private market, and stakeholders with key information.

The federal side of T-MSIS is ready for state submissions. There are seven states/agencies currently in production as of February 2016. CMS anticipates the majority of states to be complete with T-MSIS transition by December 31, 2016. However, this is predicated on state engagement and completion. Achieving state implementation will make national T-MSIS data available for stakeholder users.

Examples of expected analysis include examination of nationwide data, including encounter, claims, and enrollment data trends, understand access to and the cost of care and monitor changes in beneficiary utilization of Medicaid and CHIP services. T-MSIS will also help streamline the reporting process by reducing the number of reports and data requests CMS currently requires of states. The enhanced data available from T-MSIS will support improved program and financial management, program integrity, and more robust evaluations of demonstration programs.

**Contrary to popular belief, health insurance and/or Medicare only covers very limited Long term care services and supports (LTSS). Most Americans who receive formal LTSS and don't qualify for Medicaid have to pay out-of-pocket. Individuals purchasing formal LTSS services will pay an average of $140,000 out of pocket, many until resources are depleted enough for Medicaid coverage. More than 70 percent of individuals over the age of 65 will need LTSS. As the baby boomer wave continues, by the year 2050, the population of Americans over age 65 is expected to double and the population above 85 will triple. This will result in approximately 90 million Americans over age 65 by 2055, with half of these individuals over 75. At this trajectory, LTSS expenses are predicted to double as a share of the economy over the next 30 years.**

**21. Long term care financing is truly in a crisis state. Please describe the pilot long term care state plan option, and any other recommendations the Department has to address this issue. Please include in your response any recommendations to rebalance care in less expensive and often preferable home and community based settings.**

**Answer:** The President's FY 2017 Budget includes several proposals to address LTC financing and increase states' use of home and community-based services. The proposal to pilot a Comprehensive Long Term Care State Plan Option for up to five states, with enhanced match, would pilot a single comprehensive long-term care Medicaid state plan option. This pilot program would eliminate the current institutional bias and fragmented service systems, replacing them with a simplified benefit providing equal access to all types of long term services and supports, based on assessed need and choice. It will test a comprehensive solution to Medicaid LTC service delivery and financing, which would be of interest to states that have reached limits in reforming LTC under the present rules. [20].

**Currently, children under 21 receiving inpatient psychiatric services are excluded statutorily from coverage of comprehensive preventive and medically necessary items and**

[20] Cost projections based on the Long Term Care Scorecard.

**services to which Medicaid enrolled children are otherwise entitled. However, the Department issued guidance in 2012 to mitigate this exclusion somewhat.**

**22. Please describe, in light of 2012 guidance, why this proposal in the budget is critical to ensuring that children receiving inpatient psychiatric care receive the Medicaid benefits to which they are entitled.**

**Answer:** Section 1905(a)(16) of the Social Security Act provides a limited exception for individuals under the age of 21 to the general exclusion of federal financial participation (FFP) for Medicaid beneficiaries who are patients of an Institution for Mental Diseases (IMD). This exception authorizes coverage and payment for only inpatient psychiatric services furnished to individuals under age 21 but not for other medically necessary services they may need pursuant to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, which requires that states provide all medically necessary 1905(a) services to eligible individuals under age 21. Due to this exception, children who receive inpatient psychiatric services for individuals under age 21 have had to go without needed services during a stay in an inpatient psychiatric hospital, an inpatient psychiatric program of a hospital, or a psychiatric facility that meets the requirements of federal law.

The provision of quality, intensive behavioral health services to children, including in these inpatient settings, has been and continues to be a national priority. Amending the statute to provide Medicaid coverage for the full range of EPSDT services to children under age 21 who are receiving inpatient psychiatric services will ensure that children in inpatient psychiatric facilities do not lose access to coverage for critical preventive services, physical and behavioral health screenings, diagnostic and treatment services. It will also reduce the financial burden on states and Medicaid families associated with receiving related services from multiple facilities.

**23. The budget references a technical correction to the statute for Medicaid drug rebates with respects to abuse deterrent formulations. Please describe why this technical fix is critical in the fight against opioid abuse.**

**Answer:** There are two separate issues being addressed by this item in the budget. The first issue is a technical correction to the formula for the alternative calculation of the rebate liability that is required to be performed for line extension drugs. This technical correction would affect any drug identified as a line extension drug, and may result in a higher rebate liability. The current law was drafted using a formula that results in fewer drugs being subject to the higher rebate than was initially intended. The technical correction seeks to fix that formula so that the intended higher rebates may be collected.

The second issue is not a technical correction, but rather a change to the identification of line extension drugs, which determines whether the alternative calculation is required. Currently, the Medicaid law defines a line extension drug as "a new formulation of the drug, such as an extended release formulation." Manufacturers and other stakeholders have challenged the notion that abuse deterrent formulations (ADFs) should be subject to higher potential rebates due to the reformulation of a non-ADF drug. ADFs are generally new formulations of drugs that contain properties that make them resistant to abuse. However, the statute does not exempt ADFs from the definition of line extensions and, therefore, ADFs may be subject to higher rebates under Medicaid.

The change proposed in the President's Budget for the definition of "line extension" will help address opioid abuse. Including ADFs in the definition of line extension drugs may discourage manufacturers from being innovative because these products will potentially be subject to higher rebates. Accordingly, the President's Budget asks Congress to revise the definition of line extension to exclude ADFs, thereby eliminating the potential disincentive for manufacturers to invest in ADF technology.

**Secretary Burwell, as you know the misuse and abuse of prescription opioids and of illicit drugs has become a true public health crisis, with overdose deaths quadrupling since 1999. I applaud you and the President for your work addressing this epidemic.**

**One area that often gets lost in this debate is primary prevention. This is a critical part of our efforts to address opioid abuse – stopping it before it starts. Research supported by the National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC) has found that early intervention can reduce risky behaviors during the teen years that lead to substance abuse.**

**The research shows that we need to start prevention efforts at a younger age than we are now, before problems emerge. Addressing the very early risk signs – such as behavior and academic concerns in preschool or elementary school — and providing services that support parents as well as young children can have some of the biggest long-term payoffs. These interventions will not only help reduce substance misuse, they will also improve academic performance and reduce bullying, depression, violence, suicide, unsafe sexual behavior and other problems.**

**There is 40 years of research behind a prevention first approach and there are models underway right now that are working, but most prevention strategies are not in widespread use. Making investments to bring innovations to scale and help communities implement proven approaches that promote positive protective factors – like safe, stable families, homes, schools and communities – will help prevent youth substance use before it develops. My questions are:**

24. **The Institute of Medicine has called for 10 percent of public funds spent on young people to be directed toward effective prevention interventions that promote healthy behaviors. Can you tell us what percentage of the President's opioids initiative would be directed toward prevention? Or what percentage from the overall HHS budget?**

25. **Can you tell us how you plan to incorporate primary prevention into HHS' work addressing the opioid epidemic? How can we help communities to implement these interventions?**

**Answer**: We know that preventing substance use during youth is a key factor in preventing future substance use, especially problematic substance use in adulthood. Several NIDA-funded studies have found that universal, evidence-based prevention programs targeting youth such as

the Iowa Strengthening Families Program can reduce future nonmedical use of prescription opioids in high school and early adulthood.

In general, youth are doing the better than other age groups with respect to opioids. Rates of nonmedical use of prescription opioids among people 12-17 years old have been declining since 2002. In 2002, 7.6% of individuals 12-17 years old reported nonmedical use of prescription opioids in the past year compared to 4.7% in 2014. Similar, opioid-related mortality has remained stable among 12-17 years since 2002. In 2014, there were 115 opioid-related overdose deaths among 12-17 year olds compared to 101 in 2002.

It is critical that we focus our resources on where we can have the greatest impact. As you know, my plan for combatting opioid abuse and overdose is a coordinated, multi-faceted initiative that relies on education, prevention, and treatment strategies with the strongest evidence base, and the Department has been working diligently to develop and implement these strategies. The Department also agrees that prevention services are critical in addressing the opioid epidemic across the country. In addition to continuing support for ongoing work associated with Substance Abuse Prevention through SAMHSA's 20% set-aside for prevention within the Substance Abuse Prevention and Treatment Block Grant and through their $10 million Strategic Prevention Framework Rx, the FY 2017 Budget includes improvements to prescribing practices as a key area where we can focus our efforts to prevent opioid misuse. While actions to address prescription opioid abuse must target both prescribers and high-risk patients, prescribers are the gatekeepers for preventing inappropriate access. Therefore, HHS is focused on increasing investments in state-based prescription drug monitoring programs (PDMPs) and adoption of e-prescribing practices, disseminating guidelines for opioid prescribing, and training providers.

The FY 2017 President's Budget for the Centers for Disease Control and Prevention proposes a $10 million increase for Prescription Drug Overdose and Misuse Prevention, for a total of $80 million in discretionary resources, to support improved uptake of CDC's new "Guideline for Prescribing Opioids for Chronic Pain" among providers, and to provide ongoing support to all 50 states and D.C. through the Prescription Drug Overdose program. In addition, the Budget proposes $5 million in new discretionary funding for the Office of the National Coordinator for Health Information Technology to harmonize technical standards in support of PDMPs, improve clinical decision-making, and further the adoption of electronic prescribing of controlled substances. In addition, the SAMHSA State Targeted Response Cooperative Agreement program, a $920 million effort over two years, will enable states to develop holistic approaches to addressing the opioid crisis, including prevention.

**26. There are multiple grant programs addressing prevention at the Department of Education, HHS and Justice. How is HHS coordinating with those departments to leverage resources?**

**Answer**: We must work across HHS, with our partner agencies and other stakeholders, as well as with Congress to identify and dismantle barriers as well as leverage our resources in order to effectively implement these strategies. Coordination of HHS activities addressing opioid use disorders is being led by the Office of the Assistant Secretary for Planning and Evaluation. In addition, HHS continues to coordinate its efforts to address opioid addiction and overdose with

its federal agency partners through the Interagency Workgroup on Prescription Drug Abuse Prevention/Opioid Overdose Prevention led by the Office of National Drug Control Policy. The Department of Education and Justice are also members of this interagency group. An example of federal coordination taking place at this level is the $10 million FY 2017 President's Budget proposal to partner with the Department of Justice to implement a new Buprenorphine-Prescribing Authority demonstration to expand the types of providers who can prescribe Medication-Assisted Treatment.

**The Honorable Eliot Engel**

**The President's proposed budget again includes reduced funding for graduate medical education. Specifically, the FY17 budget proposes a cut of $17.8 billion over ten years. While the budget does include a small investment to train more primary care doctors, this effort – though appreciated – is not a substitute for supporting teaching hospitals. With the country facing a doctor shortage, this is not the time to put funding for physician training on the chopping block.**

**My home state of New York has built a premier infrastructure for training doctors. In more than one-third of the 50 states, more than 10% of active physicians have been trained by New York institutions. If funding for graduate medical education is cut, top teaching hospitals in New York and across the U.S. may be forced to reduce the number of physicians they train. As a result, patient care nationwide would almost certainly suffer. The rationale for this provision is to "encourage workforce development through targeted and more accurate indirect medical education." While this is a worthwhile goal, $17.8 billion in cuts to teaching hospitals will jeopardize their ability to train future doctors, thus hindering workforce development. Medicare funding for doctor training must remain stable – the stability of our country's teaching hospitals and the educations of future physicians are too important to put these funds at risk.**

1. **Can you describe how the Administration expects teaching hospitals to absorb cuts to GME, and how we can in turn ensure that doctor training does not suffer?**

**Answer**: HHS recognizes the importance of graduate medical education. Nonetheless, like any other category of Medicare spending, payments to teaching hospitals must be justified by incurred costs. This proposal in the President's Budget will help graduate medical education programs promote high quality primary care services that address relevant public health needs by allowing the Secretary to target funding to training activities specific to issues. HHS believes this proposal brings these payments closer to the appropriate level and provides incentives for promoting high-quality primary care. In addition, the Teaching Health Center Graduate Medical Education (THCGME) Program provides funding for residency training in primary care medicine and dentistry in community-based, ambulatory settings. The THCGME Program seeks to not only bolster the primary care workforce through support for new and expanded primary care and dental residency programs, but also improve the distribution of this workforce into needed areas through emphasis on underserved communities and populations. In addition to the $60 million in funding appropriated in MACRA, the FY 2017 Budget includes an additional $527 million over FYs 2018-2020 to support up to 876 residents.

**I'd like to address an area in which, I feel, Medicare has missed an opportunity to adopt approaches that have been proven in the private sector to both save money and improve patient care: home infusion therapy.**

**Home infusion allows patients to receive vital treatment in a cost-effective, comfortable and clinically-beneficial setting. Home infusion is widely covered by commercial payers as a means of keeping patients out of institutions for infusion treatments. As a result, both patients and these payers have benefitted from fewer hospital-acquired infections, which HHS has devoted substantial resources to curb.**

**Congressman Pat Tiberi and I have introduced H.R. 605, the Medicare Home Infusion Site of Care Act, to give patients the ability to receive life-saving therapies in their homes and avoid forcing them into institutional settings. This would, in turn, avoid unnecessary costs to the Medicare program and, most importantly, to patients' quality of life.**

2. **Can you speak to any issues that you foresee with respect to providing Medicare coverage for home infusion drugs and services? I would be pleased to work with you to mitigate any concerns you may have, and to afford patients an opportunity to receive this life-saving care in their homes as soon as possible.**

**Answer:** Thank you for raising this important issue. Coordinating care is a cornerstone of the work the Department is doing around delivery system reform. Our goal is to foster a health care system that leads in innovation, delivers the most affordable, highest quality medicines and results in healthier people. We are happy to continue to work with you and provide technical assistance on the legislation.

**In December 2014, Congress appropriated $576 million to the Assistant Secretary for Preparedness and Response (ASPR) for Ebola response and preparedness activities. This amount was higher than had initially been requested by the Obama Administration, in part because Congress wanted hospitals – particularly those designated as Ebola treatment centers in high risk areas – to be reimbursed for their preparedness costs to the greatest extent possible.**

**Nearly 15 months later, $340 million of the appropriated amount still hasn't been allocated for designated treatment center preparedness. As a result, many centers will receive only a small fraction of their preparedness costs. Furthermore, the omnibus spending bill passed in late 2015 included language requesting that ASPR allocate a portion of that unspent Ebola funding to health care facilities that have incurred Ebola preparedness expenses. Even though Congress once more expressed its will on this matter, ASPR has not released the funding.**

**I am very concerned that the failure to release this funding will discourage facilities from stepping forward to be designated centers for treatment in the future. As you know, Congress will soon debate funding to address the Zika virus, and we will once again need our nation's health care providers to help protect us from this new threat. Hospitals are not required by law to undertake this very expensive public service function, but do so in response to specific needs and requests by the federal and state governments.**

**Can you please explain why such a small proportion of the dollars appropriated for Ebola response and preparedness activities has been allocated by ASPR? How does HHS plan to use the remainder of the allocation, if not use it to reimburse hospitals?**

**Answer:** A total of $208 million of Ebola emergency funding appropriated to the Public Health and Social Services Emergency Fund was allocated to support the Hospital Preparedness Program to health care system preparedness and response to Ebola virus in the U.S. While the primary focus of the Hospital Preparedness Program Ebola funding is on preventing, preparing for, and responding to Ebola, as required by Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities. While HHS provides funds and provides guidance, ultimately decisions on the levels of funding for Ebola treatment centers are made by the program's 62 awardees, the health departments in all 50 states, the District of Columbia, Chicago, Los Angeles County, New York City, and all U.S. territories and freely associated states. Funding allocations for HPP's Ebola funds were based on a formula that accounted for population and Ebola risk. The hospital preparedness supplemental funding also provided significant resources to establish nine regional Ebola and other special pathogen treatment centers. These facilities have enhanced capabilities to ensure they are the leading providers of care and treatment for Ebola patients in the U.S. and have the capabilities needed to manage other high containment, Ebola-like infectious diseases in the future.

With the funding provided, States will be able to support treatment facilities, including academic health centers and other hospitals. States are also able to support a broad range of preparedness activities such as caring for clinical complex patients; maintaining enhanced readiness through increased training; increasing capacity to handle highly contaminated infectious waste; receiving and participating in training, peer review, and assessment of readiness to ensure adequate preparedness,; develop strategies to ensure health care worker readiness and safety; and integrate behavioral health considerations for patients and staff.

HHS is assessing the direction from Congress on hospital preparedness in the FY 2016 appropriations report and identifying the scope of current needs for building treatment capacity.

**For over 10 years, HRSA has been overseeing UNOS work on a process to revise the organ donation system so that it is more needs-based than geography-based. Current liver distribution rules require donated livers from deceased people to be offered to the sickest person in that particular region, even if there are suitable recipients in other regions who are even sicker. Acknowledging these disparities, the UNOS Committee responsible for liver distribution reform is has been exploring alternative models for distribution.**

**As this process has labored on, stakeholders in New York and elsewhere are eagerly awaiting a resolution, especially the many patients who remain on the organ transplant wait list. While UNOS has been careful to thoughtfully deliberate the adoption and implementation of liver distribution reform, needless deaths continue to occur under the current policy. It is therefore essential that UNOS reach a timely conclusion on a policy to remedy the current inequity that leads to these unfortunate and unnecessary deaths.**

3. **Can you provide information about the timeline for a decision, and an update on what progress HRSA and UNOS are making with these deliberations**?

**Answer:** Any change in the OPTN liver allocation policy must be consistent with the requirements and principles of the OPTN final rule, which articulates the goals to be achieved through OPTN organ allocation policies. These policies must, among other factors, be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements).

Consistent with OPTN processes and requirements for the development of changes to the liver allocation policy, the following recent steps have been taken with respect to the alternative approaches to liver allocation.

- The Liver and Intestinal Organ Transplantation Committee (Liver Committee) released a "Concept Paper" in June 2014 to describe geographic challenges in access to liver transplants and outline allocation concepts under consideration, as well as alternative approaches. The publication was followed by a 60-day public comment period;
- A public forum was held in September 2014, with over 400 people in attendance, to discuss the concept paper. Afterward, the OPTN convened subcommittees to address issues identified during the forum;
- A second forum was held in 2015 during which subcommittees presented recommendations being considered by the Liver Committee as it develops a final proposal for proposed changes to the liver allocation policy; and
- A Redistricting Subcommittee of the Liver Committee reviewed additional analyses of alternative approaches for liver allocation. This subcommittee is charged with developing implementation plans, and resource assessments for several options for redistricting, including the "concentric circles" option raised at the most recent forum. In April 2016, the subcommittee presented its recommendations to the full Liver Committee during its meeting in Chicago.
- The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, at its April 2016 meeting, agreed on a proposal to be shared with the public for input in order to improve liver distribution nationwide. The proposal, to be published for public comment in August 2016, is intended to increase consistency in medical urgency scores at transplant for candidates in various areas of the country.

**<u>The Honorable Jan Schakowsky</u>**

**Calorie labeling on restaurant menus allow Americans to make informed food choices for themselves and their families when eating out. Yet, the national menu labeling law (Section 4205 of the Patient Protection and Affordable Care Act of 2010) has been delayed by six years since enactment. Most recently, a rider inserted in the FY2016 Omnibus Appropriations Act states:**

***SEC. 747. None of the funds made available by this Act may be used to implement, administer, or enforce the final rule entitled ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments'' published by the Food and Drug***

***Administration in the Federal Register on December 1, 15 2014 (79 Fed. Reg. 71156 et seq.) until the later of—***
***(1) December 1, 2016; or***
***(2) the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments in accordance with paragraphs (g)(1)(i), (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of section 10.115 of title 21, Code of Federal Regulations.***

1. **Will you please confirm the impact of this rider if it delays the national menu labeling law even further by one year after the Food and Drug Administration finalizes its *Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)*?**

**Answer:** The impact of this provision would delay enforcement of the menu labeling final rule well into 2017 for covered establishments to provide calorie and other nutrition information to consumers. Considering that consumers eat 1/3 of their meals in such establishments, further delay in enforcing this rule will leave consumers without important nutrition information necessary to make more healthful food choices.

2. **When can we expect the Department to finalize this guidance so that Americans can benefit from this important law?**

**Answer**: The Agency considers finalizing the guidance a priority and expects to publish the final guidance in May of this year.

3. **Dr. Thomas Frieden, the CDC director, said, "The finding that nine of ten adults and children still consume too much salt is alarming. The evidence is clear: too much sodium in our foods leads to high blood pressure, a major risk factor for heart disease and stroke. Reducing sodium in manufactured and restaurant foods will give consumers more choice and save lives." When can we expect the Food and Drug Administration to issue its voluntary guidance to the food industry on sodium reduction?**

**Answer:** FDA is aware of the potential public health benefits associated with a reduction in sodium intake over time and continues to be highly interested in strategies that support this goal. We are working on developing draft voluntary guidelines for commercially prepared foods with the goal of gradually lowering excessive sodium in the U.S. food supply in a safe, achievable and sustainable way. We anticipate publishing the draft voluntary guidance in the spring of 2016.

**<u>The Honorable G. K. Butterfield</u>**

**Secretary Burwell, although colorectal cancer death rates in the United States have declined by half since 1970, large geographic disparities persist. I happen to represent North Carolina's First Congressional District which has the alarming distinction of hosting one of the so-called colorectal cancer 'hot spots.' That means that death rates in my district are 9 percent higher than in other parts of the country for colorectal cancer-a preventable**

**cancer in many ways. We need help in my district. Unfortunately, North Carolina was not one of the grant awardees from the CDC's Colorectal Cancer Control Program (CRCCP). I know that the program has limited resources but I'd like to see CDC develop ways to help communities like mine that have an identified public health problem.**

**1. Do you have any plans to expand the CRCCP nationally?**

**Answer**: In FY 2015, CDC began funding a new five-year cooperative agreement for the Colorectal Cancer Control Program (CRCCP). With available resources CDC was able to fund 30 grantees, including 23 states, 6 universities and 1 tribal organization. CDC does not currently have plans to expand the program.

**2. How do you see the program moving forward?**

**Answer**: Despite strong evidence to support colorectal cancer (CRC) screening, currently, only 65% of adults report being up-to-date with screening, with more than 22 million eligible adults who have not been screened. While the Affordable Care Act is helping to improve access to insurance coverage for CRC screening, many adults face other barriers which make it difficult for them to receive this effective preventive service. The goal of CDC's CRCCP is to increase population-level screening rates by implementing evidence-based interventions which affect broader health systems change and help to address these barriers.

CRCCP grantees are working to increase screening rates within a partner health system (federally qualified health center, hospital/clinic network, etc.), and defined geographical area or disparate population. Grantees must implement at least two of four Community Guide recommended interventions (provider assessment/feedback, provider reminders, client reminders, or reducing structural barriers); and may also use secondary strategies such as patient navigation. Grantees are establishing baseline screening rates in the health systems with which they partner and will measure the change in screening rates over the five year program to assess the health impact of their efforts.

To date, 226 clinics from a total of 78 health systems have been recruited for participation in the CRCCP. These clinics include nearly 441,000 patients ages 50-75 and nearly 2,000 primary care providers. The average baseline CRC screening rate for clinics is approximately 35%. Recruitment of partner health systems and their clinics will continue for the duration of the five-year grant period; therefore, we anticipate that program reach will expand considerably over time. A comprehensive evaluation of the program includes annual collection of CRC screening rates for every participating clinic so we can closely monitor our primary outcome, which is to increase screening. CDC anticipates that over the five-year program period, grantees will show increases in population-level CRC screening rates within the health systems they are collaborating with as a result of the evidence-based interventions they are executing.

**Secretary Burwell, I am a cosponsor of bipartisan legislation H.R. 1220, the Removing Barriers to Colorectal Cancer Screening Act. This legislation simply fixes a glitch in Medicare that charges beneficiaries a 20 percent copay when a polyp is found and removed during a screening colonoscopy. A colonoscopy is an A-rated service because you have the**

**opportunity to actually gain the mortality benefit through the screening process by removing the cancerous polyp. The intent of the ACA was to encourage preventive health by providing screening services for free. This financial barrier in Medicare works to discourage beneficiaries from getting their colorectal screening. I was pleased to see the Administration support this legislation in the budget documents.**

**3. Short of legislative action what else can be done to address cost barriers in Medicare and private insurance?**

**Answer:** As you noted, the President's Budget proposes to eliminate beneficiary coinsurance/copayments under Part B for screening colonoscopies that result in removal of a polyp or other diagnostic/therapeutic procedures. Under current law, Medicare beneficiaries do not have to pay the part B deductible or coinsurance/copayment when they have a screening colonoscopy. However, when a polyp is detected and removed during a screening colonoscopy or another procedure is performed, coinsurance/copayments are applicable. In that case, the service is considered to be a diagnostic or therapeutic procedure (e.g., colonoscopy with polypectomy) rather than a screening colonoscopy and patients are billed coinsurance and/or copayments. The Affordable Care Act provides that the Part B deductible is not applied in such cases, but does not waive the coinsurance/copayment. This proposal would address the inequity in beneficiary cost-sharing by waiving coinsurance and copayments on a scheduled screening colonoscopy even when the procedure actually furnished is considered to be a diagnostic/therapeutic one.

For private insurance, as you know, Section 2713 of the Public Health Service Act and its implementing regulations require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to cover, without the imposition of any cost-sharing, evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved. The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods may vary. This recommendation received an A grade. If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations.

HHS shares interpretative jurisdiction over this provision with the Departments of Labor and Treasury. Over the years, HHS, Labor and the Treasury (collectively, the Departments) have issued a series of FAQs to answer questions from stakeholders to help people understand the Affordable Care Act and benefit from it, as intended. The Departments recently issued FAQs on colonoscopies in particular.[21]

[21] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf

4. **It is my understanding that there is still a lack of clarity in both private insurance and Medicare around coverage for a colonoscopy that follows a positive FIT test. Right now, both seniors on Medicare and those with private insurance will be charged out of pocket for the follow-up test. Faced with the cost, it seems to me that they may skip the follow-up colonoscopy altogether. So, we've removed the ability to stop cancer before it starts. If you are going to pay for an initial screening tool like the FIT test and you find a problem, the follow-up screening of a colonoscopy should be covered. What is the rationale behind this strategy?**

5. **Is there a plan to clarify this issue in Medicare and private insurance?**

**Answer:** A colonoscopy furnished under the circumstance you described is covered by Medicare but would be considered a diagnostic colonoscopy, not a screening colonoscopy, for which cost-sharing is not waived under current law. We would be glad to work with the Congress on any proposals to address this scenario. As noted above, a colonoscopy furnished under this scenario is covered by Medicare but cost-sharing is not waived under current law. We would be glad to work with the Congress on any proposals to address this issue.

**The Honorable Joseph Kennedy**

1. **Madame Secretary, in light of President Obama's request for $1.8 billion in supplemental funding to address the ongoing Zika virus outbreak, can you tell us more about what mechanisms HHS currently has at its disposal to respond to emerging and re-emerging pandemic diseases like Ebola and the Zika virus? As these and other global health threats grab international attention and climate change allows vectors to spread to new territory, what steps can Congress take to strengthen HHS' ability to prevent the spread of disease, respond to outbreaks, and ensure the availability of treatments and vaccines?**

**Answer:** Today's world of increasing connectivity and mobility accelerates shared global health risks. New viral and bacterial pathogens continue to emerge and can quickly spread around the world. We do not know when or where the next threat will emerge from. Between March 2014 and now, we have tracked over 200 outbreaks in 145 countries—in addition to Ebola. Most of the world is still unprepared to prevent, detect and respond to infectious disease threats. Fewer than 1 in 3 countries report that they are fully prepared.

The Global Health Security Agenda (GHSA) was launched in February 2014 to advance global health security against natural and man-made infectious diseases. Global health security is the road map for countries to become compliant with the International Health Regulations (IHR) which means they will be better able to identify and respond to disease outbreaks in their own country—reducing the numbers of people who get sick and die and preventing diseases from spreading across borders.

With funding provided in the FY2015 Ebola emergency appropriation, HHS is working with other US government agencies to support 17 countries to develop and implement five-year plans to meet GHSA targets and comply with the IHR. 14 other countries and 1 region are also being supported to develop a five-year plan. Other countries in the G7 and countries like South Korea

are also supporting this work in additional countries. However, there are still many countries that have public health systems that are vulnerable to infectious disease threats. Until all countries are able to comply with IHR requirements, the whole world is at increased risk from infectious diseases.

Even in countries with well-developed public health systems, infectious diseases can still cause a public health crisis. This was the case in South Korea with the introduction of MERS, though South Korea was able to contain further spread of MERS. All countries, including the United States, need flexibility in order to be able to respond quickly to an emerging public health problem—before it becomes a full-blown international public health crisis.

**2. Additionally, it's my understanding that the FY2015 Ebola Emergency appropriations provided $597 million to CDC to establish and strengthen National Public Health Institutes and for other international preparedness activities. How have these funds been used in Latin America and what efforts are underway to utilize the National Public Health Institutes in the region for addressing the Zika outbreak?**

**Answer:** The FY2015 emergency appropriations provided $597 million to support national public health institutes and global health security. These funds are critical to meeting the United States commitment to the Global Health Security Agenda (GHSA) to support 30 countries to increase their ability to detect infectious disease outbreaks, respond to outbreaks effectively in order to prevent international transmission. HHS and its interagency partners identified 17 countries for initial implementation of GHSA based on an assessment of both public health vulnerability and readiness of the host country government to commit to achieving specific targets. Given the threat posed by Ebola at the time of the program launch, the initial focus was heavily weighted toward Africa. The 17 countries are: Bangladesh, Burkina Faso, Cameroon, Cote D'Ivoire, Ethiopia, India, Indonesia, Guinea, Kenya, Liberia, Mali, Pakistan, Senegal, Sierra Leone, Tanzania, Uganda and Vietnam. All of these countries have developed a five year plan to achieve GHSA targets, and have begun implementation of activities to strengthen their public health systems and develop their public health workforce in order to reduce their vulnerability to infectious disease threats. The US government is also working with 14 additional countries and 1 region to begin their GHSA planning process. These countries are: Cambodia, Democratic Republic of Congo, Republic of Georgia, Ghana, Haiti, Jordan, Kazakhstan, Laos, Malaysia, Mozambique, Peru, Rwanda, Thailand, Ukraine, and the Caribbean region.

In addition, three additional countries are currently supported by CDC with FY2015 Ebola emergency appropriations to develop or strengthen their national public health institutes. These countries are: Colombia, Guatemala, and Morocco. Having an empowered national-level public health institute with strong management, organizational and communication capacities, invested with the proper legal authorities, are key for a country's ability to sustain infectious disease prevention, detection and response capacities, as well as to carry out other essential public health services. Two regional organizations, the African CDC and the West African Health Organization, are also being supported.

HHS and the global community have been challenged to respond to two urgent public health threats in different parts of the world—Ebola in West Africa and Zika in the Americas. In

addition, MERS continues to raise public health concerns in the Middle East and beyond. Unfortunately, according the World Health Organization, 70% of the 194 countries that have ratified the International Health Regulations (IHR) have reported that they are unable to comply with the IHR requirements that keep the world safe from infectious diseases. GHSA is a critical tool to help increase global capacity to prevent, detect and respond to infectious disease but vulnerabilities remain.

**3. How are HHS-implementing agencies partnering with researchers in the affected countries to develop improved tools for detecting, treating, and preventing Zika virus infections?**

**Answer:** Various components of the Department are partnering with researchers abroad to better prevent, detect, and treat the Zika virus.

General Collaboration and Partnerships

ASPR is leading an HHS Zika Sample Sharing Working Group to identify domestic and international sources of Zika positive clinical specimens to support development and validation of diagnostics and medical countermeasures like vaccines. Through this effort, Zika-related material (virus specimens and diagnostic reagents) has been shared with a number of international partners to foster an environment for rapid global public health response to Zika. ASPR is working closely with CDC to implement a framework for sharing of samples among Global Health Security Initiative members (Canada, European Union, France, Germany, Italy, Japan, Mexico and UK). Access to a wider variety and larger quantity of live virus samples increases the U.S.'s ability to develop clinical diagnostic tools, vaccines, and other public health countermeasures.

CDC is providing clinical and zoonotic specimens to selected laboratories (academia, government, and private sector) to spur the development of diagnostics (lab-based and point-of-care), treatment regimens, and candidate vaccines. Already, we have had a notable success with the development of a next-generation molecular assay that simultaneously detects Zika virus and two others circulating in the region that can confound diagnosis and surveillance. This assay, the CDC Trioplex, has been approved by the FDA for clinical use under an Emergency Use Authorization.

Additionally, CDC is actively working through our established surveillance sites within the Global Disease Detection network (Central America, Africa, and Asia) to monitor and identify Zika cases, deploy current diagnostics and prepare for next-gen diagnostics, treatments, and vaccines in the pipeline. Another active area of collaboration and study are effective mosquito control strategies - a lynchpin of prevention. Finally we are partnering with USAID to conduct joint Zika response activities.

NIH released a Request for Applications for Zika-specific investigations through a process which allows for expedited review to ensure new research is initiated quickly to address the Zika epidemic. See http://grants.nih.gov/grants/guide/pa-files/PAR-16-106.html

Many HHS Operating and Staff Divisions, including OGA, NIH, CDC, FDA, ASPR, among others, are working closely and have participated in Zika coordination activities with WHO and

PAHO. NIH scientists have served as expert advisors and participants at PAHO and WHO convened meetings to help harmonize natural history study protocols and to identify research priorities. HHS is also providing direct technical assistance to PAHO, the WHO and affected countries and working with them to enable access to clinical samples and data to support diagnostic and vaccine development. As NIH-supported research activities proceed, NIH will closely coordinate these activities with PAHO and WHO, as appropriate.

A Selection of Country-Specific Collaboration and Partnerships

With regard to natural history, NIH is attempting to understand several key issues – the impact of Zika on pregnancy and congenital outcomes, the role of prior dengue exposure on the course of Zika infection, and the pathogenesis of Guillain-Barre syndrome. These studies include natural history research in multiple Caribbean, Central and South American sites. The largest project, co-sponsored by Fiocruz (Brazil's leading biomedical research organization), is the Zika in Infants and Pregnancy (ZIP) study, a multi-country, prospective cohort study of ~10,000 pregnant women at sites in Brazil, Colombia, Puerto Rico, Nicaragua and other locales.

FDA has been working with ANVISA, Brazil's national regulatory agency, to assist them in their efforts to expedite the development of diagnostic tests and vaccines for Zika virus.

NIH is supporting development of several vaccine candidates, and plans to begin clinical trials in endemic settings in early 2017. These activities build on existing collaborations with clinical trial sites and partners in the Caribbean and Brazil. Additional HHS-implementing agencies are providing technical and regulatory expertise to support the manufacturing infrastructure in Brazil at the Butantan Institute that facilitates in-country development and production of Zika vaccine candidate(s).

NIH is partnering with FIOCRUZ (a leading scientific institution for research and development in biomedical sciences in Brazil) on a major study focused on Zika in pregnancy.

CDC is providing on-the-ground support in Puerto Rico, Brazil, Guam, Colombia, American Samoa, the US Virgin islands, the Marshall Islands and Panama. This includes conducting studies to learn more about the link between Zika and microcephaly and GBS and collaborative surveillance and research.

In Colombia, NIH is conducting a study to look at the links between Zika virus infection and birth defects.

CDC in Mexico has been working collaboratively with the Secretariat of Health/Department of Epidemiology to analyze municipality level surveillance data on Zika, including case reports in the border states with the US. These reports are published weekly to the border health working group.

NIH/NIAID has just initiated a natural history study of Zika virus infection in Mexico, including assessment of the clinical spectrum of Zika virus disease, antibody responses, and rates of viremia.

Recently, OGA provided leadership for bilateral discussions on Zika with Brazil, Cuba and Argentina, including our collective research efforts. Internationally, HHS is strengthening diplomatic support for U.S. policies on mechanisms for data and sample sharing and fora to advance understanding of the Zika virus in the international scientific community.

4. **And finally, how do the rates of microcephaly in Brazil compare to the rates of microcephaly in other Latin American countries with ongoing Zika outbreaks? Are the rates in Brazil higher, and, if so, what are the suspected reasons for the higher rates?**

**Answer:** The rates of microcephaly in Brazil do appear to be higher than in other countries affected by the Zika virus outbreak. Some of this difference is attributable to phase of the outbreak in Brazil relative to that of other countries - the outbreak began earlier in Brazil, more women were infected early in their pregnancies and have since given birth and thus their babies can be properly evaluated. Other factors may be due to susceptibility to infection and more severe outcome in some populations as well as overestimates of microcephaly in some settings. Studies are underway in other countries (such as Colombia, Panama, Brazil) focusing on microcephaly and also Guillain-Barré syndrome that should provide answers later this summer.