

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3641

May 19, 2016

Ms. Sylvia Mathews Burwell  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Ms. Burwell:

Thank you for appearing before the Subcommittee on Health on February 24, 2016, to testify at the hearing entitled "The Fiscal Year 2017 HHS Budget."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on June 30, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [jay.gulshen@mail.house.gov](mailto:jay.gulshen@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

## Attachment — Additional Questions for the Record

### 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.
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?
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 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.

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?

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 after 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?
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.

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?
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?

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?

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?

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?
12. 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?

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.

13. How many complaints have been filed since 2011 when the enforcement regulations were finalized?
14. How many of those complaints have been resolved? How many remain outstanding?
15. 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)?
16. Is it acceptable if a complaint is never resolved?
17. 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.
18. 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?

19. 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?
- 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:

20. 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.]
21. How many meetings has OCR held on the issue internally?
22. How many interviews or meetings have been conducted with the parties who have filed complaints (or their representatives) or California officials (or their representatives)?
23. 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.
24. How many times have you personally spoken with OCR staff regarding this complaint?

25. 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 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?
26. 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?
27. 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?
28. 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 who 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?
29. 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?
30. 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?

31. I have a question about Medicaid’s approval of funding for designated state health programs through I115 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.
32. 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?
33. 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?
34. 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?
35. 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?

36. Medicare expenditures this year will total nearly \$570 billion, and are expected to roughly double over the coming decade.<sup>[1]</sup> 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.<sup>[2]</sup> 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 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?

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

---

<sup>[1]</sup> <https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf>

<sup>[2]</sup> [https://www.cbo.gov/about/products/budget\\_economic\\_data#5](https://www.cbo.gov/about/products/budget_economic_data#5)

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.

41. 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?
42. 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?

#### **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?

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?

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?
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?
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?

- 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?
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?

**The Honorable Tim Murphy**

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?
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?
3. When and how was the Common Data Platform (CDP) developed for the Substance Abuse and Mental Health Services Administration (SAMHSA)?
4. What was its intended purpose within the grants management system? Please describe:
5. Under which legislative or regulatory authority were CDP-related funds allocated?

6. When and why the solicitation notice for CDP was developed and published?
7. Which grant program(s) is/was CDP intended to support?
8. What were the specific deliverables and tasks required of the contractor in the CDP contract?
9. What procedure(s) were used to develop and award this contract?
10. Which contractor won the bid and is/has administered CDP for SAMHSA grantees?
11. Have additional contracts or contractors been engaged to supplement the original process? If so, why?
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?
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 who were unable to use CDP to report required information?
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?
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?
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?
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?
18. Did SAMHSA relieve grantees of their legal reporting burden?
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?
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?

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

### **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.
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?

### **The Honorable Leonard Lance**

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?

### **The Honorable Brett Guthrie**

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?

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

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.

1. So, could you explain why you think CMS can fund pre-vocational services, but not approve required vocational engagement for the non-disabled population?
2. 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?
3. 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?

### **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?
2. Has HHS actually determined if there was a violation?
3. Can you provide more information about this potential violation?

### **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?
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?
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?

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?
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?
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?

### **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?

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?
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.

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

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?

**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?
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?

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?
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?

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?

#### **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.
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?

#### **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?

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

The President's fiscal year (FY) 2017 budget request includes \$20.2 million in new resources to support cosmetic safety responsibilities at the FDA. According to the budget, these funds will be used to develop regulations and guidance, enhance safety evaluations, and improve communication and outreach to promote greater safety of cosmetic products.

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?

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.
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?

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?

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?

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?

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?

The Drug Quality and Security Act provided FDA with additional authorities to oversee compounding. However, compounded drugs are not regulated in the same manner as traditional drugs and pharmacies are held to different requirements than traditional manufacturers. I continue to be concerned about the safety issues associated with compounded drug products including sterility of the products and facilities in which they are prepared.

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?

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?

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?

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

In 2012, Congress passed legislation from this committee that requires the expansion of the Food and Drug Administration’s Sentinel program to devices, such as cardiac stents and artificial hips. However, the Sentinel program relies on health insurance claims data, which do not indicate the specific device used. Adding the unique device identifier (UDI) to claims forms would benefit the Sentinel program by providing it with the data needed to evaluate the safety of specific device brands. FDA and various post market surveillance experts—including those convened by the agency—have also recognized that UDI in claims would provide data on safety and quality in other ways, such as through enhancements to registries and the establishment of a national device evaluation system. In fact, the newly confirmed commissioner of FDA has said that this is a priority for the agency. However, FDA does not control the claims form, which is regulated by the Centers for Medicare & Medicaid Services (CMS). HHS has alluded to incorporating UDIs into patients electronic health records, but this does not achieve the same goals as including UDI in claims. FDA and CMS have also indicated that pilots could occur, though such an approach would not reveal the benefits in time for UDI incorporation in the next version of the claim form.

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?

Since the opening of the health care Marketplaces, there has been a growing level of interest in shopping for and enrolling in Exchange plans. About 12.7 million Americans either signed up or renewed a Health Insurance Marketplace plan for 2016 that meets their needs and fits their budget, and 85 percent of those consumers will receive tax credits to make their plans affordable. In addition, about 11.2 million more Americans are now enrolled in Medicaid and CHIP than before the ACA.

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?

Secretary Burwell, the ACA expanded Medicaid to low-income adults- some of whom have never had the benefit of health coverage. Yet, not all states have moved forward with this option.

16. Can you please describe the benefits of Medicaid expansion for state economies and providers?

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?
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?
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.
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.

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.

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

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?
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?

### **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?

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.

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.

3. 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?

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.

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

**The Honorable Jan Schakowsky**

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

**The Honorable G. K. Butterfield**

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

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?
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?

### **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?
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?

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?
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?