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RANKING MEMBER

ONE HUNDRED THIRTEENTH 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

August 22, 2013

The Honorable Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Tavenner:

Thank you for appearing before the Committee on Energy and Commerce on Thursday, August 1, 2013, to testify at the hearing entitled "PPACA Pulse Check."

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 by the close of business on Thursday, September 5, 2013. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to [brittany.havens@mail.house.gov](mailto:brittany.havens@mail.house.gov).

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

Sincerely,

  
Fred Upton  
Chairman

cc: Henry A. Waxman, Ranking Member, Committee on Energy and Commerce

Attachments

## **Attachment 1—Additional Questions for the Record**

### **The Honorable Joseph R. Pitts**

1. There has been concern voiced from the patient and provider communities that agency actions related to the ESRD Community, reflected in the FY2014 Proposed Physician Fee Schedule Rule, would reduce provider payments well below the cost of providing such care. Specifically, I have been told that these proposed reductions do not take into account the costs of doing services in real time and therefore would result in providers being reimbursed below cost. To that end, I would like answers to the following questions
  - a. How up to date is the cost data CMS used to justify reductions to dialysis reimbursement under Medicare? Please explain.
  - b. Does CMS expect that the cost data used will be updated in the next year? Please, in the context of a detailed response, provide a yes or no answer.
  - c. Congress passed the American Taxpayer Relief Act (ATRA) on January 1, 2013, which in part required the agency to modify ESRD payments. Providers of services have suggested that this modification will result in negative margins. Does CMS have data that either supports or refutes this contention? If it does not, do you believe the concerns of negative margins are valid?
  - d. When preparing its proposed rule, did CMS identify any subgroups of patients that might be negatively impacted by the proposed rule? If not, did CMS study the impact that the proposal might have on patient subgroups? Please explain.
2. In the proposed rule for the 2014 Hospital Outpatient Prospective Payment System (HOPPS), CMS packages together certain skin substitutes, including certain skin substitutes that were approved by FDA with others that were not. How did CMS take the FDA approval process into account when drafting its proposed rule?
3. For states that have deferred to a federally facilitated exchange, when does the Medicaid Maintenance of Effort (MOE) expire?
4. Will you be issuing further guidance on the Medicaid (MOE) and its expiration for states that have deferred to a federally facilitated exchange? If so, when?
5. Please provide the national average error rate associated with Medicaid eligibility errors for Fiscal Years (FY) 2012, 2011 and 2010? Please describe such errors as they related to Medicaid eligibility determinations.
6. Please provide the amount of overpayments associated with Medicaid eligibility errors for FY2012, FY2011 and FY2010?



7. CMS and CMMI have acquired by this point a good deal of experience administering the ACO and Medicare Shared Savings Programs. For example, CMMI recently announced results from the first year of the Pioneer ACO program. What remains unclear are the specific monitoring activities you have undertaken to assess ACO performance and to ensure beneficiary access to high quality care.
  - a. Would you please describe the details of the monitoring program you have in place to ensure that beneficiaries assigned to ACOs under the Shared Savings Program or other CMMI initiative have access to the care they need? Have you done claims analysis, medical record audits of persons assigned to ACOs and what have been the results?
  - b. Your report on the first year of the Pioneer ACO program compares ACO quality performance on several dimensions of care to findings of published literature—some of which, as cited by the report, is over a decade old. Are you also comparing patients inside and outside ACOs, in real time, to detect differences in their use of specific services, referrals to specialists, etc. and, if so, what have you found?
  - c. What have surveys of providers revealed about ACOs and the care they provide? Do you have a schedule for surveying beneficiaries assigned to ACOs on a regular basis?
  - d. What are your plans for monitoring the care that will be provided to beneficiaries by the approximately 450 providers you anticipate will participate in CMMI's bundling initiative?
  - e. I haven't been able to find very specific information about the quality measures that will be used in the Bundling Initiative. Could you please describe the quality measures that will be used in each of the four models of the Bundling Initiative?
8. CMMI recently announced the results from the first year of the CMMI Pioneer ACO program. According to your report, 13 of 32 Pioneer ACOs produced shared savings with CMS. However, several of these "Pioneers" will be transitioning into the Medicare Shared Savings Program, and two will leave the ACO program entirely.
  - a. How have the 13 Pioneers with shared savings used their savings? What portion of an ACO's savings was shared with providers participating in the ACO? What is the range in amounts received by individual providers?
  - b. Can you identify the participants that will not be returning to the program and their reasons for doing so?
  - c. Can you elaborate on the results of the first year of the Pioneer ACO program and the impact on patient access to new technology?

9. The ACO program requires providers to meet only 33 quality measures to qualify for shared savings. These quality measures are mostly process measures as to whether specific actions were taken in the face of a certain set of clinical circumstances.
  - a. While important, the 33 ACO quality measures are hardly sufficient to fully assess care. In fact, there are huge gaps. There are no quality standards for cancer treatment (only cancer screening). There are no quality standards for stroke. There are no quality standards for Alzheimer's disease, for Parkinson's disease, or for any neurological condition. There are no standards for arthritis. The list goes on and on. Do you believe that these few measures are sufficient to measure the quality of care provided to the millions of beneficiaries enrolled in this new ACO program? Do you anticipate changes to the quality measures in the near future to address some of these gaps?
  - b. Is it possible that a physician's quality measure score could be penalized for using more clinically appropriate technology that is in the best interests of the patient? Will you provide a mechanism to adjust the quality scores for providers who deliver advanced care not yet reflected in the quality measures?

**The Honorable Greg Walden**

1. In 2010, the local Chamber of Commerce in Bend, Oregon, received approval to sponsor its own Multiple Employer Welfare Agreement, or MEWA, health plan for member companies.

With the approval of this plan, the Chamber was able to offer a locally tailored health plan to 2000 employees working for 141 businesses in Central Oregon.

In coordination with this, I also sent a letter to the Department of Labor and the Department of Health and Human Services, dated March 31, 2010 asking that both agencies protect this plan, and plans like it, so that those employees truly could, as the President said, can keep their plan if they like it.

I greatly appreciate Secretary Sebelius' response to my letter, in which she stated that she was "pleased that the MEWA designation has worked for small business owners in your district."

In 2013, however, I received a letter from the facilitator of this plan that under new federal guidelines it is not likely to qualify.

Will HHS commit to doing all they can, by for instance working with the Department of Labor, to ensure that this plan is able to keep offering coverage to these employees, so that they truly can keep the coverage they like?

2. Patient activation and engagement, in my view, are extremely important to ensuring high quality care for patients and families. Giving patients, providers, and families, the tools to best manage their own health care decisions simply makes the most sense. In fact, research



has shown that patients who are more engaged in their health care demonstrate better outcomes.

The health law made a lot of references to patient activation and engagement, and I hope that the Administration will hold true to that promise. For example, Section 3022\1899 (2) (G-H) requires the establishment of quality and performance measures for Accountable Care Organizations (ACOs) pertaining to patient engagement, patient-centeredness and the use of patient and caregiver assessments. We're all aware of the recent struggles with the new ACO program, both in the first phase and now even with the new, supposedly more improved program.

Additionally, measurement of activation using the Patient Activation Measure is required for organizations funded through section 3026, the Community Care Transition Program CCTP). I am interested in hearing about how CMS is using patient engagement to improve care, reduce costly admissions through the CCTP; and how patient engagement is utilized to increase patient success through ACOs.

Has CMS collected data on the impact that patient activation measurement has on improving outcomes and lowering costs for ACOs and CCTP participants? As the CMS continues to test the impact of arrangements to help organizations achieve the goals of providing better care to patients and reducing costs will it require the measurement of patient activation and subsequent patient engagement efforts? What are other opportunities for CMS to utilize patient activation and engagement to secure improved outcomes?

**The Honorable Michael C. Burgess**

1. The Medicare Payment Advisory Commission projected ESRD margins to be around 3-4 percent. The 9.4 percent cut proposed by the Agency eliminates that margin and would result in negative margins, if not for every facility, at least the majority of them. Do you think it is possible for entities where 85 percent of the patients are Medicare beneficiaries to continue to provide quality care if they are getting reimbursed by Medicare below the cost of providing care?
2. Many low-cost glucose meters are the primary source of device inaccuracies in the market while many commercially marketed meters, do not meet current International Standards Organization (ISO) standards. Given the inaccuracies of blood glucose meters, are you concerned that CMS' Medicare Competitive Bidding Program is creating a dynamic where decisions are made on price alone and such decisions will put patients at risk?
3. The HHS Office of Inspector General issued a report in November 2012 entitled *Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas*. The study shows a dramatic reduction –18 percent- in claims for testing supplies associated with Competitive Bidding. If only 1 percent of the reduction in claims is due to diabetes patients stopped testing, the drop in claims is clinically significant and could be potentially devastating for the diabetes community and for our health care system. What is CMS doing to determine the reason for the dramatic reduction in claims?



4. The need to have a face-to-face encounter or direct interaction with a physician is important and needed. The question is why did CMS choose the current method for implementing the face-to-face requirement? As you are aware, prior to billing for Medicare home health services, home health agencies must obtain a signed and dated form from the physician which outlines the full plan of care. This comprehensive form, known as the 485 form, includes the complete plan of care which will be delivered by the home health agency.
  - a. Since this form is completed and signed by the physician, would CMS consider accepting a modified version of this form and or an attestation of a face-to-face from the physician to comply with this regulation? Or at a minimum why does CMS not offer a sample format or one consistent form for all physicians to use that satisfies the face-to-face documentation requirement?

### **The Honorable Marsha Blackburn**

1. On July 3, the Centers for Medicare and Medicaid Services (CMS) issued a proposed national coverage decision memorandum outlining its Coverage with Evidence Development (CED) for positron emission technology (PET) beta-amyloid imaging for dementia and neurodegenerative disease. This decision denies Medicare coverage for an FDA approved technology for Medicare patients. How does limiting access to diagnostic technology fulfill the Obama Administration's National Alzheimer's Plan, which makes early diagnosis a priority?
2. Alzheimer's disease is estimated to cost the nation \$200 billion this year alone, and about 70 percent of that - \$140 billion – is shouldered by taxpayers in Medicare and Medicaid costs. This is projected to exceed 1.2 trillion by 2050 in the absence of interventions. Leading experts as well as our government through the National Alzheimer's Plan (NAPA) have stressed the value of an early and accurate diagnosis in treating Alzheimer's to prevent costly and time-consuming misdiagnoses, as well as begin proper care planning earlier.

I am wondering how a recent draft decision by CMS to deny Medicare coverage of an FDA diagnostic tool for Alzheimer's disease is in the best interest of patients or taxpayers who would benefit from accurate diagnosis and more appropriate medical treatment plans based on an early & accurate diagnosis.

3. In May, the Tennessee Department of Health Licensure identified 29 contracted durable medical equipment companies who were initially awarded contracts were not licensed by the state of Tennessee thus becoming ineligible for Round II of competitive bidding. However, some of these companies are still listed as contract suppliers on the Medicare website and are still active suppliers in their contracted CBAs either directly or through a sub-contractor who is licensed. Both of these scenarios are in clear violation of the program rules. In a letter dated June 14, 2013, you notified TN Members of Congress that "CMS will take steps to void contracts for these suppliers in the Tennessee competitive bidding areas, consistent with the policies and guidelines established for the competitive bidding program. This applies to approximately 30 out of the 98 contract suppliers in the Tennessee Competitive Bidding



Areas". When will CMS release the names of these 30 companies who were supposedly revoked? When will CMS revoke all contracts of these ineligible suppliers as indicated?

4. On June 14, 2013, you announced that 30 of the 98 companies contracted for Tennessee's Competitively Bid Areas were in violation of the Competitive Bidding Program licensure requirement and would be revoked. Per the Final Rules, published April 10, 2007, "The single payment amount will be determined only from those bids that are considered 'acceptable,' meaning that the supplier meets all quality, financial, and eligibility standards and that the bid is in the winning range". It goes on to state, "As a result, only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers". Based on the specific and clear guidelines for calculating the Single Payment Amount, why has CMS not recalculated the Single Payment Amounts excluding the unlicensed contracted companies' bids for the affected CBAs?
5. Earlier this week, CMS reported that the number of physicians opting out of the Medicare program entirely increased more than 250% between 2009 and 2012. As the Medicare-eligible population continues to expand, it is critical that our seniors have access to care, which can only be achieved with an adequate healthcare workforce willing to treat Medicare beneficiaries. One reason physicians have referenced as their motivation for leaving the Medicare program is the inability to offer their patients cutting edge technologies that are FDA-approved but do not have adequate coverage or payment under Medicare. How can the program evolve to accommodate these physicians' wishes to offer beneficiaries the best treatment available without pushing them out of Medicare?
6. The Affordable Care Act's expanded Medicaid benefit will put new beneficiaries at a serious disadvantage by restricting their prescription drug coverage below the level currently provided by Medicaid's standard benefit. In the final rule on Medicaid Alternative Benefit Plans, CMS extended the minimum coverage requirement for qualified health plans in the health insurance marketplaces to one drug per USP category and class or the same number of drugs per USP category and class as the state benchmark plan, whichever is greater. This standard could pose serious access problems for new Medicaid patients. The impact of limiting drug access will be particularly pronounced for rare disease patients who often require very specific therapies or a combination of treatments. The USP Model Guidelines do not account for many rare diseases. For instance, the USP lacks a class for cystic fibrosis therapies. A one drug minimum standard based on the USP guidelines could leave many individuals lacking the life-saving treatments they require. How is HHS planning to address this counterproductive limitation critical drug treatment? Will any considerations be made to protecting individuals with rare diseases to ensure they receive the therapies they require?
7. On May 21, the Diabetes Technology Society hosted a conference with representatives from academia, FDA, and the diabetes industry to discuss the question, "Do currently available blood glucose meters meet regulatory standards?" There was broad consensus among



participants that the answer is a resounding “no”. And many low-cost meters are the primary source of device inaccuracies in the market. Many commercially marketed meters, do not meet current International Standards Organization (ISO) standards and the impact on patient health could be devastating.

- a. Given the inaccuracies of blood glucose meters, are you concerned that CMS’ Medicare Competitive Bidding Program is creating a dynamic where decisions are made on price alone and such decisions will put patients at risk?
  - b. At the above mentioned conference, participants highlighted many reasons why meters do not perform according to pre-market trials, underscoring the need for post-market quality enforcement. Post-market evaluations of commercially available meters highlights the problems with inaccurate systems and suggests that performance among “low cost”, “non-branded” products show the greatest variability – in other words are producing inaccurate results for patients. Until FDA is able to better enforce compliance with existing FDA standards, isn’t it irresponsible for CMS to implement Competitive Bidding that drives Diabetes Testing Suppliers to “low cost”, “non-branded” products?
  - c. The Medicare Competitive Bidding Programs drops reimbursement 72% for diabetes testing supplies. As a result, suppliers are forced to purchase the cheapest blood glucose monitoring systems available – including off shore products. FDA, at the May 21<sup>st</sup> Forum, acknowledged that it is hard for FDA to conduct inspections outside of the United States, particularly in Asia, and stated that it is concerned about unsafe blood glucose monitoring systems coming into the United States. Considering that some of the products now available to Medicare diabetes patients are from outside the US market and may not be from FDA inspected facilities, is it wise for CMS to implement a program that drives purchasers outside the US supply chain? What is CMS doing, in conjunction with FDA, to ensure that only FDA approved products reach diabetes patients? What is CMS doing, in conjunction with FDA, to ensure that blood glucose meters not only meet FDA standards at time of approval, but are undergoing post-clearance quality monitoring?
8. The HHS Office of Inspector General issued a report in November 2012 entitled *Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities in Competitive Bidding Areas*. The study confirmed that, in the 9 Competitive Bid Areas (CBA), there was a significant shift to retail suppliers with the introduction of CMS’ Competitive Bidding Program. The report suggested that the top reason for the shift was beneficiaries’ loss of their supplier.
- a. Beneficiaries lost a great deal of product access and choice in the 9 CBAs under Round 1 of Competitive Bidding. We can expect this lack of access to be replicated in National Mail Order insofar as the winning suppliers adopt similar restricted choices. Given that this information was available prior to implementation of NMO, what, if anything, did CMS do to stem this behavior among suppliers to limit product availability?



- b. The study shows a dramatic reduction - 18% - in claims for testing supplies associated with Competitive Bidding. Although CMS and OIG can point to anecdotal reports of overstocking, neither CMS nor OIG have provided data to confirm the 18% drop is due to overstocking. Furthermore, neither CMS nor OIG can show that the program is meeting the needs of beneficiaries for medically necessary testing. If only 1% of the reduction in claims is due to diabetes patients stopped testing, the drop in claims is clinically significant and could be potentially devastating for the diabetes community and for our health care system. What is CMS doing to determine the true reason for the dramatic reduction in claims?
  - c. Is CMS prepared to stop the program or significantly overhaul the program if data shows that diabetes patients are no longer testing as a result of the implementation of the Competitive Bidding Program and lack of access to preferred diabetes testing supplies?
9. On November 10, 2011, CMS published in the Federal Register a Final Rule that revised the definition of durable medical equipment ("DME") to add a three-year minimum lifetime requirement ("MLR") which products must satisfy in order to be eligible for reimbursement under the Medicare DME benefit category. The three-year MLR is only effective with respect to "new" items classified as DME after January 1, 2012. Items classified as DME on or before January 1, 2012 are considered to be "grandfathered items" and continue to fall within the DME benefit category regardless of whether they meet the 3-year MLR. Further, to the extent that a grandfathered item is "modified" after January 1, 2012 and is not a "new" product, it would continue to fall within the grandfathering provision and would not need to meet the 3-year MLR.

On July 8, 2013, CMS published in the Federal Register a Proposed Rule containing a clarification to the scope and applicability of the grandfathering provision. There may be modifications that can be made to a grandfathered product (including products with disposable components) that would result in more efficient and effective medical treatments (and thereby improve the health of Medicare beneficiaries) but reduce the minimum lifetime of the product. Under the Proposed Rule, a modified product would then be considered a "new" product that is not subject to the grandfathering provision and, therefore, not covered as DME.

- a. What considerations were taken into account when determining whether this would restrict/preclude Medicare beneficiary access to such products?
10. The Proposed Rule does not provide clarity on what is a completely "new" product that would never be subject to the grandfathering provision, and a "modified" product that would be subject to the grandfathering provision provided that the modifications did not result in a reduced minimum lifetime of the product.
- a. How will CMS determine what constitutes a "modified (upgraded, refined, reengineered, etc.)" product under the Proposed Rule?



- b. Is a “modified” item required to fall within the same HCPCS code and/or DME product category as a grandfathered item in order for it to also fall within the grandfathering provision?
- 11. The Proposed Rule also proposes to reclassify certain items of DME from the “routinely purchased” payment category to the “capped rental” payment category. This would eliminate the purchase option for these items. Ultrasound BGS products are included in the proposal. CMS’s proposal does not appear to account for the FDA regulatory framework that is inextricably tied to the development of DME products, including BGS products. BGS products are approved by the FDA for single patient use only, which is inconsistent with the purpose of a rental payment methodology. Rental permits suppliers to re-purpose an item of DME used for only a short time by one patient for another patient. This is not possible for BGS products as they are currently approved by the FDA. We are concerned that the proposal could create a significant regulatory burden for BGS manufacturers trying to reconcile FDA regulatory requirements with Medicare reimbursement.
  - a. How were these FDA regulatory requirements into consideration when deciding to move certain single-patient-use products to the “capped rental” payment category?
- 12. The Consumer-Oriented Plan Option in the ACA, otherwise known as CO-OPs, provide taxpayer backed startup and operational loans to health plans. One recipient in New York, the Freelancers Union, received a \$340 million loan from the program. Rates filed by the Freelancers Union are not line in with other for-profit and non-profit insurers that have filed insurance rates with the state. Given this fact, has CMS reviewed these rates to ensure that the Freelancer Plan is meeting solvency requirements? Can CMS assure this Committee that the Freelancers Union, and other CO-OP recipients, will pay taxpayers back for the loans they have received under this program?

**The Honorable Leonard Lance**

- 1. Given the Administration’s focus on Alzheimer’s disease via the National Alzheimer’s Project Act and the recently announced BRAIN initiative, can you comment on why the agency recently issued a draft coverage decision to deny Medicare patients timely access to a FDA approved technology for diagnosing Alzheimer’s disease?
- 2. As you know, the Administration’s National Alzheimer’s plan makes early diagnosis of Alzheimer’s a priority for the country. In that context I am perplexed and disappointed that CMS recently issued a draft coverage decision that would deny Medicare coverage of FDA approved diagnostic tests to determine whether certain patients might have Alzheimer’s disease. Can CMS revisit this draft decision denying coverage and instead adopt the appropriate use guidelines developed by the Alzheimer’s Association and medical experts from the Society of Nuclear Medicine and Molecular Imaging that already deters any potential overutilization?

**The Honorable David McKinley**



1. The President's Executive Order #13563 requires that detailed and cumulative impact analyses be conducted for any proposed rule that is deemed to be economically significant like the Home Health Prospective Payment System (HHPPS) proposed rule. On page 111 of the HHPPS proposed rule, CMS correctly noted that "rebased must be phased-in over a 4-year period in equal increments" -- meaning that the rebasing adjustment proposed in this rule will be implemented not only in 2014 but in 2015, 2016 and 2017 too. On that same page, however, CMS notes that it's "analysis describes the impact in 2014 only."

Why has CMS not complied with the Executive Order and publish its analysis of the impact of this rule in each of the 4 years in which it will take effect?

2. CMS has expressed uncertainty as to whether it has any flexibility in the rebasing adjustment that is to be imposed on the Medicare home health benefit. The statutory language in Section 3131 of the PPACA is clear in several important respects: (1) it does not require the Secretary to reduce home health payment rates as a result of rebasing; (2) it does not specify any specific adjustment that is to be imposed as a result of rebasing; and (3) it prohibits the Secretary from adjusting rebasing rates by any more than 3.5% per year.

In light of these facts, would you agree that the Secretary does in fact have flexibility in setting the rebasing adjustment and is not required to set it at the maximum level of 3.5%?

3. Several states' Attorneys General have expressed concern that the privacy of new customers in the health insurance exchanges under PPACA is not adequately protected in the new health insurance exchanges. The worry is that navigators and other organizations that would assist consumers are not being adequately trained to protect data. In a recent letter to the Secretary, the Attorneys General stated that, "your agency's current guidance regarding these groups suffers numerous deficiencies."

How are you guaranteeing the private medical data collected on consumers for the new health exchanges is protected against fraud?

### **The Honorable Gus Bilirakis**

1. Over 5 million people in the United States have Alzheimer's disease. Getting a timely and accurate diagnosis is an important part of addressing this disease. Leading experts, the government's own Alzheimer's website, and National Alzheimer's Plan (NAPA) have stressed the value of early and accurate diagnosis. Diagnosing Alzheimer's has long been a challenge for the medical community but new technologies are emerging that can help determine whether memory problems may be Alzheimer's or another condition.

Can you tell me why CMS recently issued a draft coverage decision that would deny timely access for the appropriate Medicare patients to an FDA approved diagnostic tool for detecting Alzheimer's disease?

Can CMS revisit this draft decision which denies coverage, and instead adopt the appropriate use guidelines developed by the Alzheimer's Association and medical experts from the Society of Nuclear Medicine and Molecular Imaging that already deters any potential overutilization?



2. Although we continue to make strides in the detection of breast cancer, it still remains the most common cause of cancer among women of all races. The most recent technology advance in the field of mammography is 3D Mammography, which numerous published peer reviewed studies show 40% fewer women needing to be recalled for additional diagnostic appointments -- including ultrasounds and biopsies -- after their screening with 3D mammography. And, studies show much higher cancer detection rate -- in fact they are finding 40% more invasive cancers than conventional mammography. Two and a half years after FDA approval, with numerous published US studies with thousands of patients showing 3D as a game changer in women's health, Medicare has not set a payment code. Why has CMS not issued a code for this technology and does CMS have any plans to issue a code?
3. In your testimony, you mentioned that States were in various stages of readiness when it comes to making Medicaid determination with the Health Exchanges. You stated that CMS was working on contingency plans with the states. How many and which states have submitted contingency plans to CMS? Can you provide the committee with a copy of those plans and CMS' communications with state agencies on contingency plans?
4. What protections are in place for states and individuals who are improperly deemed eligible for Medicaid when they do not meet the criteria or in cases when someone is improperly deemed ineligible for Medicaid when they did meet the criteria?
5. Could an individual have purchased a plan on the Exchange and then mid-year be required to enroll in Medicaid because their initial Medicaid eligibility determination was wrong? Would they have to repay the premium subsidy?
  - a. If someone did transition mid-year, does CMS have any plans to mitigate the potential harm from a break in the continuity of care for individuals that had their Medicaid eligibility assessed improperly and must transition mid-year to/from Medicaid and the individual suffers from complex medical conditions?
6. As you know, the ACA implements an \$8 billion tax on health insurance companies in 2014 growing to \$14.3 billion in 2018. Do you think this tax will increase premiums for small businesses and individuals?
7. Is CMS planning to assume that Congress will prevent the scheduled SGR cuts when calculating Medicare Advantage rates for 2015 as part of the February's 45 Day Notice?

**The Honorable Diana DeGette**

1. Ms. Tavenner, I wanted to bring to your attention an issue of concern to me as it related to families in Colorado who will be receiving benefits from our state Exchange. I understand that the premium assistance subsidy is calculated using the second lowest cost silver plan on the Exchange. My concern is that a particular benchmark plan may or may not include pediatric dental coverage. As a result, families receiving premium assistance who wish to purchase pediatric dental benefits on the Exchange may be limited in their ability to do so.



Is this true? If yes, could you explain the reasoning as to why oral health coverage for children has been excluded from important financial assistance when we know the health and cost benefits of access to dental services?

**The Honorable G.K. Butterfield**

1. Thank you for your testimony about the significant benefits available to states under Affordable Care Act provisions to expand Medicaid. Unfortunately states like North Carolina have governments which have taken the short-sighted and harmful approach and decided not to expand Medicaid. **Is there evidence that opting out of Medicaid expansion will cost states money for uncompensated care?**
2. Not only does states unwillingness to expand Medicaid cost money—it also means more Americans will be uninsured in 2014. In North Carolina, there are 587,000 adults who would be newly eligible for Medicaid if the state expanded. **Will some North Carolinians fall between qualifying for Medicaid and qualifying for tax credits in the individual marketplaces? What will their options be for coverage?**
3. I am encouraged by the many improvements made to our health care system due to the ACA which you have shared with us today. In my district alone, 8,200 young adults have access to health insurance on their parents' plan and 7,300 seniors have saved \$9.7 million on prescription drugs. And once the Marketplaces go into effect in 2014, 137,000 people who lack health insurance will have access to quality and affordable coverage. **Has CMS observed that costs for plans in the individual markets are lower than projected by the Congressional Budget Office? Has CMS also observed that costs for small employers in small group plans are lower than those plans absent the ACA?**
4. It is also encouraging that CCIIO is also beginning to see that costs for coverage for young adults in the individual marketplaces will remain low, even though they are joining a larger pool. **CCIIO has seen plans for 21-year-old, non-smokers that are approximately \$90 per month, is that correct? And if I am a 21-year-old non-smoker from Rocky Mount, North Carolina and I make \$25,000 a year, I can receive tax credits to help me pay that low premium cost, correct? In fact, most Americans will qualify for assistance to make their insurance affordable, is that correct?**
5. I want to shift gears for a minute and talk about the commendable work you are doing to spread the word to the many uninsured that will benefit from the Affordable Care Act. It is clear that CMS and many states are setting up websites and networks to keep citizens informed. **In states that are unwilling to tailor marketing efforts about the Affordable Care Act, like North Carolina, what is CMS doing to reach key populations like young adults? Has CMS considered working with communities of faith or educational institutions to help spread the word about the many benefits of the ACA?**
6. The ACA also ensures that people get more value from their insurance plans and makes insurance more transparent so rates aren't increased arbitrarily. **Under ACA, insurance companies have to provide justification if they wish to increase rates by 10 percent or**



**more. Can you discuss what sort of impact this has had on the number of requests made by insurance companies to increase rates by 10 percent or more?**



## **Attachment 2—Member Requests for the Record**

*During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.*

### **The Honorable Joseph A. Pitts**

1. Will the navigators and other assistants personnel be expected to properly explain cost sharing levels under the sequester?
  - a. If not, does this mean applicants might not be aware of financial liability?
2. The Department has had significant time to prepare for reductions, is this information available to the public? If so, please elaborate.
3. Please provide detailed information on the cost sharing subsidy program.
4. Has CMS conducted live testing involving all parties responsible for implementation? If so, please elaborate.
5. What vulnerabilities have the live end testing revealed?
6. Please have HHS provide any reports, audits, or work plans to show the contractors work.

### **The Honorable Lee Terry**

1. Please provide the Committee with the schedule of live testing for the data hub with all of the federal agencies.
2. How much money has HHS paid United/QSSI to date on the data hub contract?

### **The Honorable Michael C. Burgess**

1. Who informed your chief of staff about the employer mandate delay? Please elaborate.

### **The Honorable Leonard Lance**

1. Please explain where New Jersey stands with regards to the Medicaid application process.

### **The Honorable Bill Cassidy**

1. Please explain to the Committee how CMS is individually working for each state based exchange regarding attestation.



**The Honorable Adam Kinzinger**

1. How many agencies are involved with implementing the Affordable Care Act?
2. How often is there a regular interagency meeting on the implementation of the Affordable Care Act?
3. Is there a deputies, or any other type of, meeting regularly convened by the White House staff on implementation of the Affordable Care Act?
4. Please submit written updates of the implementation of the Affordable Care Act that you receive within the agency.
5. How much will the Affordable Care Act cost to implement (including Hub, advertising, implementation, etc.)?

**The Honorable Gus Bilirakis**

1. Please submit your projections regarding the amount of improper payments that have been made with respect to the Affordable Care Act.

**The Honorable Rene Ellmers**

1. The rule that came out on January 22, 2013, reporting under Section 6055 and 6056 of the code, said that the employer mandate could contribute to the integrity of employer verification into the future. Is this correct?
2. Please provide the Committee with information on the income verification process.

**The Honorable John D. Dingell**

1. Will the new health insurance marketplaces be up and running for open enrollment as scheduled 60 days from now? If so, please elaborate on how the different states will be ready for open enrollment.
2. Please provide the Committee with a paragraph explaining if the decision to delay the employer mandate impacts the timetable for the implementation of the Affordable Care Act. If so, how?
3. Would you please elaborate on how consumers across the country will reap the benefits of increased competition through lower rates?
4. Please submit your comments on Americans saving money due to the rate review provision and how the average premium increase was 30 percent less in 2012 than it was in 2010.



5. Please provide the Committee with a summary of potential trends in the future regarding the average premium decreases.

**The Honorable Diana DeGette**

1. Please provide the Committee with a paragraph describing what the agency is doing to ensure consumer privacy.