

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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April 10, 2015

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
Washington, D.C., 20504

Dear Secretary Burwell:

Thank you for appearing before the Subcommittee on Health on Thursday, February 26, 2015, to testify at the hearing entitled "Examining the FY 2016 HHS Budget."

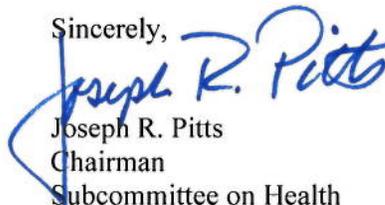
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose 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.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Friday, April 24, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@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. FDA has issued a few draft guidances on some BPCIA implementation topics.
 - a. When does FDA intend to issue final guidance on these topics?
 - b. If FDA has already issued final guidance on any of these draft guidances, with respect to each please indicate when such final guidance was submitted for formal clearance by HHS and OMB and where such final guidance currently resides in the formal clearance process.
2. FDA's 2015 guidance development agenda lists four topics for biosimilars guidance, including such key issues as biosimilar labeling and interchangeability.
 - a. Please indicate when in 2015 FDA expects to issue draft guidance on each of these topics and when it expects issue final guidance on those topics.
3. The BPCIA was enacted in 2010. In 2009 President Obama called for heads of executive agencies and departments to create an "unprecedented level of openness...to promote efficiency and effectiveness." Later that year, Commissioner Hamburg launched FDA's Transparency Initiative noting that "increasing our openness will help us effectively implement our mission". FDA's 2011 "Report on Good Guidance Practices: Improving Efficiency and Transparency", notes the need for reducing the time between issuing draft and final guidance documents. The report describes FDA's good guidance procedures for Level 1 guidances as including the solicitation of input, review and consideration of comments received, and issuance of final guidance. The report further notes that "because guidances are critical to support industry efforts to comply with the law and to develop new products that may benefit the public health, they must be relevant, timely, and easy for stakeholders to find." Clearly, FDA's implementation of the BPCIA, particularly its BPCIA guidance development does not comport with its own policies.
 - a. Please describe in detail the steps you will take this year to align the FDA's BPCIA guidances with FDA's good guidance regulations and policies.
4. Secretary Burwell: You likely know that approximately 50% of the world's supply of Mo-99 is consumed here in the U.S. to ensure that American patients suffering from some of the most debilitating and life-threatening conditions (like cancer) receive state-of-the-art detection and care for their conditions. And yet, there is NO domestic source for Mo-99. In light of the Department's interest in avoiding shortages of drugs and materials that help American patients, and in light of the Department's long-held interest in ensuring safe domestic supplies of essential drugs and materials used by American manufacturers:
 - a. Would you generally support policies that promote domestic supplies of Mo-99?
 - b. Would you be willing to convey to your colleagues at the Department of Energy the value of these policies?
 - c. Would you be willing to work with the Department of Energy to improve and optimize its use of existing and other tools to achieve this result?

- d. Would you be willing to devote HHS staff and resources toward this end, particularly in light of the value of these Mo-99-reliant procedures to Medicare and Medicaid beneficiaries?
 - e. What has the Department done already in this regard?
5. How many Healthcare.gov applicants whose citizenship or immigration statuses were unverified in the first enrollment year (2014) were referred to Medicaid by Healthcare.gov? Please provide the Committee with the number.
6. How many Medicaid and Children's Health Insurance Program (CHIP) applications are still being processed as part of the unresolved pending federal Medicaid applications?
 - a. By when will these applications be resolved? How many Medicaid and CHIP applications that are currently pending and unresolved have been so for more than 45 days?
7. The Drug Quality and Security Act (DQSA) took great steps forward to improve the safety and integrity of the compounded drug products of the drug supply chain in the United States.
 - a. Do you have plans to locate, inspect and, if appropriate, take necessary regulatory action against large-scale compounding pharmacies that that continue to produce compounded sterile injectable drugs in mass quantities, violating provisions of the Drug Quality and Security Act?
 - b. It has been more than a year and a half since the DQSA was signed into law, yet the Committee notes that the number of large-scale compounding facilities who have voluntarily registered as 503B outsourcing facilities has actually declined to 50, from a high of 57 registered facilities. How does FDA intend to monitor these large-scale compounders who continue to operate outside the law, especially when many of them have not elected to voluntarily register as 503B outsourcing facilities under the law? Please outline your specific enforcement efforts to date, as well as efforts to track interstate shipments of compounded sterile injectables.
8. HHS is advancing the implementation of value-based purchasing (VBP) across an array of health care settings in the Medicare program in response to requirements in the Affordable Care Act. VBP refers to a broad set of performance-based payment strategies that link financial incentives to providers' performance on a set of defined measures in an effort to achieve better value by driving improvements in quality and slowing the growth in health care spending. This new program marks CMS' most extensive effort yet to hold hospitals financially accountable for the quality of care they provide and the patient's overall experience.
 - a. If you look at the highest performing providers -- specifically the top 100 recipients of bonus payments in year one of the VBP program -- what were the common characteristics of these hospitals?
 - b. For this same year, what type of hospital was predominantly represented in the top 10 of bonus payment recipients and what is their ownership model for these higher-performing facilities?
 - c. For the same year's top 100 bonus payment recipients, what type of hospital and hospital ownership model was predominantly represented?

9. Your agency has said it is committed to advancing population based models, and coordinated care models. However, by continually reducing Medicare Advantage reimbursement rates, your agency's policies are cutting some of the best existing examples of population-based care and payment, and even of coordinated care. How do you respond to the charge that reductions to Medicare Advantage make it harder for providers to achieve the care models you support and are effectively recreating on the fee-for-service side what is already working in Medicare Advantage?
10. Although the ACA only funded CHIP through fiscal year 2015/September 30, 2015, it included a 23% bump in the federal matching rate for the program beginning in fiscal year 2016. CBO has indicated that the 23% FMAP bump will not increase net coverage, yet this will increase federal spending. In fact, CBO has said that keeping the 23% increase from the ACA would cost taxpayers \$10 billion over a 4 year period. As part of a concession to achieve the bipartisan Medicare Access and CHIP Reauthorization Act of 2015, the legislation retained the 23% FMAP increase. However, the cost of the Administrations' preferred policy—a four-year extension of CHIP with the enhanced match—would cost an additional \$5 billion. How would the Administration justify this gross (vs. net) cost when it would not extend coverage to one more child?
11. Medicaid is an important safety net for lower income Americans? HHS regulations specify that in determining Medicaid and CHIP eligibility under Modified Adjusted Gross Income (MAGI), lump sum income, such as lottery winnings, can only be counted in the month such funds are received. As a result, we have heard from states that they currently have lottery winners currently enrolled in Medicaid—that they cannot disenroll from the program because of these federal rules. In fact, in 2014, one state reported to us that roughly one in four of their lottery winners were enrolled in Medicaid or had a family member in Medicaid. This includes at least one individual who won more than \$25 MILLION, but still was receiving Medicaid services.
 - a. If Medicaid is for lower-income Americans, do you think it is fair for lottery winners to be on Medicaid?
 - b. Would the Administration support a common-sense tweak to the law to allow states to save money and target resources to the truly vulnerable by disenrolling multi-million dollar lottery winners?
12. The President's budget calls for making Express Lane Eligibility permanent. As you know, Express Lane Eligibility is basically an option for states to enroll people in Medicaid or CHIP by using TANF or food stamp enrollment information. However, many of the programs used for Express Lane Eligibility are on OMB's list of high-error rate programs. I know that must concern you as a former OMB official. The CHIP reauthorization in 2009 required HHS to conduct an evaluation to determine the percentage of children that were wrongly enrolled through Express Lane Eligibility. However, to date, CMS has refused to finalize a methodology for states to use to report error rates and is therefore effectively out of compliance with the intent of the law.
 - a. Why hasn't CMS determined a methodology for calculating express lane error rates?
 - b. When will HHS provide Congress with data on the percentage of children that were erroneously enrolled through Express Lane Eligibility?
 - c. Will you commit to trying to recoup for taxpayers dollars spent on individuals who were not eligible for Medicaid or CHIP because of problems with Express Lane Eligibility?

- d. How can the administration call for making Express Lane permanent when it has yet to complete its evaluation of the program?
13. Today, some Medicare Advantage plans focus on enrolling the sickest patients – the ones that have the greatest health care needs. And, through clinically based interventions and care programs, they are helping seniors live longer and more active lives. So I have heard concerns about CMS proposing to cut 2.5 percent out of risk adjusted payments to plans for 2016. In the past, due to serious objections raised over this proposal, CMS has moderated its policy on this issue the last two years. Yet this year, the Administration has once again endorsed an approach that could disadvantage care for the sickest patients. Do you believe that the current CMS proposal on risk adjustment is the right course of action when policymakers are expecting health plans to do more for seniors with the greatest needs?
14. MedPAC evaluated CMS' 2014 risk adjusted policy and found "fairly large systematic errors" for predicting cost of beneficiaries, such that plans with the highest cost seniors could be paid 29 percent less than their actual costs. I certainly don't believe that we should be over-paying plans, but I do think we should pay them fairly for taking care of seniors. CMS' proposal falls far short, in my view. Why did CMS feel it was a good idea to double-down on a policy that effectively penalizes plans for taking care of the sickest patients?
15. According to analysis from the Congressional Research Service (attached), Medicare Advantage plans serve a higher percentage of minority seniors than fee-for-service Medicare providers. So isn't it fair to say that reductions and disruptions in the MA program could disproportionately impact minority seniors?
16. The MA program has a robust quality performance system in place, and plans have been demonstrating industry improvement since the program's inception. However, even with robust outreach and care coordination programs not offered in fee-for-service Medicare, some MA plans focused on serving low-income beneficiaries face unique challenges that make it more difficult to achieve high star ratings compared to plans that do not focus on this underserved population.
- a. Has CMS considered implementing enhanced strategies that consider this difference?
- b. To be fair, shouldn't the same quality standards be measured in fee-for-service Medicare to allow beneficiaries to make an accurate comparison of their choices?
17. The 340B drug discount program has come under increased scrutiny due to numerous reports raising alarm about its rapid growth, evidence of program integrity concerns, and, most importantly, questions about whether the program is serving the needs of the vulnerable populations it should be supporting. We recently had HRSA testify before our Subcommittee. I appreciate that HRSA is looking to provide more clarity and certainty to all stakeholders by issuing comprehensive guidance that will address numerous aspects of the program. How do you intend to enforce these guidance and police program participants, and what can Congress do to help the agency ensure that the program serves the needy as intended?
18. A major benefit provided to non-profit hospitals is their tax-exempt status. In my mind, it would make sense that, in order to qualify for this benefit, certain level of charity care standards should be met and disclosed through appropriate public reporting to ensure that these entities are serving the segments of the population in need. Certain 340B hospitals that receive tax-exempt status also make significant spread on their outpatient drug purchases, so I would expect their charity care levels to be appropriately reflective of those benefits. To the contrary, I read an article the other day about a 340B non-profit hospital garnishing the wages of uninsured or underinsured

patients with unpaid hospital bills. We should do a better job of publicly reporting the amount of revenue that tax-exempt, non-profit hospitals obtain through their participation in the 340B program and then compare that to the amount of charity care they provide. Would you support such a transparency effort?

19. We were pleased to note that the President's budget includes a recommendation to expand the successful Program of All Inclusive Care for the Elderly to serve younger individuals with disabilities and other high-risk populations. We are strongly supportive of this proposal and understand that the Center for Medicare and Medicaid Innovation is considering a demonstration project to do just that. Can you tell us more about the demonstration? What is the agency doing to move this initiative forward? When might we expect an RFP?
20. I also wanted to inquire about revised regulations for existing PACE programs. As you may know, the PACE community has been clamoring for regulatory reforms that would allow them to be more efficient, innovative and nimble. In its fall 2012 Regulatory Agenda, CMS published that a Notice of Proposed Rulemaking to revise the PACE regulation would be issued in July 2013. Since then, this deadline has been extended to December 2013, again to August 2014, and most recently, to Spring 2015. This delay creates numerous burdens for the PACE community and stifles their ability to innovate and grow. What assurances can you offer that CMS will meet its own deadlines and issue a revised PACE regulation this spring?
21. CMS and the Innovation Center have put forth a range of new demonstrations and initiatives to improve quality of care and cost effectiveness. Many of these initiatives are untested and it's unclear whether they'll be able to deliver on their promise. However, there are several proven, successful care models that provide high-quality, cost-effective care for frail seniors, notably the PACE program. Yet the agency appears to be doing very little to promote PACE growth. I'm all in favor of trying new things, but think we're missing a major opportunity to expand on what we know works. What is the agency doing to facilitate the growth of the PACE program?
22. You recently announced your plans to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients by shifting more Medicare dollars toward value based models. I'm a strong supporter of the PACE program and see it as a very high-value, cost-effective model that provides fully integrated care for very frail seniors. What is HHS doing to promote the growth of PACE as part of this initiative?
23. Do you believe it is fair for physician-owned hospitals, which according to both the CMS Value Based Purchasing program as well as charge master data released by the agency are predominantly the higher quality, lower cost provider of health care services in a hospital setting, should be subject to a set of onerous requirements that are preventing them from increasing access to care for Medicare and Medicaid patients?
24. In a previous letter to a member of the Committee, CMS said that as part of the Massachusetts section 1115 demonstration quarterly reports, the state is required to report on the number of individuals who qualified for the Marketplace, Medicaid, or no assistance to CMS. So, how many individuals enrolled in Massachusetts' temporary Medicaid coverage were ultimately determined to NOT be eligible for Medicaid?
25. With regard to Medicaid, can you elaborate on what steps are you taking to ensure that your agency Administrators are addressing and coordinating on an ongoing basis on issues and programs that intersect? With regard to Medicaid, there are financing, quality of care and

program integrity issues that providers and public entities have identified as duplicative and sometimes conflicting (e.g. with FQHCs and Medicaid, with 340B entities and Medicaid, with SAMHSA funded entities and Medicaid funding streams including the new Sec. 223 behavioral health clinics, privacy regulations that prevent care coordination, etc.). From among these, what are you as the Secretary prioritizing? How is the Department managing other issues on an ongoing basis to ensure the integrity of the Medicaid program?

26. What, if any, roles have state Medicaid agencies or states more generally had in the new Medicare Health Care Payment and Innovation Network? Can you describe how the Department plans to incorporate them going forward?
27. How is HHS/CMS planning to work with states to advance community integration initiatives and balancing competing priorities given limited state and federal resources? Specifically, there is a new HCBS rule that requires states to submit and act on statewide transition plans, potentially new payment increases required under a Department of Labor rule, as well as goals that the Department has set to increase access to community based services and new guidance that states must meet pertaining to EPSDT services. Does CMS require specific new authority to support states that seek to improve Medicare and Medicaid coordination using the Medicare Advantage Duals Special Needs Plans? If not, what have you done to accomplish this to date and what are your plans for doing so? What are the barriers to aligning traditional MA, MA-DSNPs and Medicaid?
28. Congress has passed statutory language related to Medicaid provider enrollment issues. CMS has indicated that it is also focusing resources on this issue. What barriers (policy and/or systems) are you encountering to streamline and improve efficiencies for processes within and between Medicare and Medicaid?
29. The President's budget includes several proposals impacting Medicaid prescription drugs and the drug rebate program. In years past CMS held meetings to facilitate and expedite the process between state Medicaid agencies and manufacturers to resolve rebate disputes. Is the agency still doing so? Did this result in a positive ROI for states? The federal government? If CMS is no longer convening this, what other regulatory steps could the agency take to assist states in recovering taxpayer dollars?
30. The ACA included a line extension provision based on this CBO option. The law defines a line extension, for purposes of the rebate calculation, as "a new formulation of the drug such as an extended release formulation." ACA § 2501(d). Congressional intent was clear that it was defining a "line extension" to target those new formulations that are merely "slight alterations" of existing products. House Energy and Commerce Committee Report 111-299, Part I on America's Affordable Health Choices Act of 2009, Section 1742, p. 635 (2009) (describing the law in effect prior to the ACA as permitting manufacturers to circumvent additional rebate requirements "by making slight alterations to existing products, sometimes called line-extensions[.]" (emphasis added). In its *February 2012* proposed rule, *Medicaid Program: Covered Outpatient Drugs* (CMS-2345-P), CMS interpreted the ACA's "line extension" provision broadly and explicitly stated that abuse deterrent formulations of opioids should be considered line extensions. CMS completely ignored the intent of Congress as well as the stated policies of federal agencies including the Office of National Drug Control Policy, the Food and Drug Administration, the Drug Enforcement Administration, and a broad coalition of State Governors, Attorneys General, and elected officials. Yet your *Dec. 18, 2014* response to Energy and Commerce Members states, "HHS shares your concerns about prescription drug abuse, including the misuse and abuse of opioid analgesics, which has resulted in many injuries and deaths across the United States.

Agencies across HHS are committed to partnering with states to address this public health crisis . . .” However, this rationale seems to apply to all agencies within HHS except CMS, as evidenced by the “line extension” policy outlined in its proposed rule. It has now been five years since enactment of the law and three years since the proposed rule was issued by CMS. CMS’s proposal has already caused a disincentive and uncertainty for those who wish to invest in abuse deterrent technology which does nothing to support the battle against prescription drug abuse that affects patients, their families and society at large.

- a. Having now waited three years since the proposed rule, when can we expect a final rule?
 - b. How can HHS reconcile the different positions held by FDA, DEA and ONDCP that manufacturers should be encouraged and incentivized to develop new formulations with abuse deterrent properties, which are in direct conflict with the CMS proposal? How does HHS resolve such significant internal differences even among its own agencies?
 - c. CMS states in its own proposed rule that “abuse deterrent formulations have the potential to decrease abuse of prescription drugs and improve patient and public safety” and acknowledges that the technologies are under development. How is it possible that CMS then argues that these same formulations are considered to be “slight alterations” and included in the definition of “line extension” simply because medications with abuse deterrent properties are not specifically excluded from the definition by statute?
 - d. While the “line extension” provision is part of a much larger CMS proposal to modify the Medicaid rebate program, what reason exists to not finalize the “line extension” portion of the proposed rule now?
 - e. Having now waited three years since the proposed rule, when can we expect a final rule?
 - f. How can HHS reconcile the different positions held by FDA, DEA and ONDCP that manufacturers should be encouraged and incentivized to develop new formulations with abuse deterrent properties, which are in direct conflict with the CMS proposal? How does HHS resolve such significant internal differences even among its own agencies?
 - g. CMS states in its own proposed rule that “abuse deterrent formulations have the potential to decrease abuse of prescription drugs and improve patient and public safety” and acknowledges that the technologies are under development. How is it possible that CMS then argues that these same formulations are considered to be “slight alterations” and included in the definition of “line extension” simply because medications with abuse deterrent properties are not specifically excluded from the definition by statute?
 - h. While the “line extension” provision is part of a much larger CMS proposal to modify the Medicaid rebate program, what reason exists to not finalize the “line extension” portion of the proposed rule now?
31. As you know, on August 22, 2014 the California Department for Managed Health Care (DMHC) issued a directive mandating that all plans under DMHC authority immediately include coverage for all legal abortions. This mandate is a clear violation of federal law and the Weldon amendment – which provides civil rights protections and prohibits funding to government entities discriminating against health care entities for following their conscience.
32. We have spoken directly about my concern that the conscience rights of Americans are being violated here. 133 member of Congress have written to you expressing their concern. In addition, Congress acted on this very issue in the FY2015 appropriations bill and directed your Department

to expedite resolution of this case. Madame Secretary, with all due respect, my patience is wearing thin. Will HHS finally take action to protect the conscience rights of Americans facing discrimination due to the actions of the California Department for Managed Health Care?

The Honorable Joe Barton

1. In 2009, I authored the Biologics Price Competition and Innovation Act (BPCIA), along with Congresswoman Eshoo, that provided a pathway for biosimilars. That bill ultimately became part of the Affordable Care Act in 2010. I am pleased that according to public reports, there are five biosimilar applications pending before the Food and Drug Administration (FDA), with the first potentially to be approved as early as next week. However, Congress intentionally left a number of the final scientific questions open to guidance—these include; the criteria needed to establish interchangeability, whether these products would have the same or a distinct name and whether the Agency would allow for indication extrapolation. Despite the FDA publicly stating multiple times, including before this Committee, that we could expect guidance before the end of the year on these enormously complex, but critical patient safety questions, we have yet to see this guidance.
 - a. Does the Agency intend to issue guidance as encouraged by Congress so that patients, providers, payers and Congress could have an opportunity to review and comment?
 - a. If so, when can the Committee expect to see such guidance?
 - b. If not, please explain that decision and comment on how biosimilar manufacturers will know what the Agency expects without this insight?
2. The patent provisions contained within BPCIA were carefully crafted after much debate among all stakeholders. They create a two-round scheme for resolution of potential patent disputes. The first opportunity for patent litigation is designed to provide resolution of at least some relevant patents far in advance of a biosimilar approval. The mandatory nature of this step is evident in two provisions of the BPCIA:
 - a. Under section 351(l)(1), “[w]hen” the biosimilar applicant submits its application, the applicant “*shall*” provide certain representatives of the innovator with “confidential access” to the biosimilar application and information about the biosimilar manufacturing process, unless the applicant and innovator “otherwise agree[]” to an alternative arrangement for information exchanges.
 - b. Under section 351(l)(2)(A), the applicant “*shall*” provide the biosimilar application and manufacturing process information to the innovator within 20 days after FDA notifies the applicant that the biosimilar application was accepted for review.
 - c. Based on the complaint in the Amgen case, “Sandoz opted not to provide Amgen with Sandoz’s biosimilar application within 20 days of the FDA’s notification of acceptance.” As the author of this law, I can affirmatively attest this exchange of information was not meant to be optional as evidenced by the word “shall.” I am disappointed to witness the lack of enforcement of these provisions play out in this manner. I am further disappointed to read that Sandoz will be delayed in the launch of their biosimilar (assuming it is approved March 8 on their user fee date) due to this pending litigation.

- i. In order to assist you in ensuring the letter of the law is being followed, would you consider a patent certification process?
- ii. And if not, what action/s is/are the Department and Agency able and willing to take? If none, please explain.

The Honorable Ed Whitfield

1. The President's budget for HHS includes almost \$100 million in new funding to support efforts to reduce the prevalence and impact of opioid use disorders. In your prepared remarks, you state that the budget includes a proposal that requires states to track high prescribers and utilizers of prescription drugs. According to HHS, one of the most promising clinical tools to address prescription drug abuse are state prescription drug monitoring programs (PDMPs). One method that has been suggested to increase use of PDMPs is to leverage health information technologies such as electronic health records and clinical decision support tools that would streamline access to the PDMP system. I am working on reintroducing NASPER reauthorization which would improve interoperability between state PDMPs.
 - a. Could you further discuss how improving the interoperability between state PDMPs and the workflow systems of the states' provider community help achieve the department's goal to reduce prescription drug and opioid abuse?
2. As you may know, skin cancer rates in the U.S. continue to grow. In July 2014, the U.S. Surgeon General issued *A Call to Action to Prevent Skin Cancer* which states that skin cancer impacts 5 million Americans each year at a cost of over \$8 billion. The Call to Action directs the federal government to work with stakeholders on strategies to prevent skin cancer; however that does not seem to be the message your agencies are conveying to the American public. Last year, my colleagues and I responded to this public health crisis by passing the bipartisan **Sunscreen Innovation Act**. Yet, the FDA has now failed to clear any of the 8 backlogged applications, which have been in use around the globe for almost 20 years, including rejecting an application for a sunscreen that has already been approved under an NDA and is currently being safely used across the United States.
 - a. What are you doing to resolve this inconsistency between the Surgeon General's Call to Action declaring skin cancer "a serious public health concern" and the FDA's declaration that the United States is closed for business for new preventative sunscreen products that are widely used around the world?

The Honorable Michael C. Burgess

1. CMS's press release touting the success of the recent ICD-10 end-to-end testing provided no transparency in the actual data. Providers remain concerned that CMS is not, and will not, be prepared come October 1. Is there any reason CMS could not release the actual data from their testing?
2. In the last two years CMS has cut Medicare Advantage nearly 10 percent, and CMS proposes yet another year of additional cuts to the Medicare Advantage program. As a result, I am hearing from seniors in my district that benefits are being reduced, they no longer have access to their preferred physicians, and their out-of-pocket costs are increasing. In fact, a recent analysis from Milliman found that out-of-pocket costs for Medicare Advantage beneficiaries increased by as much as \$761 since 2012. I am concerned that the additional proposed cuts are likely to exacerbate the problems my constituents are currently experiencing, such as reduced benefits and

higher out-of-pocket costs. Can you comment on the impact additional cuts to the Medicare Advantage program will have for the seniors in my district?

3. Unfortunately, Medicare Advantage plans are unavailable in more than 200 counties this year, an increase from just 55 counties in 2012. I am concerned that the proposed new Medicare Advantage cuts – both in CMS’ recent rate notice and the budget – will continue to increase the number of counties not offering Medicare Advantage as an option in the future. What actions are you taking to ensure continued availability of Medicare Advantage plans across the country in the future?
 - a. Can you send us the details on this troubling development? How many counties in America do not have access to Medicare Advantage plans?
 - b. Can you please let us know how many in each state? Can you send the committee a breakdown by congressional district?
 - c. Is CMS in possession of evidence that shows a disproportionate impact on rural communities?
4. When FDA Commissioner Hamburg was before this Committee last April, I asked her a direct question — has anyone outside FDA provided the agency with substantive suggestions or recommendations with respect to biosimilars guidance? Her answer was neither direct nor reassuring. So I would like to ask you whether anyone in your Department outside FDA or at the White House has been engaged — directly or indirectly — in the guidance process. This law was enacted as part of Obamacare almost exactly five years ago and yet we have zero final guidance from FDA on the incredibly important challenges present in providing safe biosimilar products to Americans. Nothing on naming. Nothing on interchangeability. Nothing on extrapolation. I fear that politics have found its way into this process and I would like you to ensure this Committee — which passed this provision by an overwhelming bipartisan vote — that you will ensure that the scientists at FDA are able to do their job and that sensible guidance will be quickly forthcoming on these many topics. Patients and the doctors and other health care professionals are not being afforded the opportunity to comment on specific policy proposals from the FDA.
5. When will HHS be finalizing its recommendation to set the level for optimally fluoridated water at 0.7 parts per million? We supported the proposed change and have been waiting four years to see a final recommendation.
6. The HHS Oral Health Coordinating Committee (with representatives of all DHHS agencies) has submitted a federal oral health framework to you for your signature. As public/private collaboration is important, when will this framework be available to help guide our collective efforts?

The Honorable Leonard Lance

1. I’ve recently heard from a number of home health agencies in my district concerning the 2015 Home Health Prospective Payment System final rule. As you know, the rule now requires a physician to have sufficient documentation in his/her medical record to support the physician's certification that the patient is "homebound" and in need of skilled care. Home health agencies in New Jersey recently convened a state-wide meeting to discuss this new rule and attempt to develop processes for compliance. However, many questions remain as to how physicians and home health agencies can effectively comply with the new rule in addition to a general lack of education about the new requirements.

- a. How will CMS ensure that home health agencies, referring physicians, and Medicare Administrative Contractors are sufficiently educated about the new documentation rules and how to use a standardized template?
- b. Will CMS provide a transition period during which home health agencies will not be subject to Additional Documentation Requests or other audit procedures related to face-to-face documentation requirements?

The Honorable Pete Olson

1. Secretary Burwell, the last time Congress took a coordinated, prolonged, and thoughtful look at the problem of diabetes was in 1974 with the passage of the National Diabetes Mellitus Research and Education Act (P.L. 93-354) establishing an intergovernmental diabetes commission to focus on a long range plan to combat diabetes. Forty years ago, there were 4.78 million people in the United States diagnosed with diabetes. Today, there are 29 million people with diabetes accounting for nearly 10% of the population. Even more shocking, 86 million are living with prediabetes, more than the entire population of Germany. Because of these escalating statistics, diabetes is now costing the United States \$322 billion a year in medical expenditures and lost productivity, up \$100 billion from \$218 just five years ago. And one out of three Medicare dollars is currently being spent on people with diabetes. These numbers are only going to get worse, with the potential of bankrupting this government, unless we again take a coordinated approach to combating this chronic disease. There are currently, 35 federal agencies that have programs or policies related to diabetes. Yet these programs are largely uncoordinated and may be redundant. Legislation has been introduced, the National Diabetes Clinical Care Commission bill, that would again establish a commission to evaluate current programs and makes recommendation to Congress on how best to coordinate and leverage these programs to tackle diabetes. Last Congress, this legislation had 183 bipartisan Members of Congress supporting it.
 - a. My question to you is do you support a federal, coordinated approach to combating diabetes?

The Honorable Gus Bilirakis

1. The home health community and the seniors it serves are feeling the very real effects of the 4-year rebasing adjustment called for in ACA. The final rule issued to implement rebasing assessed the impact of rebasing in 2014 only – not in 2014, 2015, 2016 and 2017—despite the law requiring a 4-year impact analysis be conducted. In the Labor/HHS Appropriations Act for 2015, Congress required CMS to “provide a public analysis related to rebasing Medicare home health agencies within 90 days of the enactment” of the act.
 - a. Has CMS completed a four-year analysis to project the impact of the 3.5 percent annual rebasing adjustment on all home health provider types, regardless of location or outliers?
 - b. Has CMS completed the public analysis required within 90 days of the enactment of the Labor/HHS Appropriations Act for 2015?
2. Secretary Burwell, Congress and the Administration have been very supportive of efforts in the private sector to produce abuse deterrent formulations of prescription opioid painkillers. In 2013, the FDA published draft guidance to industry regarding the development of abuse deterrent

formulations. In that draft guidance, FDA requires abuse deterrent formulations to address "relevant" routes of abuse. One concern that has been raised is that FDA's application of this so-called "relevance" standard suggests that certain routes of abuse, i.e. ingestion, are more "relevant" with respect to abuse deterrence than formulations which seek to deter abuse by inhalation or injection. We know, and the FDA acknowledges, that drug abusers will pursue other routes of abuse once one has become blocked or undesirable.

- a. Can you describe the FDA's "relevance standard" and is it FDA's intent to deter or privilege the development of abuse-deterrent opioids for certain routes of abuse?
 - b. In addition, does the FDA have any intention on providing clarity with regard to when and how this relevance standard will be applied?
 - c. When does FDA expect to issue final guidance on abuse deterrent formulations?
3. I previously wrote to CMS Administrator Marilyn Tavenner to express concern over CMS's pricing for certain laboratory tests that represent critical advances in cancer care. My concern is specifically with the Medicare payment amounts CMS established for certain in situ hybridization (ISH) tests. It is my understanding that CMS may have made a number of mistakes in determining the payment amounts for these tests. Mrs. Tavenner responded to my letter stating that future changes should alleviate my concerns; however, CMS is allowing these harmful changes to remain in effect in the present. If these errors remain uncorrected, and the Medicare payment amount is below the cost of purchasing and furnishing the test, laboratories will be unable to offer these services and further investment in research in this area will be discouraged. I understand from CMS's reply that the Agency will be considering the comments it has received on this issue in setting rates for CY2016.
- a. I would like to know more specifically about the data on which CMS will be relying when it sets rates for these tests for 2016 and would like assurances that the Agency will be transparent to stakeholders about all of the data inputs the Agency is relying upon to establish these rates.
 - b. Please explain to me why CMS is unable or unwilling to make mid-year revisions sooner than the CY2016 rulemaking?

The Honorable Renee Elmers

1. FDA officials stated several times last year that we would see a number of pending guidance documents on biosimilars before the end of the year, including guidance on interchangeability and naming, but we have not seen those and to date, we have five pending biosimilar applications before the Agency.
 - a. Can you please inform the Committee when we can expect to see guidance on interchangeability, naming, labeling and indication extrapolation?
2. The Center for Drug Evaluation and Research (CDER) Guidance Agenda for 2014, listed a number of draft guidances related to biosimilars that were under development. Those same guidance documents are listed on CDER's Guidance Agenda for 2015.
 - a. When can we expect FDA to release guidance on key public health issues related to implementation of biosimilars?

3. BARDA maintains a stockpile of roughly \$1.75 billion worth of Pandemic Influenza vaccine. Yet this year you have only budgeted about \$20 million – or 1% of the stockpile – in replenishment and maintenance of these vaccines. In fact, for several years now, the Pandemic Influenza stockpile has not been properly maintained or replenished, and the request you provided Congress explicitly stated insufficient funding has resulted in a gap in US preparedness against pandemic influenza. How does BARDA plan to maintain and replenish the stockpile of influenza vaccines given the dynamic nature of the threat and the age of the stockpile assets, many of which are now a decade old? What funds are you planning to use? Would the H5N1 vaccines in the stockpile – which were acquired ten years ago – be effective against the H5N1 influenza strains circulating today? As we saw in this year’s seasonal influenza vaccine mismatch, these strains can drift which resulted in significant reductions in vaccine effectiveness.

The Honorable Susan Brooks

4. The Emergency Supplemental funding on Ebola allowed \$157 million specifically for BARDA to develop countermeasures for Ebola. I understand that no task orders have been awarded by BARDA for any Ebola Drugs, or any medical countermeasures, including proposals that were submitted by the HHS manufacturing centers over six months ago. We heard during a 60 Minutes interview last week that that this process has been plagued by bureaucracy. This is ultimately your responsibility. What is the status of Ebola countermeasures via BARDA efforts and, specifically, what is the status of all task orders for the centers?
5. Is HHS going to allocate any component of the \$700 million in Supplemental Ebola funding at your discretion to BARDA to develop Ebola countermeasures? As I understand it, BARDA will have to raid a significant (at least \$500 million) amount of the BioShield Reserve Fund established for medical countermeasures to pay for Ebola drugs and vaccine development in the pipeline. This strategy will significantly weaken our state of preparedness. How engaged are you in making sure that BARDA has what it needs – in authority, leadership, funding, and responsive contracting practices -- to deliver on the critical work it was created to do, not just for Ebola but for every threat?
6. As you know, in 2013 Congress reauthorized \$2.8 billion in funding for Project BioShield’s Special Reserve Fund (SRF). For over a decade, the SRF has created a market for biodefense medical countermeasure development and signaled the government’s commitment to procure MCMs against national security threats. Each year, SRF funds are used to stockpile millions of doses of drugs and vaccines against threats like anthrax, smallpox, nuclear radiation – and hopefully soon against Ebola. HHS recently released the long-awaited 5-year budget plan outlining all the MCM projects that will rely on this funding. Unfortunately, only \$510 million has been appropriated to the SRF over the last two years. We are now on pace to fund less than 50% of the federal government’s most important biodefense program.
 - a. Can you please describe the impact to our medical countermeasure enterprise if the SRF is not fully funded?
 - b. At this pace, the SRF will be funded \$1.5 billion below its authorized level in 2013. What medical countermeasures will we lose as a result of this dramatic funding shortfall? How will you pick and choose which MCMs in HHS’ 5-year budget to abandon?
 - c. What is the Administration doing to work with Congress to avoid this outcome?

7. I want to commend you and Dr. Lurie at ASPR for the work you put into the 5-year budget plan Congress required as part of PAHPRA. Without objection, I would like to enter this plan into the record. This type of transparency and planning is what will help the MCM enterprise be successful in the future – it is critical to attracting more private sector partners and ensuring you have the resources you need.
 - a. Given how important this budget plan is both to Congress and your MCM partners, can you commit to ensuring this plan is completed on an annual basis as required by PAHPRA?
 - b. Will HHS also make this plan available to the public to provide greater clarity to your MCM partners?

8. Madam Secretary I noticed in the President's budget submission that you all outlined a list of chronic diseases (P. 39 of attached Budget in Brief document) that are important to combat. Within that list is obesity, which was recognized by the American Medical Association on June 18, 2013 as a chronic disease. As we've learned more about obesity we know that for some it's not as simple as more exercise and less food. For some people that may be enough -- but others need more comprehensive interventions. As such, Medicare recognizes this need and provides nutrition counseling and even bariatric surgical procedures. However, as you noted in your letter dated December 29, 2014 to now Senator Bill Cassidy you do not "believe we can construe the statute to permit basic Part D coverage to include FDA-approved weight loss drugs used to treat obesity, because these drugs are agents used for weight loss."
 - a. Would you agree that if obesity is a major threat to our country's future that we should provide all treatment options for Medicare beneficiaries?
 - b. Do you believe that if we reduce the obesity rates that we could save money in the near and long term?
 - c. Would you commit to working with me and the Committee to find a way to provide all options to Medicare beneficiaries, including making the necessary legislative changes?

The Honorable Gene Green

1. Per regulation [Section 422.112 (a)(1)], Medicare Advantage Organizations are required to "maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served." CMS released its draft 2016 Call Letter for Medicare Advantage Organizations in which it announced its intended development of a new audit protocol for assessing the availability and accessibility of network providers in Medicare Advantage plans.
2. It is my understanding that plans, both Medicare Advantage Organizations and Qualified Health Plans in the Exchanges, may be using specialty designations to assess network adequacy, which may be insufficient to capture whether a network includes physicians who are highly specialized in their fields.
3. Can you explain how this new audit protocol will work and whether HHS considered how network adequacy for subspecialists will be assessed, particularly for those subspecialists who do not have a specialty designation that is recognized by Medicare and other payers?

4. The President has announced a major initiative to combat the growing threat of antibiotic resistance. The importance of this issue is well established, and the recent rash of infections and deaths in hospitals in California and North Carolina from CRE, reminds us of how dire the situation is. The strategy the President has laid out calls for a comprehensive approach to combatting antibiotic resistance which includes a focus on drug development.
5. Representative Shimkus and I have been working on legislation to require FDA to establish a new regulatory pathway to encourage the development of antibiotics to treat serious and life-threatening infections for which there are few or no other option. This legislation has the support of antibiotic developers, public health groups, and provider groups, among others. Can you speak about the importance of developing new antibiotics as part of a comprehensive effort?

The Honorable Ben Ray Lujan

1. Madam Secretary, this past December, CMS awarded the last round of Exchange Establishment grants. Unfortunately, my home state of New Mexico was the only state to apply and not receive funding. As a result, the state will likely delay its transition to a full state-based exchange by a couple of years. This greatly concerns me. New Mexicans deserve a state exchange that meets their unique health needs.
 - a. Secretary Burwell, can you detail the opportunities now available to my state to support the eventual rollout of a New Mexico Health Insurance Exchange?
 - b. Are there Medicaid grants opportunities? If so, would CMS actively engage with the Exchange and the State of New Mexico to entertain all possible avenues?
 - c. And, are New Mexicans' advanced premium tax credits at risk with the upcoming Supreme Court decision?
2. Madame Secretary, I do want to raise an issue that is of great concern to my constituents. It has now been over 18 months since the State of New Mexico claimed credible allegations of fraud against 15 behavioral health providers - resulting in their eventual closure and replacement by 5 Arizona behavioral health providers. This transition and turmoil has raised significant concerns about access to care, particularly in light of recent reports that the new providers are financially unstable. In fact, one provider is already pulling out of the state. The recently elected New Mexico Attorney General has also released the audit that led to the suspension and it shows a lack of underlying basis for many of the allegations of fraud. My staff has had several meetings with CMS and I am very concerned that we are not making progress.
 - a. When Payment suspensions are put into place, what can CMS do to ensure states are acting in good faith?
 - b. Given the vulnerability of the affected population, what can HHS/CMS do to protect access and quality of care for this population?
 - c. What is CMS doing to stop the reoccurrence of this happening, both in New Mexico and in other states?
 - d. Can I have your commitment that HHS and CMS will work with me to ensure that the health needs of New Mexico's most vulnerable populations are met? Will you meet with our delegation to discuss this?

The Honorable Tony Cardenas

1. Preserving access to prescription drugs that work for every senior is very important to me.
 - a. What proposals in the President's budget would increase access for seniors? Also, I would like to ask unanimous consent to submit the following letter for the record sent to my office that lays out the issue clearly.
2. Latino children are among those most at risk for health problems because of poor access to health coverage and affordable health care services. In fact, in 2012, Latino children represented two-fifths of the uninsured children in the U.S. and are more than twice as likely to be determined in fair or poor health by their parents. My district is home to many families that are one doctor's visit away from bankruptcy. And in a report published last year by your department, eight in 10 uninsured Latinos may qualify for Medicaid, CHIP or lower costs on monthly premiums in the Health Insurance Marketplace.
 - a. In the President's budget, CHIP funding is extended for four years, similar to a bill that I introduced by the Ranking Member with myself and all of my colleagues on this subcommittee. Can you elaborate a little more about how CHIP is important for kids from these historically underserved communities?
3. In the President's budget request, he highlights the need to foster a more diverse health workforce by providing support for individuals from disadvantaged backgrounds, including underrepresented racial and ethnic minorities.
 - a. Can you talk about the benefits of having greater diversity among health professionals? Particularly among underserved communities, like the ones in the San Fernando Valley?
4. During the first year of open enrollment, my office helped sign up over 1,000 families.
5. I met a man, providing for a family of four, on minimum wage (\$9/hour). A friend recommended he learn more about the plans offered through our state exchange, Covered California, and he seemed visibly unsure about what he was signing up for. He was already paying \$60 a month for an individual plan provided through his employer, while his family was going without coverage. Even that individual plan was too expensive for him. When he found out how much he could afford through the exchanges and with the help of subsidies, he was shocked and had tears in his eyes. This man's story is not unique. There are so many other Latino families in need that can benefit from implementation of the ACA.
 - a. What is the Administration doing to make sure more Latino families sign up for the ACA and how is that reflected in the President's budget?
6. I believe that the Affordable Care Act is good for small businesses. They are not subject to the employer responsibility provision, but those that choose to offer coverage have increased purchasing power and consumer protections not available in the past. And some small businesses are eligible for tax credits to help cover the cost of employee insurance benefits.
 - a. Secretary Burwell, could you please describe the benefits that are available to small businesses from the ACA?
7. I am concerned that the patient costs of the exchange plans for patients with chronic conditions are untenable, and not in line with the ACA's intent that they resemble employer-sponsored plans. According to an analysis by an actuarial firm that should be published in the next few weeks, member cost sharing for individuals with diabetes taking insulin or GLP-1 drugs was 1.5 to 2.1 times more in a silver exchange plan than in a typical employer plan.

- a. What are you doing to ensure that exchange plans meet the needs of individuals with chronic conditions?