Marilyn Tavenner's Response to Questions for the Record
"PPACA Pulse Check"
Before
Energy & Commerce Committee

August 1, 2013

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.**

Answer: The ESRD Prospective Payment System (PPS) uses the most currently-available claims data to annually update the payment rate. As required by section 1881(b)(14)(A)(ii) of the Social Security Act ("the Act"), the ESRD PPS base rate was developed using Calendar Year (CY) 2007 claims data which was the lowest per patient utilization year, updated to CY 2011. The ESRD PPS base rate is then adjusted for patient-specific case-mix adjustments, applicable facility adjustments, geographic wage differences in area wage levels using an area wage index, as well as applicable outlier payments, or training payments, in accordance with section 1881(b)(14)(D) of the Act. Finally, in accordance with sections 1881(b)(14)(F)(i)(I) and (II) of the Act, the ESRD PPS payment amounts are annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment.

With respect to reductions to dialysis reimbursement, the American Taxpayer Relief Act of 2012 (ATRA) provision specifies, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012. Therefore, in the ESRD PPS CY 2014 proposed rule, CMS calculated the amount of the per treatment adjustment by applying CY 2014 prices for ESRD-related drugs and biologicals to the utilization data for CY 2007 and CY 2012. Lastly, we proposed to price the ESRD- related drugs and biologicals for 2014 because we believe that they should be priced for the year in which the adjustment applies. We are taking comments on our proposed methodology to implement the reduction for drug utilization required by ATRA.

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.

Answer: No. The ATRA provision requires that the adjustment be implemented beginning January 1, 2014. The provision also requires that the adjustment reflects the change in utilization by comparing 2007 and 2012 utilization data, which is the data the Agency is using in the proposal. CMS is carefully reviewing public comments to the proposed rule related to this adjustment.

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?

Answer: An impact analysis is completed for every proposed and finalized payment rule. Included in the CY 2014 ESRD PPS proposed rule is an impact analysis estimating that the overall impact of the CY 2014 changes are projected to be a 9.4 percent decrease in payments (compared to estimated payments in CY 2013). Hospital-based ESRD facilities have an estimated 9.3 percent decrease in payments compared with freestanding facilities with an estimated 9.4 percent decrease.

Although we proposed to implement the full reduction in CY 2014, we noted our concern that a one-time reduction to the ESRD PPS base rate could be a significant payment reduction to ESRD facilities for the year and potentially impact beneficiary access to care. Therefore, we solicited comments on a potential transition or phase-in period of the reduction and the number of years for such transition or phase-in period.

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.

Answer: Although, the CY 2014 ESRD PPS proposed rule only includes an impact analysis for providers, we do have a separate monitoring program in place where beneficiary outcomes are monitored.[1] As CMS did in implementing the ESRD PPS in 2011, we will continue to closely monitor health outcomes and access using our active claims surveillance system when we implement the reduction required in section 632(a) of ATRA.

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?

[1]This data is made public on the CMS Website at www.cms.gov/Medicare/Medicare-Fee-for-Servicepayment/ESRDpayment/Spotlight.html.

Answer: CMS is proposing to package categories of items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service. Skin substitutes are integral to the treatment of a wound. Therefore, we are proposing to package skin substitutes with the primary wound treatment procedure under the Outpatient PPS (OPPS). While all products classified by CMS as skin substitutes are regulated by the Food and Drug Administration (FDA) as either medical devices or as human cell, tissue, cellular and tissue-based products, the precise type of FDA approval or clearance route was not a factor in our packaging proposal. All of the skin substitutes that are currently separately paid are proposed to be packaged for the 2014 OPPS. CMS is carefully reviewing public comments related to this proposal.

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?**

Answer to #s 3 and 4: The Medicaid maintenance of effort (MOE) requirement, first implemented as part of the Recovery Act and extended by the Affordable Care Act, generally ensures that states' coverage for adults under the Medicaid program remains in place pending implementation of coverage changes that become effective in January 2014. The MOE for children under age 19, in both Medicaid and the Children's Health Insurance Program (CHIP) is effective through September 30, 2019.

CMS has issued several State Medicaid Director letters related to the implementation of the MOE provisions[i]. That guidance describes the applicability of the MOE as well as the period of time in which the MOE is in place. CMS staff works closely with states to answer questions related to guidance issued by the Agency and remains engaged with states on issues of Affordable Care Act implementation. CMS does not anticipate releasing further guidance. On January 1, 2014, when an Exchange will be fully operational in every state, the MOE for adults will end.

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.**

Answer: CMS annually estimates the amount of Medicaid improper payments and submits those estimates to the Congress. The Payment Error Rate Measurement (PERM) program uses a 17-state three-year rotation for measuring improper payments in Medicaid, so that CMS measures each state once every three years. This process generates national rolling error rates based on data from the most recent three state cycles. The national PERM rates associated with Medicaid eligibility for Fiscal Year (FY) 2012 was 4.9 percent; for FY 2011 was 6.1 percent, and for FY 2010 was 5.9 percent.[2]

[2] http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/PERM/Downloads/PERM-MedicaidErrorRates.pdf ; http://wayback.archive-it.org/3922/20131030171300/http://www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf

6. Please provide the amount of overpayments associated with Medicaid eligibility errors for FY2012, FY2011 and FY2010?

Answer: Overpayments associated with Medicaid eligibility errors totaled $424,500 from FYs 2010-2012.

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?

Answer: In the short time that the programs have been running, we have implemented several monitoring activities to ensure beneficiaries have access to the care they need. CMS requires an annual survey of beneficiaries assigned to all Medicare accountable care organizations (ACOs) in either the Shared Savings Program or the Pioneer ACO Model. These surveys are intended to hold ACOs accountable for patient experiences of care, and scores on patient surveys affect the amount of shared savings or shared losses that the ACO may incur. In addition to the annual survey of beneficiaries, ACOs are required to report their performance on quality measures. As of July 2013, all Pioneer ACOs successfully reported quality measures and achieved the maximum reporting rate for the first performance year, with all earning Physician Quality Reporting System (PQRS) incentive payments for their reporting accomplishments. Overall, Pioneer ACOs performed better than the national average for all 15 clinical quality measures for which published comparable data are available. Quality measurement results for the first performance year of Shared Savings Program ACOs are expected in summer 2014.

CMS also oversees ACO participants themselves in several ways. CMS screens all ACO participants to ensure they are Medicare enrolled providers and have not been excluded from participation in Medicare programs. We review marketing materials used by ACOs to ensure they make clear that beneficiaries may see any Medicare provider they choose. We ensure ACOs are publicly reporting information such as the ACO's name, contact information, and leadership.

In addition, CMS funds an ACO compliance oversight, monitoring, and audit design and operational support contractor. The services provided by this contractor are primarily centered on developing protocols and performing compliance audits to ensure ACOs and their participating providers are in compliance with the terms and conditions of their formal agreement with CMS. Finally, to safeguard against reductions of necessary care, CMS analyses data on service utilization and may investigate utilization patterns through comparison surveys of beneficiaries aligned with the ACO and those in the general beneficiary population.

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?

Answer to #s 7b and c: For the first year, Pioneer ACOs were paid for reporting the measures, given that the model was in its first year. CMS will be moving to pay-for-performance quality reporting in Pioneer ACO quality performance year 2, based on benchmarks that CMS established using available empirical data. All Pioneer ACO providers earned their PQRS incentive payments as a result of Pioneers reporting on quality measures which continue CMS' efforts to align our quality reporting and performance initiatives and reduce provider burden.

CMS requires an annual survey of beneficiaries assigned to all Medicare ACOs (in either the Shared Savings Program or the Pioneer ACO Model). These surveys are intended to hold ACOs accountable for beneficiary experiences of care. The ACO's scores on beneficiary surveys affect the amount of shared savings or shared losses that the ACO may incur.

Pioneer ACOs performed very well on the patient experience survey. Of the seven survey questions used to assess ACOs, four have published national Medicare fee-for-service results from 2011. Pioneer ACOs were rated higher by ACO beneficiaries on all four measures when compared to the 2011 Medicare fee-for-service results. For example, ACO beneficiaries rated Pioneer ACOs higher on receiving timely care and appointments (81 percent vs. 74 percent) and experiencing good provider communication (93 percent vs. 90 percent) than the national Medicare fee-for-service results.

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?

Answer: Organizations participating in the Bundled Payments for Care Improvement initiative must meet rigorous standards for care quality and beneficiary satisfaction. To assess the quality of care furnished by the organizations and safeguard against stinting of care, CMS has created a monitoring program that includes asking beneficiaries about their experiences and measuring the quality provided by participating organizations. Organizations participating in the Bundled Payments for Care Improvement initiative must achieve certain quality thresholds in order to continue participating in the initiatives.

CMS will also monitor patient access to care to determine if providers are engaging in inappropriate activities, such as stinting on care. We will focus on monitoring utilization and cost increases to look for patterns of utilization that are indicative of poor quality (e.g., increased

readmissions). We will monitor for changes in patient case-mix and episode costs at participating and non-participating providers. A key source of information in this area will be claims records, which will allow us to examine patterns of care among participants relative to comparison groups, and the B-CARE Tool, a streamlined version of the Continuity Assessment and Record Evaluation (CARE) Item Set. The B-CARE Tool measures the health and functional status of Medicare beneficiaries at discharge from the acute setting.

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?

Answer: The Bundled Payments for Care Improvement initiative will include measures that examine structural and organizational characteristics, patient case-mix, clinical care and patient safety, patient experience of care, and utilization and cost. The proposed measures and evaluation strategies for the Bundled Payments for Care Improvement models and clinical episodes were assessed based on their scientific rigor, validity, reliability and associated provider data collection burden. The data sources for these measures include CMS administrative data such as claims and post-acute assessment data, CMS quality reporting program data, survey data, provider submitted data, primary data gathered through modalities such as focus groups, and registry data as feasible.

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?

Answer: Pioneer ACOs had to submit a preliminary plan for shared savings distribution in their applications and are required to keep a record of how they distribute shared savings. All Medicare ACOs are also required to publicly report at an aggregate level how they distribute earned shared savings. However, CMS does not prescribe the distribution methodologies or require detailed reporting (for example, at the level of individual providers). In some cases, information on provider compensation may be proprietary, particularly in markets where multiple Medicare ACOs operate.

b. Can you identify the participants that will not be returning to the program and their reasons for doing so?

Answer: Nine Pioneer ACOs submitted notices of intent to withdraw in the second year of the Pioneer ACO model: Prime Care Medical Network Inc., University of Michigan, Physician Health Partners LLC, Seton Health Alliance, Plus (North Texas Specialty Physicians and Texas Health Resources), Healthcare Partners Nevada ACO LLC, Healthcare Partners California

ACO LLC, JSA Care Partners LLC, and Presbyterian Healthcare Services. Seven out of these nine are applying to transition to the Medicare Shared Savings Program.

The Pioneer ACO Model is testing whether ACOs can succeed in payment arrangements that include higher levels of risk and reward than in the Medicare Shared Savings Program. Each of these organizations made its decision to apply for the Shared Savings Program or leave the Pioneer ACO model based on its particular business priorities and concerns. CMS fully expected that some ACOs would change the model in which they participate in over time, and our model savings projections took these changes into account. The Pioneer Model continues to test innovative models and generate important data and lessons learned for CMS.

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?

Answer: Medicare ACOs must meet rigorous standards for care quality and beneficiary satisfaction. To assess the quality of care furnished by the organizations and safeguard against stinting of care, CMS has created a vigorous monitoring program that includes asking beneficiaries about their experiences as well as measurement of the quality provided by participating organizations. ACOs must achieve certain quality thresholds in order to continue participating in the initiatives.

Beneficiaries retain their original Medicare benefits and may choose to receive care from providers not participating in the initiative. Nothing in the initiatives will in any way restrict the ability of beneficiaries to access care from participating or non-participating providers, nor will it restrict the ability of participating ACOs to offer the latest medical technologies. ACOs have significant flexibility to invest in redesigned care processes for high quality and efficient service delivery, including implementing innovative technologies.

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?

Answer: In the Medicare Shared Savings Program, ACOs are accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. ACOs have significant flexibility to invest in redesigned care processes for high quality and efficient service delivery, including implementing innovative technologies.

The quality metrics proposed for ACOs and finalized after consideration of public comments were a careful balance between ensuring that quality of care is maintained while decreasing the reporting burden on ACOs. CMS is committed to developing and adopting a mix of process, outcome, and patient experience of care measures, including measures of safety, care transitions, and changes in patient functional status. As the science of quality measurement evolves, we will be able to make determinations on which measures are the most meaningful to providers and health care professionals and will most effectively drive progress and improvement. In future rulemaking for the Medicare Shared Savings Program, we anticipate reviewing the selected quality measures and seeking public comment on other measures that could be used by ACOs.

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 provides who deliver advanced care not yet reflected in the quality measures?

Answer: CMS established the 33 quality measures through notice and comment rulemaking and reviewed extensive comments on the proposed measures from provider groups, industry associations, patient organizations, medical associations, and other parties before finalizing the list of quality measures through the rule making process.

These quality measures employed in the Pioneer ACO Model and the Shared Savings Program are developed by measure stewards and many are endorsed through a National Quality Forum (NQF) endorsement process, a thorough vetting process which relies on input from numerous stakeholders including the provider community to ensure that measures are in line with best practice and appropriate for the purpose of assessing quality. Because CMS prioritizes using measures that are NQF-endorsed, the agency relies on measure developers and measure stewards to incorporate new standards of care and/or exceptions for new technologies/treatments into measure specifications.

The selected measures align with those included in other CMS quality reporting programs (such as the Physician Quality Reporting System, the EHR Incentive Program, and the Value-Based Payment Modifier/Quality Resource Use Reports) in an effort to reduce provider reporting burden and harmonize requirements across programs.

We believe that an ACO's quality measurement score would be enhanced when ACO providers use clinically appropriate technology and we think ACOs have an incentive to use the latest medical technology to improve their quality scores. We note that several of the quality measures incorporate risk adjustment, to account for differences in patient populations (such as by age, sex, and condition), so that an ACO's performance on those quality measures accounts for ACOs that happen to see a more sick or elderly population of patients.

The Honorable Greg Walden

10. 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?

Answer: Your question raises the issue of how health insurance coverage provided to an association of employers is treated under the Public Health Service Act, as amended by the Affordable Care Act. We continue to examine these issues and are working with the Department of Labor.

11. 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?

Answer: CMS shares your belief in the importance of patient engagement and activation. We put the patient at the center of all of our ACO programs and the Community-Based Care Transitions Program. CMS requires an annual survey of beneficiaries assigned to all Medicare ACOs in either the Shared Savings Program or the Pioneer ACO Model. These surveys are intended to hold ACOs accountable for patient experiences of care, and scores on patient surveys affect the amount of shared savings or shared losses that the ACO may incur. Pioneer ACOs have completed their first performance year and they performed very well on the patient experience survey. Of the seven survey questions used to assess ACOs, four have published national Medicare fee-for-service results from 2011. Pioneer ACOs were rated higher by ACO beneficiaries on all four measures when compared to the 2011 Medicare fee-for-service results. For example, ACO beneficiaries rated Pioneer ACOs higher on receiving timely care and appointments (81 percent vs. 74 percent) and experiencing good provider communication (93 percent vs. 90 percent) than the national Medicare fee-for-service results. Quality measurement results for the first performance year of Shared Savings Program ACOs are expected in summer 2014.

While participating in the Shared Savings Program or the testing of the Pioneer ACO model, ACOs take part in learning and diffusion activities in which topics such as patient engagement are discussed. This allows ACOs to share their experiences and learn from other ACOs how to improve on their patient engagement processes.

Under the Community-based Care Transition Program (CCTP), data collected by a patient experience survey is used as part of the intervention. Patient activation and engagement are key to determining how to tailor an intervention plan so that it meets not only the medical needs of the patient but also their psychosocial needs.

The Patient Experience Survey draws questions from three existing and validated instruments. The survey items assess: beneficiaries' perception of their hospital experience specifically related to medicines and discharge plans for a recent hospital stay; how well the hospital prepared patients to care for themselves after discharge; and beneficiaries' perceptions of self-efficacy (knowledge, confidence, and skills) for managing their own health behaviors and health care following a hospital stay.

By comparing survey responses from questions presented at both the first and second administration of the survey, sites are able to determine if the intervention has made a difference in the patient's level of activation. In turn, this data aggregated across sites is critical in determining whether the interventions are having their intended impact. The community based organizations that work with eligible hospitals to help reduce readmissions will use the information to tailor the care transition services to the specific needs of the beneficiary and target areas where gaps in knowledge have been identified.

The patient experience survey has been available for voluntary use by CCTP participants since the program's inception. Required use of the survey will start in August 2013 and all CCTP sites

will be required to submit the patient experience survey by September 2013. A contractor will collect, analyze and report the survey data to CMS and the individual CCTP programs on a quarterly basis.

The Honorable Michael C. Burgess

12. 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?

Answer: The proposed reduction is required under section 1881(b)(14)(I) of the Act, as added by section 632(a) of ATRA. Section 1881(b)(14)(I) requires that the Secretary make reductions to the Medicare single payment amount for ESRD facilities under the PPS to reflect the Secretary's estimate of the change in utilization of drugs and biologicals (other than oral-only ESRD-related drugs) from 2007 to 2012. While we proposed to implement the full reduction to the ESRD PPS in CY 2014, we are soliciting comments on use of a potential transition or phase-in period for the reduction and the number of years for such transition or phase-in period. As CMS did in implementing the ESRD PPS in 2011, we will continue to closely monitor health outcomes and access using our active claims surveillance system when we implement this required reduction.

13. 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?

Answer: All Medicare DMEPOS suppliers must furnish items that meet applicable FDA regulations and medical device effectiveness and safety standards. In order to furnish any DMEPOS for Medicare beneficiaries, all suppliers must be in compliance with the Medicare supplier standards and quality standards. The Medicare quality standards require suppliers to implement a program that promotes the safe use of equipment.

In response to concerns about beneficiary access to their preferred brand of test strips under the DMEPOS competitive bidding program, Congress mandated in section 1847(b)(10) of the Act that suppliers competing under the national mail order program for diabetic testing supplies demonstrate that their bid covers the cost of at least 50 percent of the brands of test strips on the market by volume. The HHS Office of Inspector General gathers the market volume data needed to implement this rule, and CMS uses invoices and purchase orders from suppliers to verify that their bids cover these costs. In addition to this "50 percent rule," Medicare rules include an "anti-switching" provision as a term of the contract for suppliers under the national mail-order competition for diabetic supplies. This regulation prohibits contract suppliers from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand. The anti-switching rule requires contract suppliers to furnish the brand of testing supplies that work with the monitor selected by the beneficiary. This rule was established to protect beneficiary and physician choice of glucose monitors. The DMEPOS competitive bidding

program also includes an anti-discrimination policy, meaning that suppliers have to offer their Medicare beneficiaries the same products they offer their other customers. Further, contract suppliers are required to furnish a particular brand prescribed by a physician or assist the beneficiary in finding another contract supplier who will furnish the item, or consult with the physician to find a suitable alternative and obtain a revised prescription. This requirement applies to all product categories.

14. 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?

Answer: CMS has implemented a robust monitoring program to track and resolve any issues that might occur with program implementation. To date, the program has maintained beneficiary access to quality products from accredited suppliers in the Round 1 Rebid areas. Extensive real-time monitoring data have shown successful implementation with very few beneficiary complaints and no negative impact on beneficiary health status based on measures such as hospitalizations, length of hospital stay, and number of emergency department visits compared to non-competitive bidding areas. We have investigated the reduction in claims for diabetic testing supplies in the Round 1 competitive bidding areas and found that this reduction is due to beneficiaries having an oversupply of these products. Specifically, we contacted a sample of beneficiaries who were using diabetic testing supplies before the Round 1 Rebid phase of the program began in nine areas in 2011, and for whom no claims for diabetic testing supplies were received during the first six months of the program (*i.e.*, through June 2011).

We found that most of these beneficiaries were still using diabetic testing supplies to manage their diabetes, and in some cases, beneficiaries had more than enough diabetic testing strips to last them over six months without having to reorder. We will continue to monitor access to quality products and promptly address any issues.

15. 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?

Answer: In an effort to implement the face-to-face requirements with as much flexibility as possible for both home health agencies and physicians, CMS allows the certifying physician or his or her support staff to generate or extract documentation for the certifying physician's signature from the physician's electronic medical record entries. In the case of patient admitted to home health from an acute or post-acute care facility, discharge planners who have access to medical record entries of the physician who attended to the patient during the institutional stay may extract the encounter documentation for the certifying physician's signature.

CMS does not require certifying physicians to document, sign, and date an additional form in order to satisfy the home health face-to-face requirements. CMS does not require a specific form for face-to-face documentation or for the certification which includes the face-to-face documentation. Our regulations require that the documentation of the face-to-face encounter be a separate and distinct section of, or addendum to, the certification, and that the documentation include why the clinical finding of the encounter supports home health eligibility. The face-to-face documentation must be clearly titled and dated, and signed by the certifying physician.

Access to care is of paramount importance to CMS. We will continue to monitor the effects of the face-to-face requirements for unintended consequences and to work proactively with HHAs and other stakeholders to ensure eligible Medicare beneficiaries maintain access to home health care.

The Honorable Marsha Blackburn

16. 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 neurogenerative 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?

17. 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.

Answer to #s 16 and 17: The proposed decision represents an expansion of coverage rather than a denial. As such, it exemplifies our ongoing efforts to review new technology to ensure timely access to innovative products that may benefit our beneficiaries, including those with Alzheimer's disease. In October 2012, CMS opened a National Coverage Analysis (the first step in the National Coverage Determination (NCD) process) to reconsider a prior NCD on the use of Positron Emission Tomography (PET) scans that allowed Medicare coverage of PET using only specified radioisotopes for certain indications. Reconsideration of this NCD was requested by Eli Lilly & Company to consider coverage of PET using a new type of radiopharmaceutical approved by FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline.

To help inform this evidence review, CMS convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) in January 2013. On July 3, 2013, CMS issued a proposed coverage decision, followed by a 30-day public comment period. As you noted, the proposed NCD would allow Medicare coverage of beta amyloid PET scans for diagnosis of dementia and neurodegenerative disease under the process known as "coverage with evidence development" (CED) for patients enrolled in an approved clinical study. CED is used as an alternative to non-coverage for certain items and services for which CMS has determined that the best available evidence does not support unrestricted coverage. This process allows access to emerging technologies while promoting the development of further clinical evidence. CMS' evidence-based coverage decision-making process (including use of CED) is not meant to replace or duplicate FDA's determination of a product's safety and effectiveness; rather, it is designed to meet CMS' statutory obligation to

ensure that Medicare covers only items and services determined to be "reasonable and necessary" for our beneficiaries.

CMS received 202 comments on the proposed decision, which are currently under review. CMS will carefully consider those comments in developing a final coverage decision.

18. 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?

Answer: We carefully examined Tennessee licensing requirements and spoke to state officials in order to obtain clarity on these requirements. We determined that certain out-of-state suppliers were licensed in their home state, but did not meet aspects of existing Tennessee licensing requirements at the time of bid submission for DMEPOS competitive bidding. As a result, in June 2013, CMS voided contracts for 30 out of 98 contract suppliers in the Tennessee competitive bidding areas, consistent with the policies and guidelines established for the competitive bidding program. CMS is required by law to protect the confidentiality of suppliers' confidential bid information, which includes information related to voided contracts. Therefore, we cannot release the names of contract suppliers whose Tennessee contracts have been voided. We are closely monitoring beneficiary access to competitive bidding items in Tennessee. We may consider making new awards to qualified and licensed suppliers in the future if needed.

19. 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?

Answer: CMS does not make changes to the single payment amounts calculated for each item under each DMEPOS competitive bidding program. These amounts are paid for the duration of

the competitive bidding program and will not be adjusted for any update factor. During the contract process, suppliers agree to accept the single payment amounts for a competitive bidding area. Any changes to the contracts, including the single payment amounts, would require CMS to reissue contracts to suppliers, which could potentially delay the program or terminate a competition in a competitive bidding area if suppliers decline contracts after prices are adjusted.

20. 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?

Answer: According to HHS' latest findings on access to physicians' services by Medicare beneficiaries, the percentage of office-based physicians who report accepting new Medicare patients has not changed significantly between 2005 and 2012, with 87.9 percent accepting new Medicare patients in 2005 and 90.7 percent in 2012. The HHS analysis also notes that the percentage of physicians who report accepting new Medicare patients is similar to, and in recent years slightly higher than, the percentage accepting new privately insured patients.[3] Currently, approximately 9,500 physicians have opted out of Medicare while about 735,000 remain in Medicare.

In addition, CMS is continually engaged in reviewing new technologies through our national coverage determination process, notice-and-comment rulemaking, and other initiatives, with ample opportunities for public input. While CMS has separate statutory responsibilities from those of FDA, governed by different standards, we are exploring ways to better coordinate FDA and CMS processes. For example, in 2010, the two agencies jointly announced their consideration of, and requested public comments on, a voluntary "parallel review" process for overlapping evaluations of premarket, FDA-regulated medical products. In 2011, the agencies launched a "parallel review" pilot program for concurrent review of medical devices for FDA approval and Medicare coverage. CMS and FDA are currently working on two parallel review pilot projects. We believe the interactions between CMS, FDA and the sponsors have been encouraging for all participants.

21. 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

[3] Available at http://aspe.hhs.gov/health/reports/2013/PhysicianMedicare/ib_physicianmedicare.cfm.

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?

Answer: States have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of prescription drug coverage under an Alternative Benefit Plan. In developing these plans, states must include prescription drug coverage consistent with the Essential Health Benefit benchmark plan standards. These standards include the requirement that health plans have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan. We believe such requirements will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

22. 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?

Answer: All Medicare DMEPOS suppliers must furnish items that meet applicable FDA regulations and medical device effectiveness and safety standards. In order to furnish any DMEPOS for Medicare beneficiaries, all suppliers must be in compliance with the Medicare supplier standards and quality standards. The Medicare quality standards require suppliers to implement a program that promotes the safe use of equipment.

In response to concerns about beneficiary access to their preferred brand of test strips under the DMEPOS competitive bidding program, Congress mandated in section 1847(b)(10) of the Social Security Act that suppliers competing under the national mail order program for diabetic testing supplies demonstrate that their bid covers the cost of at least 50 percent of the brands of test strips on the market by volume. The HHS Office of Inspector General gathers the market volume data needed to implement this rule, and CMS uses invoices and purchase orders from suppliers to verify that their bids cover the costs. In addition to this "50 percent rule," Medicare rules include an "anti-switching" provision as a term of the contract for suppliers under the national mail-order competition for diabetic supplies. This regulation prohibits contract suppliers

from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand. The anti-switching rule requires contract suppliers to furnish the brand of testing supplies that work with the monitor selected by the beneficiary. This rule was established to protect beneficiary and physician choice of glucose monitors. The DMEPOS competitive bidding program also includes an anti-discrimination policy, meaning that suppliers have to offer their Medicare beneficiaries the same products they offer their other customers. Further, contract suppliers are required to furnish a particular brand prescribed by a physician or assist the beneficiary in finding another contract supplier who will furnish the item, or consult with the physician to find a suitable alternative and obtain a revised prescription. This requirement applies to all product categories.

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?

Answer: CMS has implemented a number of requirements in the DMEPOS competitive bidding programs specifically for contract suppliers of diabetic testing supplies to ensure beneficiaries continue to have access to quality items. The law requires bidders for mail-order diabetic supplies to demonstrate that their bids cover at least 50 percent, by volume, of all types of diabetic testing strips on the market. In addition, bidders are required to submit the brands of the diabetic testing strips in their bids and this information is available on the Supplier Locator Tool for beneficiaries to determine which contract suppliers have the brands they want to use.

Medicare rules include an "anti-switching" provision as a term of the contract for suppliers under the national mail-order competition for diabetic supplies. This regulation prohibits contract suppliers from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand. The anti-switching rule requires contract suppliers to furnish the brand of testing supplies that work with the monitor selected by the beneficiary. This rule was established to protect beneficiary and physician choice of glucose monitors. The DMEPOS competitive bidding program also includes an anti-discrimination policy, meaning that suppliers have to offer their Medicare beneficiaries the same products they offer their other customers. Further, contract suppliers are required to furnished a particular brand prescribed by a physician or assist the beneficiary in finding another contract supplier who will furnish the item, or consult with the physician to find a suitable alternative and obtain a revised prescription. This requirement applies to all product categories.

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 21st 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?

Answer: All Medicare DMEPOS suppliers must furnish items that meet applicable FDA regulations and medical device effectiveness and safety standards. In order to furnish any DMEPOS for Medicare beneficiaries, all suppliers must be in compliance with the Medicare supplier standards and quality standards. Currently, the name brand products made in the United States are being offered to Medicare beneficiaries by both the mail order and non-mail order outlets. The non-mail order suppliers are required to be paid the same Medicare payment rate as mail-order suppliers. Suppliers must accept the new payment amount as payment in full and may not charge the beneficiary any additional amount above the Medicare rates. As the products are available by mail order and non-mail order outlets, we believe that the DMEPOS competitive bidding program is not affecting access to name brand products and that beneficiaries are not improperly incurring any additional cost to secure name brand products. We will continue to monitor access to quality products and will act promptly to address any issues.

23. 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?

Answer: CMS has implemented a number of requirements in the DMEPOS competitive bidding programs specifically for contract suppliers of diabetic testing supplies to ensure beneficiaries continue to have access to quality items. The law requires bidders for mail-order diabetic supplies to demonstrate that their bids cover at least 50 percent, by volume, of all types of diabetic testing strips on the market. In addition, bidders are required to submit the brands of the diabetic testing strips in their bids and this information is available on the Supplier Locator Tool for beneficiaries to determine which contract suppliers have the brands they want to use.

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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 in 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?

Answer: CMS has implemented a robust monitoring program to track and resolve any issues that might occur with program implementation. We have investigated the reduction in claims for diabetic testing supplies in the Round 1 competitive bidding areas and found that this reduction is due to beneficiaries having an oversupply of these products. Specifically, we contacted a sample of beneficiaries who were using diabetic testing supplies before the Round 1 Rebid phase of the program began in nine areas in 2011, and for whom no claims for diabetic testing supplies were received during the first six months of the program *(i.e.,* thru June 2011). We found that almost all of these beneficiaries were still using diabetic testing supplies to manage their diabetes, and in some cases, beneficiaries had more than enough diabetic testing strips to last them over six months without having to reorder. We will continue to monitor access to supplies and equipment and promptly address any issues.

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?

Answer: CMS has implemented a robust monitoring program to track and resolve any issues that might occur with program implementation. To date, the program has maintained beneficiary access to quality products from accredited suppliers in the Round 1 Rebid areas. Extensive real-time monitoring data have shown successful implementation with very few beneficiary

complaints and no negative impact on beneficiary health status based on measures such as hospitalizations, length of hospital stay, and number of emergency department visits compared to non-competitive bidding areas. To the extent an issue arises, CMS will act promptly to address it.

24. 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.

Answer: We believe you are requesting confirmation of what will be grandfathered. In a proposed rule published in the Federal Register on July 8, 2013, we clarified that the three-year minimum lifetime requirement would not be applied to grandfathered items that are modified (*e.g.*, refined or upgraded versions of the same product), provided the modified product did not have an expected life shorter than the expected lifetime for that item covered as DME prior to January 1, 2012. We invited public comments on this issue in this rule. The comment period for this rule ends August 30, 2013.

25. 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?

Answer: We believe that the vast majority of the categories of items that were classified as DME before January 1, 2012 did function for three or more years. As beneficiaries have been relying on these items for treatment, applying the three-year minimum lifetime requirement could affect the continuity of care for these beneficiaries. We believe that continuing Medicare coverage for items that qualified as DME prior to the effective date helps avoid disrupting the continuity of care for beneficiaries that received these items for medical treatment prior to January 1, 2012.

26. 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?

Answer: The three-year minimum lifetime requirement is designed to represent a minimum threshold for determination of durability of a piece of equipment and would apply prospectively only to new equipment furnished to a beneficiary after the regulation was effective on January 1, 2012. We proposed that if the product is modified after January 1, 2012, the item would still be classified as DME as a grandfathered item unless the modified product now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. For example, if a product is modified such that it no longer lasts two years, we consider the modified product as a new item that is subject to the three-year minimum lifetime requirement. Our proposed rule has solicited comments on this issue.

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?

Answer: For purposes of providing additional guidance on the scope of grandfathered items, we invited public comments on this issue in this proposed rule. The comment period for this rule ends August 30, 2013. We will consider comments we received in order to provide additional guidance on this issue.

27. 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?

Answer: In the proposed rule, we are soliciting comments on reclassification of items that were previously classified as routinely purchased equipment to the capped rental payment class to comply with our current regulations. The proposal included the list of the HCPCS codes that would be reclassified so that stakeholders may comment. The comment period for this rule ends

August 30, 2013. We will consider this comment and other comments received on this issue when we make our final decision.

28. 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?

Answer: As you know, the state of New York, along with 16 other states plus the District of Columbia, has elected to operate a state-based marketplace. The state reviews all prospective qualified health plans (QHPs) applications including benefits and rates. The state also has prior approval authority over all rates charged. Once an issuer submits proposed rates, consumers have the opportunity to submit a public comment, the state reviews the materials, and the final approved rates are posted.

The CO-OP program provides start-up and solvency loans to help create new health insurance companies that will give more choices and control to consumers, promote competition, provide new models of care delivery and improve quality in the health insurance market. CMS shares the Committee's goal of assuring that CO-OP loans are fully repaid. We have in place extensive policies and procedures to monitor and support CO-OPs as they enter the market, gain membership, build adequate reserves, and, taking into account state reserve laws and regulations as required by the statute, ultimately repay CMS in a timely manner. The dual regulation of CO-OPs by both the state departments of insurance and CMS provides effective monitoring and mitigates risks.

The Honorable Leonard Lance

29. 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?

30. 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?

Answer to #s 29 and 30: The proposed decision represents an expansion of coverage rather than a denial. As such, it exemplifies our on-going efforts to review new technology to ensure timely access to innovative products that may benefit our beneficiaries, including those with Alzheimer's Disease. In October 2012, CMS opened a National Coverage Analysis (the first step in the NCD process) to reconsider a prior NCD on the use of PET scans that allowed Medicare coverage of PET using only specified radioisotopes for certain indications. Reconsideration of this NCD was requested by Eli Lilly & Company to consider coverage of PET using a new type of radiopharmaceutical approved by FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline.

To help inform this evidence review, CMS convened a meeting of the MEDCAC in January 2013. On July 3, 2013, CMS issued a proposed coverage decision, followed by a 30-day public comment period. The proposed NCD would allow Medicare coverage of beta amyloid PET scans for diagnosis of dementia and neurodegenerative disease under the process known as "coverage with evidence development" (CED) for patients enrolled in an approved clinical study. This process allows access to emerging technologies while promoting the development of further clinical evidence. CMS received 202 comments on the proposed decision, which are currently under review.

The Honorable David McKinley

31. 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 "rebasing 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?

Answer: Based on the requirements of Executive Orders 12866 and 13563, respectively, the economic impact analysis for a prospective payment rule like the Home Health PPS proposed rule assesses many factors. including the rebasing adjustment, and presents the cumulative effects of the complete regulation (both costs and benefits) for the applicable year of implementation. As a part of the annual rulemaking process, the Home Health PPS impact analyses for subsequent years will be assessed in the applicable years of implementation, at which point all relevant data sources will be available, so that a cumulative effect of the complete regulation may be presented.

32. 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%?

Answer: Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that this rebasing must be phased-in over a four-year period in equal increments, not to exceed 3.5 percent The rebasing must be fully implemented by CY 2017. In the proposed rule, we did an extensive analysis of cost report and claims data. We found that the difference between average payment and cost per episode for 2013 was -13.63 percent. Phasing in the -13.63 percent over four years in equal increments would result in an annual reduction of

3.60 percent; therefore we proposed to reduce payment in each year from CYs 2014-2017 by 3.5 percent because, as required by the Affordable Care Act, the reduction may be no more than 3.5 percent. We are soliciting comments on our proposal and will make a final decision to be published in the final rule by November 1, 2013.

33. 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?

Answer: The single, streamlined application does not collect personal health information, except from consumers seeking Medicaid coverage who need to provide information about pregnancy status and disability status in order to receive a determination of Medicaid eligibility, and the tobacco use status from consumers seeking private insurance. Applications for private health insurance available through the Marketplace are no longer permitted to seek information about a consumer's health history in light of the Affordable Care Act's market reforms.

The privacy and security of consumer data included in the single, streamlined application is a top priority for CMS and our Federal, state, and private partners. When processing these applications through the Federally-facilitated Marketplace (FFM) and the Data Services Hub, CMS will use appropriate policies, procedures, standards and implementation specifications to ensure the privacy and security of consumer data in accordance with applicable law. CMS will ensure that the IT used for the Marketplaces comply with applicable Federal laws, NIST controls, and security agreements through a stringent monitoring and evaluation system. CMS has a robust security monitoring system that reviews all security events, tools, requirements, and network device logs to identify, assess, and manage vulnerabilities and threats.

In addition to the privacy safeguards of the Federal Marketplace systems themselves, the privacy of consumer information will also be protected by Navigators and others that have been approved and certified by the FFM and the State Partnership Marketplace to assist consumers in applying for and enrolling in Marketplace coverage. In the FFM and the State Partnership Marketplace, Navigators and other Marketplace-approved assistance personnel will be required to comply with the privacy and security standards applicable under the Affordable Care Act as a condition of their agreements with CMS. CMS, as the operator of the Federally-facilitated Marketplace, will be monitoring Navigators and other FFM-approved and State Partnership Marketplace-approved assistance personnel and will take appropriate action if complaints of fraud and abuse arise. Should a grantee fail to comply with the Terms and Conditions of the award, HHS, in conjunction with the Office of Acquisitions and Grant Management, will evaluate the situation and will work with the grantee to address the situation, including considering the termination of the award or other appropriate enforcement actions.

The Honorable Gus Bilirakis

34. 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.

a. 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?

b. 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?

Answer to #s 34a & 34b: The proposed decision represents an expansion of coverage rather than a denial. As such, it exemplifies our on-going efforts to review new technology to ensure timely access to innovative products that may benefit our beneficiaries, including those with Alzheimer's Disease. In October 2012, CMS opened a National Coverage Analysis (the first step in the NCD process) to reconsider a prior NCD on the use of PET scans that allowed Medicare coverage of PET using only specified radioisotopes for certain indications. Reconsideration of this NCD was requested by Eli Lilly & Company to consider coverage of PET using a new type of radiopharmaceutical approved by FDA in 2012 to image beta-amyloid plaques in certain patients being evaluated for Alzheimer's disease and other causes of cognitive decline.

To help inform this evidence review, CMS convened a meeting of the MEDCAC in January 2013. On July 3, 2013, CMS issued a proposed coverage decision, followed by a 30 day public comment period. The proposed NCD would allow Medicare coverage of beta amyloid PET scans for diagnosis of dementia and neurodegenerative disease under the process known as CED for patients enrolled in an approved clinical study. CED is used as an alternative to non-coverage for certain items and services for which CMS has determined that the best available evidence does not support unrestricted coverage. CMS' evidence-based coverage decision-making process (including use of CED) is not meant to replace or duplicate the Food and Drug Administration's determination of a product's safety and effectiveness; rather, it's designed to meet CMS' statutory obligation to ensure that Medicare covers only items and services determined to be "reasonable and necessary" for our beneficiaries.

CMS received 202 public comments on the proposed NCD including many comments on whether CED is appropriate for beta amyloid PET scans. CMS will carefully consider those comments in developing a final coverage decision.

35. 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?

Answer: We agree that early and accurate detection of breast cancer is of extraordinary importance to women's health. Breast tomosynthesis (3D mammography) is a new screening technology that produces three-dimensional digital images and has been approved by FDA when used in conjunction with regular two-dimensional mammography. We are currently evaluating the payment for this digital mammography service, and have met twice with its manufacturer to discuss appropriate payment approaches.

36. 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?

Answer: We have worked individually with each state to determine the readiness of their information technology systems based on a set of critical success factors. These factors include accepting the single streamlined application and applying modified-adjusted-gross-income-based rules to determine eligibility. States are making good progress towards meeting the requirements of a seamless enrollment system. As with any major undertaking, in the private or public sectors, CMS and States have developed mitigation plans to ensure a smooth process for transitioning into the enrollment and eligibility improvements.

37. 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?

Answer: The Marketplace will always check the income information submitted by individuals applying for insurance affordability programs against electronic data sources, such as tax filings from the Internal Revenue Service (IRS), Social Security benefit income data, and current wage information. If an individual reports an income that cannot be verified with our data sources, they will be asked to provide additional documentation to substantiate their current income.

When there is an inconsistency between an applicant's information and a data source, the Marketplace will notify the individual and give him or her 90 days to provide satisfactory

documentation (*e.g.*, pay stubs or immigration documentation) or otherwise resolve the inconsistency. In the meantime, the applicant will be able to enroll in Medicaid if they are otherwise eligible.

38. 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?

Answer: An individual that purchases a qualified health plan through the Marketplace but is later determined to be eligible for government-sponsored minimum essential coverage, such as Medicaid, would transition to government-sponsored minimum essential coverage no earlier than the first day of the first calendar month beginning after the approval. The individual would not be liable for repayment of advanced premium tax credits received while enrolled in a qualified health plan because at the time of their enrollment in the qualified health plan the Marketplace determined the individual to not be eligible for government-sponsored minimum essential coverage.

39. 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?

Answer: The Affordable Care Act is increasing transparency and competition among health insurance plans and driving premiums down. Consumers will have access to better coverage at a lower cost in 2014. For small businesses, the Affordable Care Act fixes the broken insurance market of the past by giving small businesses the tools and opportunities to control costs and increase value.

40. 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?

Answer: For the 2014 plan year, CMS changed our longstanding approach to the SGR when calculating the national MA growth percentage.

Given the increasing number of years in a row for which Congress enacted an SGR fix after the MA rates for the upcoming year have been released in April, CMS in response to comments determined for the 2014 plan year that it was appropriate to base our estimate on what we actually expect to happen, rather than on what would happen under current law.

Accordingly, we changed our interpretation of how we calculate the estimate of projected per capita rate of growth from an estimate of what would occur to the physician fee schedule for the following year under current law to an estimate of what CMS believes actually will occur to the

physician fee schedule for the following year based on recent history, and we revised the growth rate to assume a zero percent change for the physician fee schedule for 2014.

We made this change to reflect the fact that the Congress has annually changed the law every year since 2003 such that the projected sustainable growth rate cut does not occur. We believe it is more reasonable to base the estimate of projected growth in Medicare expenditures on the assumption that a fix will occur than it would be to base the estimate on current law.

Given the market sensitive nature of MA payment, I cannot comment on how CMS plans to address MA payment policies for the 2015 plan year. Like always, we will issue an Advance Notice in February 2014 that will include a comment period and finalize our MA payment policies in April 2014 for the 2015 plan year.

The Honorable Diana DeGette

41. 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?

Answer: The statute provides that the amount of premium tax credit is computed based on the second-lowest cost silver plan available to an individual in a particular rating area. IRS is responsible for the implementation of the premium tax credit under section 36B of the Internal Revenue Code ("the Code"). Final Regulations implementing section 36B of the Code were published in the Federal Register on May 23, 2012. These regulations provide that the second-lowest cost silver plan, also known as an "applicable benchmark plan" is either a self-only plan or family plan, depending on whether the applicant seeks to enroll a spouse or dependents on their plan.

In addition, section 1302(b)(4)(F) of the Affordable Care Act allows qualified health plans offered through the Marketplace to exclude coverage of the pediatric dental essential health benefits if a stand-alone dental plan is offered in that Marketplace. Because of the flexibility afforded to QHPs by statute, it is possible that some QHPs may not include pediatric dental coverage. If a qualified health plan does not include pediatric dental coverage, it may still be considered a potential "applicable benchmark plan" for purposes of computing the premium tax credit.

Individuals wishing to apply premium tax credits to the purchase of a major medical and a stand-alone dental plan may choose to purchase a lower cost silver level plan, or a bronze level plan, thereby increasing the proportion of the premium that the premium tax credit that they are eligible for will cover.

The Honorable G.K. Butterfield

42. 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?

Answer: As you are aware, beginning in January 2014, the Federal Government will pay 100 percent of the medical assistance costs associated with adults who are considered newly-eligible in the Medicaid program. The Federal Government will continue to pay 100 percent of these costs in 2015 and 2016 as well, with the percentage of the Federal share declining to 90 percent in 2020 where it will remain in perpetuity. In fact an independent state-specific report showed the potential for significant cost savings from the reduction in uncompensated medical care.[4] We believe that this remains a good deal for states and offers the opportunity for states to expand affordable health insurance to their low-income residents while significantly reducing uncompensated care.

If North Carolina does not expand Medicaid, the state will experience a smaller drop in the number of uninsured than envisioned when Congress passed the Affordable Care Act. Regardless of whether a state decides to offer Medicaid enrollment to the new adult group, the statute requires yearly aggregate reductions to states in Medicaid disproportionate share hospital payments. These payments are currently made to states, which then make payments to hospitals, to offset the costs of serving uninsured individuals. North Carolina, should it not expand, is therefore foregoing generous Federal support for Medicaid expansion at the same time that there will be less Federal support for uncompensated care.

43. 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?

Answer: In states that choose not to extend coverage to the new adult group, individuals at and above 100 percent of the Federal Poverty Level (FPL) may be eligible for tax credits and cost-sharing reductions to assist them in purchasing health coverage through the new Marketplaces. These tax credits and cost-sharing reductions, per the statute, are not available to individuals under 100 percent FPL. These individuals can purchase insurance through the Marketplace, but such purchase would be at the full cost and may be unaffordable for low-income families.

44. 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,

[4] http://www.ncjustice.org/?q=budget-and-tax/btc-brief-medicaid-expansion-transformative-and-fiscally-sustainable-policy-north

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?

Answer: Yes, CMS has observed that costs for plans in the individual market are lower than projected by the Congressional Budget Office (CBO) and costs for plans in the small group market are lower than they would be absent the Affordable Care Act. A report by the HHS Assistant Secretary for Planning and Evaluation (ASPE) found that in the 11 states for which data are available, the preliminary rate for the lowest cost silver plan in the individual market in 2014 is, on average, 18 percent less expensive than the estimate based on CBO projections.[5] Additionally, five states (CO, NM, OR, VT, and WA) and the District of Columbia have released information showing that for the small group market, proposed premiums for the lowest cost silver option are estimated to be 18 percent lower than the premium a small employer would pay for similar coverage without the ACA.

45. 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?

Answer: Several states have already released rates for 2014 that provide many affordable coverage options for individuals. For example, as detailed in an ASPE report analyzing public rates in the individual market,[6] in Albuquerque, New Mexico, a 25-year-old would pay $109 per month for the lowest cost catastrophic plan, and a 25-year-old in Portland could pay $89 for a catastrophic plan. Rates vary from state to state, by issuer, and by plan level. In addition, a 21-year-old making $25,000 a year would be eligible to receive tax credits toward their premiums. CBO has projected that about 85 percent of Americans who obtain coverage through the Marketplaces will qualify for assistance to make their insurance more affordable, an estimated 20 million Americans by 2017.

46. 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?

Answer: The Affordable Care Act authorizes, and CMS is implementing, a variety of ways to provide outreach, education, and enrollment assistance. We are leveraging forms of assistance

[5] http://aspe.hhs.gov/health/reports/2013/MarketCompetitionPremiums/rb_premiums.pdf
[6] http://aspe.hhs.gov/health/reports/2013/MarketCompetitionPremiums/rb_premiums.pdf

that exist in the insurance market today, as well as new forms of assistance provided by the Affordable Care Act to help educate Americans about the options for enrolling in affordable, high quality coverage beginning on October 1, 2013.

47. 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?

Answer: The Affordable Care Act is bringing an unprecedented level of scrutiny and transparency to health insurance rate increases. The law ensures that, in any state, any proposed rate increase by individual or small group market insurers at or above 10 percent will be scrutinized by independent experts to make sure it is justified. This analysis will help moderate premium hikes and lower costs for individuals, families, and businesses that buy insurance in these markets. Additionally, insurance companies must provide easy to understand information to their customers about their reasons for unreasonable rate increases, as well as publicly justify and post on their website any unreasonable rate increases. These steps allow consumers to know why they are paying higher rates.

The Affordable Care Act makes $250 million available to States to take action against insurers seeking unreasonable rate hikes. To date, 43 States and the District of Columbia are using grants provided by HHS to help them improve their oversight of proposed health insurance rate increases. State rate-review activities are paying off for consumers:

- Rhode Island's Insurance Commissioner used his rate-review authority to reduce a proposed increase by a major insurer in that State from 7.9 percent to 1.9 percent.
- Californians were saved from rate increases totaling as high as 87 percent after a California insurer withdrew its proposed increase after scrutiny by the State Insurance Commissioner.
- Nearly 30,000 North Dakotans saw a proposed increase of 23.7 percent cut to 14 percent following a public outcry.
- Connecticut's Insurance Department rejected a proposed 20 percent rate hike by one of the State's major insurers.

[i] http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD081909.pdf; http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD11001.pdf

Attachment 2—Member Requests

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.**

Answer to 1 & 2: Navigators and other assistance personnel will be required to assist individuals applying for Marketplace insurance affordability programs, including cost-sharing reductions. 45 CFR 155.215(b)(2)(iv) requires Navigators in Federally-facilitated Marketplaces (FFMs) and State Partnership Marketplaces to be trained on "eligibility requirements for premium tax credits and cost-sharing reductions, and the impacts of premium tax credits on the cost of premiums," such that they can explain the eligibility rules to consumers. Cost-sharing reductions are provided to qualified individuals who enroll in a qualified health plan that has a cost-sharing structure (*e.g.*, co-pays, deductibles) such that the out-of-pocket costs paid by individuals are less than under the standard qualified health plan. Cost-sharing reductions are built into a qualified health plan's structure for out-of-pocket costs.

3. **Please provide detailed information on the cost sharing subsidy program.**

Answer: Individuals and families applying for coverage through the Marketplace may choose to have the marketplace determine whether they are eligible for any financial assistance including premium tax credits and cost-sharing reductions. In general, individuals and families with incomes between 100 percent and 250 percent of the Federal Poverty Level (FPL) may be able lower their costs for out-of-pocket expenses such as deductibles, copayments and coinsurance. The level of cost-sharing reductions depends on household income and plan design.

Any individual or family that is determined eligible for a cost-sharing reduction based on their income would have to enroll in a silver plan in the Marketplace to benefit from the cost-sharing reduction. The law also contains special provisions that eliminate cost-sharing for American Indians and Alaska Natives with incomes below 300 percent FPL and for essential health benefits for American Indians and Alaska Natives when such services are delivered through the Indian Health Service (IHS), and Indian Tribe, Tribal Organization, Urban Indian Organization or through referral under contract health services. These "plan variations" are variations of silver level plans that have their cost-sharing features modified to reflect a higher actuarial value (AV) than a standard silver plan, which has a 70 percent AV. For example, individuals with incomes between 100-150 percent FPL will enroll in a plan variation with an AV of 94 percent, those

with incomes between 150-200 percent FPL will enroll in plans with an AV of 87 percent, and those with incomes between 200-250 percent FPL will enroll in plans with an AV of 73 percent.

The statute also specifies that in order to achieve these relevant actuarial values, plans must first reduce the out of pocket maximum for essential health benefits. So, for example, individuals between 100-200 percent FPL will automatically have their out of pocket maximum reduced by two-thirds to $2250 for plan year 2014. Details regarding these figures and plan variations can be found in the *HHS Notice of Benefit and Payment Parameters for 2014*, published in the Federal Register on March 11, 2013.

4. Has CMS conducted live testing involving all parties responsible for implementation? If so, please elaborate.

Answer: The majority of states and Federal Agencies have engaged in successful live testing with the Hub. CMS began testing in October 2012 with the Internal Revenue Service (IRS); in May 2013 with the Social Security Administration (SSA), Department of Homeland Security (DHS), Department of Veterans Affairs (VA), and Peace Corps; and in July 2013 with the Office of Personnel Management (OPM) and the Department of Defense (DOD). CMS has also begun connectivity testing with a limited number of issuers.

5. What vulnerabilities have the live end testing revealed?

Answer: The Hub has gone through extensive testing and testing will continue to ensure it is compliant with applicable FISMA and NIST security standards.

6. Please have HHS provide any reports, audits, or work plans to show the contractors work.

Answer: We will work with your staff to provide this information.

The Honorable Lee Terry

7. Please provide the Committee with the schedule of live testing for the data hub with all of the federal agencies.

Answer: CMS began testing in October 2012 with IRS; in May 2013 with SSA, DHS, VA, and Peace Corps; and in July 2013 with OPM and DOD. Testing will continue after the system goes live on October 1, 2013.

8. How much money has HHS paid United/QSSI to date on the data hub contract?

Answer: CMS has paid QSSI $45 million to date in support of the Data Services Hub contract.

The Honorable Michael C. Burgess

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

Answer: My Chief of Staff learned of the delay when she attended a meeting in June 2013.

The Honorable Leonard Lance

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

Answer: CMS developed a single, streamlined application for use in assessing eligibility for Marketplace coverage, Medicaid, and the Children's Health Insurance Program (CHIP). States have the option of using the model application or developing an alternative application. We have been meeting regularly with states, including New Jersey, to provide technical assistance to facilitate either the adoption of the model application or throughout the development of an alternative application.

The Honorable Bill Cassidy

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

Answer: Marketplaces will always use data from tax filings from IRS and Social Security benefit income data to verify household income information provided on an application, and in many cases, will also use current wage information that is available electronically. The multi-step process begins when an individual applies for insurance affordability programs (including advance payments of the premium tax credit and cost-sharing reductions) through the Marketplace and affirms or inputs their projected annual household income. The inputted income is then compared with information available from IRS and SSA. If the information submitted cannot be verified using IRS and SSA data, then it is compared with wage information from employers provided by Equifax. If Equifax data does not substantiate the inputted information, the Marketplace will request an explanation or additional documentation to substantiate the inputted income.

The Honorable Adam Kinzinger

12. How many agencies are involved with implementing the Affordable Care Act?

Answer: Below is a list of the participating Federal Departments and executive agencies or operating divisions assisting, in various capacities and consistent with their individual mission and authorities, with implementing the Affordable Care Act:

U.S. Department of Agriculture
Department of Commerce
    Census Bureau
DOD (Tricare)
Department of Education
HHS
    Office of the Secretary
    CMS
    Health Resources and Services Administration (HRSA)
    IHS
    Substance Abuse and Mental Health Services Administration
    Centers for Disease Control and Prevention
    Agency for Healthcare Research and Quality
DHS
HUD
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of the Treasury
    IRS
VA
Corporation for National and Community Service
Environmental Protection Agency
Executive Office of the President
    Office of Management and Budget
    Office of National Drug Control Policy
General Services Administration
OPM
Peace Corps
Small Business Administration
Social Security Administration
U.S. Agency for International Development
U.S. Postal Service
Government Accountability Office

13. How often is there a regular interagency meeting on the implementation of the Affordable Care Act?

Answer: Inter-agency meetings on a variety of topics related to Affordable Care Act implementation are held on a regular basis.

14. Is there a deputies, or any other type of, meeting regularly convened by the White House staff on implementation of the Affordable Care Act?

Answer: Executive branch entities, including those within the Executive Office of the President, meet regularly to discuss policy issues.

15. Please submit written updates of the implementation of the Affordable Care Act that you receive within the agency.

Answer: I receive regular verbal implementation updates in meetings.

16. How much will the Affordable Care Act cost to implement (including Hub, advertising, implementation, etc.)?

Answer: Affordable Care Act responsibilities are now a part of CMS' core mission and many of the activities are supported through CMS base operations. CMS is able to breakout the costs associated with CMS' Marketplace responsibilities. In FY 2011 and FY 2012, CMS spent approximately $118 million and $304 million, respectively, on Marketplace activities from the $1 billion Implementation Fund, CMS Program Management, and the Secretary's Transfer from General Departmental Management. In FY 2013, CMS is planning to spend $1.5 billion from Program Management, the Secretary's Transfer Authority, Non-Recurring Expenses Fund, the $1 Billion Implementation Fund, and the Prevention Fund. The President's FY 2014 Budget proposed a total of $2 billion for Marketplace implementation, including $1.5 billion in appropriated funds and $450 million in user fees. Additionally, HRSA is devoting approximately $150 million in FY 2013 funding to Affordable Care Act Outreach and Enrollment efforts to benefit Health Centers and their patient populations. These efforts will facilitate enrollment of eligible health center patients and service area residents into affordable health insurance coverage through the Health Insurance Marketplaces, Medicaid or CHIP.

The Honorable Gus Bilirakis

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

Answer: CMS measures the national payment error rate for Medicaid annually, through the Payment Error Rate Measurement (PERM) program. Through the PERM, CMS measures three areas of Medicaid and CHIP: fee-for-service (FFS) claims, managed care claims, and eligibility cases. Using CMS' guidelines, the states lead the effort in measuring errors in the eligibility cases. A sample of 17 states is measured each year to produce and report national program error rates.

The national Medicaid error rate reported for FY 2012 is 7.1 percent, or $19.2 billion in gross improper payments, which reflects a three-year weighted average national error rate including data from 2010, 2011, and 2012. The weighted national error component rates are as follows: Medicaid FFS: 3.0 percent; Medicaid managed care: 0.3 percent; and Medicaid eligibility: 4.9 percent. The FY 2012 national CHIP improper payment rate is 8.2 percent or $700 million. The national component improper payment rates are as follows: CHIP FFS: 6.9 percent; CHIP managed care: 0.1 percent; and CHIP eligibility: 5.8 percent.

In light of changes to the way states adjudicate eligibility for applicants for Medicaid starting in 2014, CMS will be implementing an annual 50-state pilot program strategy with rapid feedback for improvement, in place of the PERM eligibility reviews, starting January 1, 2014, for FYs 2014-2016. These programs will help inform CMS's approach to rulemaking that it will undertake prior to the resumption of the PERM eligibility measurement component in FY 2017. During this period, PERM managed care and fee-for-service payment reviews will continue uninterrupted on the normal cycle schedule, and CMS will continue to report Medicaid improper payment rates based on that data. In addition, CMS will continue to report comprehensive Medicaid error rates in FYs 2015, 2016, and 2017 based on the FFS and managed care PERM reviews and an estimated eligibility component rate based on historical data.

The Honorable Rene Ellmers

18. 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?

Answer: Yes, the Proposed Rule said that "reporting under sections 6055 and 6056 of the Code will not begin until 2015, although it is anticipated that this reporting could greatly contribute to the integrity of employer verification in the future."[1]

19. Please provide the Committee with information on the income verification process.

Answer: The Marketplace will always check the income information submitted by individuals applying for insurance affordability programs against electronic data sources, such as tax filings from IRS, Social Security benefit income data, and current wage information. When there is an inconsistency between the income information to which an applicant attests and that contained in an electronic data source, the Marketplace will notify the individual and provide her with 90 days to provide satisfactory documentation (*e.g.*, pay stubs) or otherwise resolve the inconsistency. In the meantime, the applicant will be able to enroll in a qualified health plan with an advanced premium tax credit or a cost-sharing reduction, if the applicant is otherwise eligible. If an individual reports an income that cannot be verified with our data sources, they will be asked to provide additional documentation to substantiate their current income. Any applicant receiving a tax credit must file a tax return the next year.

[1] The full text of the rule is available at http://www.gpo.gov/fdsys/pkg/FR-2013-01-22/html/2013-00659.htm.

The Honorable John D. Dingell

20. 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.

Answer: Yes, the new health insurance Marketplaces will be up and running for open enrollment as scheduled 60 days from now. Some states will have FFMs, relying on the Federal Government to establish and operate a marketplace in the state. Other states are partnering with the Federal Government to operate a marketplace. For these states, CMS has already completed the majority of the development of the services required to support open enrollment beginning on October 1, 2013 for coverage starting January 1, 2014.

21. 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?

Answer: Numerous experts agree that the delay of the employer shared responsibility provisions will have little impact on the overall implementation of the law, mainly because about 96 percent of employers with more than 50 workers already provide insurance. The one-year delay in the application of the employer shared responsibility provision does not have a large operational impact on Affordable Care Act implementation, and does not affect the law's overall goals.

22. Would you please elaborate on how consumers across the country will reap the benefits of increased competition through lower rates?

Answer: We are already seeing evidence that the Marketplace is encouraging plans to compete for consumers, resulting in affordable rates. While many states are still finalizing or finishing final review of their rates, some, like New York, California, Washington, Vermont, Oregon, and the District of Columbia, have released preliminary rates, and in some cases, independent experts say that these rates have been lower than expected. In the eleven states for which data are available, the preliminary rate for the lowest cost silver plan in the individual market in 2014 is, on average, 18 percent less expensive than the estimate based on CBO projections.

This is good news for consumers. In fact, some states have released initial bids only to have insurers request to amend their bid after competitors' publically-available bids come in at lower prices. In Washington, D.C., United Health Care and Aetna both reduced their small group rates, by 10 percent and 5 percent, respectively. In Oregon, two plans requested to lower their rates by 15 percent or more. Some rates submitted to California's Marketplace, Covered California, are as much as 29 percent below the 2013 average premiums for small employer plans in California's most populous regions. New York State has said on average, the approved 2014 rates for even the highest levels of coverage of plans individual consumers can purchase on New York's Health Benefits Exchange (gold and platinum) represent a 53-percent reduction compared to last year's direct-pay individual rates. Furthermore, states are using their rate-review powers to review and adjust rates accordingly. In Oregon, the state has reduced rates for

some plans by as much as 35 percent, offering consumers an even better deal on their coverage for the 2014 plan year.

23. 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.

Answer: The Affordable Care Act is bringing an unprecedented level of scrutiny and transparency to health insurance rate increases. The law ensures that, in any state, any proposed rate increase by individual or small group market insurers at or above 10 percent will be scrutinized by independent experts to make sure it is justified. This analysis will help moderate premium hikes and lower costs for individuals, families, and businesses that buy insurance in these markets. Additionally, insurance companies must provide easy to understand information to their customers about their reasons for unreasonable rate increases, as well as publicly justify and post on their website any unreasonable rate increases. These steps allow consumers to know why they are paying higher rates.

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- Californians were saved from rate increases totaling as high as 87 percent after a California insurer withdrew its proposed increase after scrutiny by the State Insurance Commissioner.
- Nearly 30,000 North Dakotans saw a proposed increase of 23.7 percent cut to 14 percent following a public outcry.
- Connecticut's Insurance Department rejected a proposed 20 percent rate hike by one of the State's major insurers.

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

Answer: We are already seeing evidence that the Marketplace is encouraging plans to compete for consumers, resulting in affordable rates. While many states are still finalizing or finishing final review of their rates, some, like New York, California, Washington, Vermont, Oregon, and the District of Columbia, have released preliminary rates, and in some cases, independent experts say that these rates have been lower than expected. In the eleven states for which data are available, the preliminary rate for the lowest cost silver plan in the individual market in 2014 is, on average, 18 percent less expensive than the estimate based on CBO projections.

This is good news for consumers. In fact, some states have released initial bids only to have insurers request to amend their bid after competitors' publically-available bids come in at lower

prices. In Washington, D.C., United Health Care and Aetna both reduced their small group rates, by 10 percent and 5 percent, respectively. In Oregon, two plans requested to lower their rates by 15 percent or more. Some rates submitted to California's Marketplace, Covered California, are as much as 29 percent below the 2013 average premiums for small employer plans in California's most populous regions. New York State has said on average, the approved 2014 rates for even the highest levels of coverage of plans individual consumers can purchase on New York's Health Benefits Exchange (gold and platinum) represent a 53-percent reduction compared to last year's direct-pay individual rates. Furthermore, states are using their rate review powers to review and adjust rates accordingly. In Oregon, the state has reduced rates for some plans by as much as 35 percent, offering consumers an even better deal on their coverage for the 2014 plan year.

The Honorable Diana DeGette

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

Answer: The protection of consumer privacy is a high priority for CMS in the implementation of the Marketplace and strict security and privacy standards govern the Marketplace information technology (IT) systems. The Congress acknowledged the importance of protecting personal information through the Privacy Act of 1974, which establishes requirements that govern the collection, use, and disclosure of information about individuals that is maintained by a Federal executive agency in a "system of records." Since then, the Congress has passed amendments to the Privacy Act and additional legislation to assure Americans that information collected, created, used, and disclosed by Federal agencies is appropriately safeguarded. These additional protections include the Computer Matching and Privacy Protection Act, which amended the Privacy Act, and the e-Government Act of 2002. IT projects undertaken by Federal Agencies and their contractors in support of the Affordable Care Act will comply with these and all other applicable Federal laws, so that the American public is assured that their personal information is protected.

Additionally, certain classes of data may be subject to additional restrictions or protection on data use or transmission. For example, information systems containing tax return information must also comply with the taxpayer privacy and safeguards requirements of section 6103 of the Internal Revenue Code.

In order to establish controls and checkpoints within the Marketplace IT systems, CMS established a series of agreements, business processes, and protocols to ensure privacy controls have been met. Because the databases connected to the Marketplace eligibility systems by the Hub are secure and closed government databases that already exist and comply with Federal privacy standards, most of the work of implementing privacy controls is conducted through business agreements between CMS and its Federal and state partners to assure data is being handled appropriately by all parties before data is exchanged through the Hub. To fulfill the Computer Matching and Privacy Protection Act requirements, CMS is establishing Computer Matching Agreements between CMS and each Federal and state partner. These agreements describe how each partner will exchange information, using the Hub, in a way that ensures the privacy, integrity, and verification of data disclosed during this exchange. CMS and our Federal partners have signed additional agreements about the use of data and information exchanges, as applicable. CMS began formalizing these processes with our partners in July 2011, and has refined and updated them as the Marketplace IT work has progressed.

To ensure these agreements are met, CMS conducts Privacy Impact Assessments. Before State-based Marketplaces are able to use the Hub, CMS conducts a Privacy Impact Assessment to ensure that the State-based Marketplace has met all Federal privacy requirements. CMS is currently reviewing the State-based Marketplaces' Privacy Impact Assessments. Before the Hub is used to route information from Federal databases to Marketplace eligibility systems, CMS completes Federal Privacy Impact Assessments to ensure this information exchange meets the agreed-upon privacy requirements.