November 26, 2013

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20101

Dear Secretary Sebelius:

Thank you for appearing before the Committee on Energy and Commerce on Wednesday, October 30, 2013, to testify at the hearing entitled "PPACA Implementation Failures: Answers from HHS."

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

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

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Thursday, December 12, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Sydne.Harwick@mail.house.gov and mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C., 20515.

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

Sincerely,

Fred Upton
Chairman

cc: The Honorable Henry Waxman, Ranking Member

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Fred Upton

1. **Will you please update the committee on the timing of the interagency framework on mobile medical apps and other software? When you do expect it will be released? What areas do you expect it will cover?**

    a. **Do you expect that the interagency report will detail the barriers to successful regulation within each agency?**

    b. **Will you commit to working with this committee to take into account its concerns with the framework?**

Answer: As directed by the Congress in Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), the Food and Drug Administration (FDA) in consultation with the Federal Communications Commission (FCC), and the HHS Office of the National Coordinator for Health Information Technology (ONC) are working towards publishing a report that contains a proposed strategy and recommendations on a risk-based regulatory framework for health information technology (health IT) that promotes innovation, protects patient safety, and avoids regulatory duplication. We expect that the report will be issued soon.

As part of seeking broad input on developing that regulatory framework, FDA, FCC, and ONC established a multi-stakeholder working group under ONC's Health IT Policy Committee to provide recommendations on what to consider when proposing such a framework. The working group submitted its final recommendations to ONC's Health IT Policy Committee in September 2013.[1] These recommendations highlighted the importance of treating device functionality the same across platforms, and stated that FDA should expedite finalizing its guidance on mobile medical apps because of that guidance's critical importance in providing clarity to innovators.

FDA, FCC, and ONC are taking into account all of ONC's Health IT Policy Committee's recommendations, which adopted in full the working group's recommendations, in the development of a report that will propose a strategy and recommendations on a risk-based regulatory framework, as required by section 618 of FDASIA.

In addition**,** the three Agencies commit to working with the Energy and Commerce Committee and other stakeholders on the development of this regulatory framework. FDA, FCC, and ONC intend to seek public comment on the proposed framework via a number of mechanisms, including publishing a notice in the *Federal Register* and establishing a public docket at *www.regulations.gov*.

As Jeffrey Shuren, M.D., J.D., Director of FDA's Center for Devices and Radiological Health (CDRH), testified at the November 19, 2013, hearing of the Energy and Commerce Health Subcommittee, it is essential for the three Agencies to also work closely and collaboratively with the stakeholder community in trying to put in place a mobile medical apps regulatory framework that is responsive to the needs of the entire stakeholder community, including innovators, patients, and practitioners. Indeed, FDA considered all comments received from the stakeholder community as it worked to finalize its guidance on Mobile Medical Applications.

[1] http://www.healthit.gov/facas/FACAS/health-it-policy-committee/health-it-policy-committee-recommendations-national-coordinator-health-it.

For the report, FDA, FCC, and ONC have already received a great deal of input from stakeholders through the recommendations provided by the working group and adopted by ONC's Health IT Policy Committee, and from other meetings and venues in which the three agencies' representatives have participated. This input is helping to inform the report that will be and made available on each Agency's website, as required by section 618.

Although FDA does not expect that the report will explicitly discuss barriers to successful regulation, FDA, along with FCC and ONC, intends to continue working closely with the stakeholder community to identify and address barriers to the successful implementation of a regulatory framework for health IT, including mobile medical apps.

2. **On November 8, 2013, the Food and Drug Administration (FDA) issued a proposed rule which would enable a generic drug manufacturer to independently update product labeling without having to wait until the corresponding brand name product has received approval from the agency to do so.**

    a. **FDA stated that "[i]f this proposed regulatory change is adopted, it may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs." Please explain how FDA came to this conclusion and provide the Committee with all documents and communications relating to this assessment.**

Answer: Because there is an ongoing rulemaking process at FDA concerning these issues, our responses to this and other questions reflect statements made publicly in the preamble to the proposed rule.

In two recent cases, the U.S. Supreme Court considered the issue of whether Federal law preempts State law tort claims against pharmaceutical manufacturers for failing to provide adequate warnings in drug product labeling ("failure-to-warn claims") (see *Wyeth v. Levine*, 555 U.S. 555 (2009) and *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011)). In *Wyeth v. Levine*, the Court decided that Federal law does not preempt a State law failure-to-warn claim that a brand drug's labeling did not contain an adequate warning. The Court found that the drug manufacturer could have unilaterally added a stronger warning to product labeling under the "changes being effected" (CBE-0) regulation as applied to NDAs, and absent clear evidence that FDA would not have approved such a labeling change, it was not impossible for the manufacturer to comply with both Federal and State requirements. The Court reaffirmed that "through many amendments to the [Federal Food, Drug, and Cosmetic Act] and to FDA regulations, it has remained a central premise of Federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" (555 U.S. at 570-571).

Two years later, in *Pliva v. Mensing*, the Court decided that Federal law does preempt a State law failure-to-warn claim that a generic drug's labeling did not contain an adequate warning. The Court deferred to FDA's interpretation of its CBE-0 supplement and labeling regulations for ANDAs, and found that Federal law did not permit a generic drug manufacturer to use the CBE-0 supplement process to unilaterally strengthen warnings in its labeling or to issue additional warnings through "Dear Health Care Professional" letters, which FDA "argues . . . qualify as 'labeling'" (131 S.Ct. at 2576). The Court found that, under the current regulatory scheme, it was impossible for a generic drug manufacturer to comply with its Federal law duty to have the same labeling as the corresponding brand drug (the reference listed drug or RLD) and satisfy its State law duty to provide adequate labeling (131 S.Ct. at 2578). Therefore, the Court held that the difference between new drug application (NDA or brand drug application) and abbreviated new drug application (ANDA or generic drug application) holders' ability to independently change product labeling through CBE-0 supplements leads to different outcomes on whether Federal labeling requirements preempt State law failure-to-warn claims.

FDA's proposed revisions to its regulations would create parity between brand drug manufacturers and generic drug manufacturers with respect to submission of CBE-0 supplements for safety-related labeling changes by allowing generic drug manufacturers to independently update product labeling under the same conditions as brand drug manufacturers. The proposal would allow generic drug manufacturers to independently change and promptly distribute revised product labeling (including a "Dear Health Care Provider" letter) at the time of submission of a CBE-0 supplement in order to communicate important, newly-acquired drug safety information. A generic drug manufacturer's CBE-0 supplement would be approved upon the approval of the same safety-related labeling change for the corresponding brand drug, unless approval of the NDA for the corresponding brand drug has been withdrawn. FDA intends for this proposed rule to level the playing field and to increase incentives for generic drug manufacturers to participate more actively in ensuring the timeliness, accuracy, and completeness of drug safety labeling.

b. Please explain how this assessment factored into the agency's decision to propose this rule.

Answer: The U.S. Supreme Court's decision in *Pliva v. Mensing* prompted FDA to evaluate its current regulations. This decision, as well as the recent decision in *Mutual v. Bartlett* (discussed below), may alter the incentives for generic drug manufacturers to comply with current statutory and regulatory requirements to conduct robust postmarket surveillance, evaluation, and reporting and to ensure that their product labeling is accurate and up to date. In the current marketplace, approximately 80 percent of dispensed drugs are generic drugs, and brand drug manufacturers may discontinue marketing after generic drug entry. FDA believes it is time to provide generic drug manufacturers with the means to independently update their product labeling to reflect data obtained through postmarket surveillance, even though this will result in temporary labeling differences among products.

c. In light of the *Mensling* (2011) and *Bartlett* (2013) decisions by the Supreme Court, please explain FDA's authority to promulgate such a rule.

Answer: FDA's authority to extend the CBE-0 supplement process for safety-related labeling changes to ANDA holders arises from the same authority under which our regulations relating to NDA holders and biologics license application (BLA) holders were issued. The FD&C Act provides authority for FDA to permit NDA holders and BLA holders to change their product labeling to include certain newly acquired safety-related information through submission of a CBE–0 supplement prior to FDA approval, and the statute similarly authorizes permitting ANDA holders to make the same type of changes prior to FDA approval.

As a result of the decisions in *Wyeth v. Levine* and *Pliva v. Mensing,* an individual can bring a product liability action for failure to warn against a brand drug manufacturer (NDA holder), but generally not a generic drug manufacturer (ANDA holder), and thus access to the courts is dependent on whether an individual is dispensed a brand drug or generic drug. This different result is based on the fact that, under current regulations, an NDA holder can file a CBE-0 supplement for safety-related changes but an ANDA holder cannot. In *Pliva* v. *Mensing,* the U.S. Supreme Court, after noting that "[w]e recognize that from the perspective of Mensing and Demahy, finding pre-emption here but not in Wyeth makes little sense," stated its view that ''Congress and the FDA retain the authority to change the law and regulations if they so desire'' (131 S. Ct. 2567, 2582).

3. **Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (FFDCA) generally requires generic drug manufacturers to have the same labeling as the reference listed drug at the time of approval. FDA has long interpreted this provision as requiring generic drug products to maintain the same labeling as the corresponding brand name product throughout the lifecycle of the generic drug product. With respect to the rule proposed on November 8, 2013, how does FDA plan on addressing these seemingly inconsistent positions? Does FDA plan on amending other regulations in order to do so?**

Answer: At the time of FDA's adoption of the generic drug regulations in 1992, FDA believed it was important that product labeling for the reference listed drug (RLD or brand drug) and any generic drugs be the same to assure physicians and patients that generic drugs were, indeed, equivalent to their RLD. However, as the generic drug industry has matured and captured an increasing share of the market, tension has grown between FDA's requirement that a generic drug have the same labeling as its RLD, which facilitates substitution of a generic drug for the prescribed product, and the need for an ANDA holder to be able to independently update its labeling as part of its independent responsibility to ensure that the labeling is accurate and up to date.

In the current marketplace, in which approximately 80 percent of drugs dispensed are generic and, as we have learned, brand drug manufacturers may discontinue marketing after generic drug entry. FDA believes it is time to provide ANDA holders with the means to update product labeling to reflect data obtained through postmarket surveillance, even though this will result in temporary labeling differences among products while the FDA reviews the proposed labeling change. During its review of a generic drug manufacturer's CBE-0 supplement, FDA would consider submissions by the brand drug manufacturer and other generic drug manufacturers related to the safety issue and determine whether the labeling update is justified and whether modifications are needed. FDA would make an approval decision on proposed labeling changes for the generic drug and the corresponding brand drug at the same time, so that brand and generic drug products have the same FDA-approved labeling.

The proposed rule would likely reduce the variation between brand and generic drug labeling that currently takes place. Under current regulations, only brand drug manufacturers can independently update product labeling with certain newly acquired safety information and distribute revised labeling, before FDA reviews or approves the labeling change, by submitting a CBE-0 supplement. FDA generally has advised that a generic drug manufacturer may use the CBE-0 supplement process only to update its product labeling to conform with the FDA-approved labeling for the corresponding brand drug or to respond to FDA's specific request to submit a labeling change through the CBE-0 process. Accordingly, while FDA reviews a brand drug manufacturer's CBE-0 supplement, there currently is a difference between the brand drug labeling and generic drug labeling. Once FDA approves a change to the brand drug labeling, the generic drug manufacturer is required to revise its product labeling to conform to the approved labeling of the corresponding brand drug. FDA advises that this update should occur at the very earliest time possible; however, FDA has determined that there is often a delay, of varying lengths, between the date on which revised brand drug labeling is approved and the date on which the generic drug manufacturer submits such labeling updates. The proposed rule, if finalized, generally would reduce the time in which all generic drug manufacturers make safety-related labeling changes by requiring generic drug manufacturers to submit conforming labeling changes within a 30-day timeframe.

4. **FDA acknowledged in issuing the proposed rule that "there may be concerns about temporary differences in safety-related labeling for drugs that FDA has determined to be therapeutically equivalent." This is an understatement and very concerning. FDA proposes to address this by establishing a website listing all of the proposed labeling changes that are pending at the agency.**

    a. **Please explain in detail the various methods and plans FDA has considered to alleviate this inevitable confusion. In addition to the website, what else is FDA planning to do to consistently inform provider decision-making and ensure patient safety?**

    b. **Please explain how a website listing all of the proposed labeling changes pending at the agency does not add to the confusion.**

    c. **Please explain how this decision to allow different labels on therapeutically equivalent drug products enhances patient safety.**

Answer: To minimize confusion and make safety-related changes to generic drug labeling readily available to prescribing health care professionals and the public while the FDA is reviewing a CBE-0 supplement, FDA proposes to establish a dedicated Web page on which FDA would promptly post information regarding the safety-related labeling changes proposed by brand and generic drug manufacturers in CBE-0 supplements while FDA is reviewing the supplement (see proposed 21 CFR 314.70(c)(8) and 601.12(f)(2)(iii)). The proposed FDA web page is expected to enhance transparency and facilitate public access to new safety-related information for all products – biological products licensed under the Public Health Service Act as well as drug products approved under the FD&C Act. The public may subscribe to FDA's free email subscription service to receive an email message each time there is an update to this proposed FDA Web page.

The proposed FDA Web page would provide information about pending CBE-0 supplements for safety-related labeling changes, including but not limited to: The active ingredient, the trade name (if any), the application holder, the date on which the supplement was submitted, a description of the proposed labeling change and source of the information supporting the proposed labeling change (*e.g.*, spontaneous adverse event reports, published literature, clinical trial, epidemiologic study), a link to the current labeling for the drug product containing the changes being effected, and the status of the pending CBE-0 supplement (*e.g.*, whether FDA is reviewing the proposed labeling change, has taken an action on the CBE-0 supplement, or has determined that the supplement does not meet the criteria for a CBE-0 supplement).

It is expected that a valid safety concern regarding a generic drug product also would generally warrant submission of a supplement for a change to the labeling by the corresponding brand drug manufacturer, as well as other generic drug manufacturers. The CBE-0 supplements would remain posted on FDA's Web page until FDA has completed its review and issued an action letter. If the CBE-0 supplement is approved, the final approved labeling will be made available on the proposed FDA Web page through a link to FDA's online labeling repository.[2] After an adequate time period to communicate FDA's decision regarding approval of the CBE-0 labeling supplements and to facilitate submission of conforming CBE-0 supplements by other application holders, as appropriate, the original entry on FDA's Web page would be archived.[3]

[2] http://labels.fda.gov
[3] Approved labeling would continue to be available at http://labels.fda.gov.

If finalized, this rule would help ensure that healthcare practitioners and the public have access to the most current drug safety information, which may be used to inform treatment decisions based on the balance of potential benefits and risks of the drug product for each patient.

5. **FDA asserts in the proposed rule that the *Mensing* decision "alters the incentives for generic drug manufacturers to comply with current requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and to ensure that the labeling for their drugs is accurate and up-to-date."**

    a. **Please explain how FDA came to this conclusion.**

    b. **Does FDA have evidence that generic drug manufacturers are not fulfilling such requirements?**

    c. **Does FDA have evidence that the *Mensing* decision led generic drug manufacturers to be less compliant with postmarketing surveillance, evaluation, and reporting requirements?**

Answer: Because this is an ongoing rulemaking process, in which the submission of comments on the proposed rule will result in an administrative record that FDA must review before deciding on what final regulation would be justified, it would not be appropriate for us to respond fully to these questions at this time. We do note, however, that a potential link between tort liability and regulatory compliance has been discussed in other contexts. As several Supreme Court Justices observed, *Pliva v. Mensing,* which exempted generic drug manufacturers from tort liability based on a failure to warn theory,

> creates a gap in the parallel Federal-state regulatory scheme in a way that could have troubling consequences for drug safety. As we explained in *Wyeth v. Levine*, '[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.' 555 U.S., at 579... Thus, we recognized, 'state law offers an additional, and important, layer of consumer protection that complements FDA regulation.' Ibid. (*Pliva v. Mensing*, 131 S.Ct. at 2592) (dissenting opinion).

We do wish to clarify that the proposed rule focuses on the obligation to update labeling to reflect important newly acquired safety information, not on the more general legal obligation to report adverse drug experience information to FDA**.** Brand and generic drug manufacturers currently have the same requirements for developing written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA. All drug manufacturers (both brand and generic) must promptly review all adverse drug experience information obtained or otherwise received from any source, including published literature, and comply with applicable reporting and recordkeeping requirements. Reporting requirements include submission of 15-day alert reports for serious and unexpected adverse drug experiences, periodic reports, an annual report (including a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, and a description of actions the applicant has taken or intends to take as a result of this new information) and, if appropriate, proposed revisions to product labeling.

6. **Please provide CMS's most up to date information on Recovery Audit Contactors (RAC) denials that have gone all the way through the appeals process – both in terms of claim numbers as well as dollar amount.**

Answer: CMS is diligent in its oversight of Recovery Auditors and their decisions. Each month CMS conducts accuracy reviews of decisions made by the Recovery Auditors. CMS reports appeal statistics in the annual Report to Congress and on its website.[4] The most recent published appeal statistics are for Fiscal Year (FY) 2011, and the total overturn rate for all Recovery Auditor decisions was 2.9 percent. The FY 2012 Report to Congress will include updated appeals statistics and will be released in Calendar Year 2014.

7. **Should CMS include metrics on the impact to hospitals in its RAC report to Congress, such as an evaluation or measurement of the amount of funds that are spent by providers in responding to RAC audits, pursuing appeals, and the length of time hospitals must wait for Administrative Law Judge?**

Answer: The annual report includes information on the performance of contractors in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of RACs and savings to the program.

CMS is sensitive to the concerns of the provider and supplier communities and continues to work with these communities to reduce the burden of the review process. CMS has imposed documentation request limits on the number of medical records a Recovery Auditor may request in a 45-day timeframe. These limits help providers prepare for potential audits and encourage the Recovery Auditors to select only those claims with the highest risk of improper payment.

CMS ensures that claims reviewed by one entity are not reviewed by another contractor again, unless there is a concern of potential fraud. CMS also works to ensure that multiple review entities such as Recovery Auditors, Medicare Administrative Contractors, and Zone Program Integrity Contractors do not review the same providers and the same topics at the same time.

Requesting provider self-reported data would be difficult to acquire and independently validate as a part of the RAC report to the Congress, and would introduce additional provider burden.

8. **RACs are paid on a percentage basis in order to finance the program and to incentivize thorough reviews of Medicare paid claims. To what extent do you believe that changes in the financial incentives should be considered? For example, RACs must return any fee associated with an overpayment determination that is reversed on appeal. Should the program be changed so that RACs are paid only after a claim becomes final on appeal? Should there be a graduated incentive program that pays lower contingency fees the more RAC determinations are overturned on appeal?**

Answer: CMS continues to make improvements to the Recovery Audit Program to help alleviate provider burden, ensure the accuracy of Recovery Auditor determinations, and promote transparency within the program. CMS carefully and routinely monitors Recovery Auditor appeal overturn rates. CMS reviews this information, as well as other Recovery Audit program statistics, as we consider future revisions to the Recovery Auditor contracts.

[4] www.cms.gov/rac

9. **We understand that CMS has directed RACs to provide education and feedback to hospitals arising from their audit activity. However, we also hear that this education and feedback does not always occur. What has CMS done to investigate the extent to which RACs are providing education and feedback? Does CMS set standards for what type and quantity of education RACs must provide? Does CMS take into consideration how RACs provide education and feedback to providers when CMS evaluates the RACs? If so, by what measures are the RACs evaluated?**

Answer: As directed in their Statement of Work, Recovery Auditors are required to fully document their rationale for determinations in a Review Results Letter. However, the Recovery Auditors are not required to educate providers on correct CMS billing and payment policy. Educating providers in these areas is the responsibility of the Medicare Administrative Contractors (MACs). Through regularly scheduled meetings and provisions of their contractor Joint Operating Agreements, Recovery Auditors and MACs work closely together to ensure the MACs are supplying the providers timely and accurate information related to problem billing areas.

In addition to using the Recovery Auditors to identify overpayments, CMS also uses their findings to prevent future improper payments. Since October 2010, CMS released thirteen Medicare Provider Compliance Quarterly Newsletters that provided detailed information on 100 findings identified by the Recovery Auditors to educate the provider community on how to correct improper billing behavior.

<u>The Honorable Marsha Blackburn</u>

1. **I've recently heard from providers in my district who were terminated from their managed health care plans. What responsibility does CMS/HHS have in overseeing this process and do they have an understanding as to the reasons behind these actions?**

Answer: Issuers often alter provider networks and payments rates as a regular course of business. While issuers must adhere to new network sufficiency and essential community provider standards, they still have room to make business decisions that work for them. There are now Federal standards that require health plans to include sufficient networks of providers as well as essential community providers.

With regard to provider networks in the Medicare program, under Medicare rules, Medicare Advantage Organizations have the ability to establish and manage contracted provider networks as they choose, as long as they continue to furnish all Medicare Part A and B services, fully meet Medicare access and availability standards, and have a process in place to ensure that, in the case of a provider termination, continuity of care is maintained for patients affected by those terminations.

Medicare Advantage Organizations (MAO) may change provider networks at any time during the year. The Medicare statute (section 1854(a)(6)(B)(iii) of the Social Security Act) prohibits CMS from requiring any MAO to contract with a particular hospital, physician, or other entity or individual to furnish Medicare items and services, or requiring a particular price structure for payment under such a contract.

The Medicare Advantage network access standards are based on local patterns of care and are evaluated using the following criteria: (1) the number of providers by county and specialty type; (2) the travel distance to providers and facilities by county and specialty type; and (3) in some counties, the travel time to providers and facilities by county and specialty type. As it deems necessary, CMS requires MAOs to submit reports and a table that displays the physicians who remain in the network. CMS staff use this information to ensure that the provider network, including specialty providers, meet Medicare access and availability standards.

CMS' role is to ensure the plan's network remains adequate and monitor that the MAO is notifying affected beneficiaries (members) and providers according to the required timeframes: 30-day notice to beneficiaries and 60-day advance notice to providers.

CMS recognizes that Medicare regulations must be sufficiently flexible to allow Medicare Advantage Organizations develop high performance provider networks to ensure cost effective, quality care for enrollees.

2. **Under the current technology infrastructure, how many separate servers or virtual servers in the cloud are being used to host and store data for healthcare.gov?**

Answer: The FFM and State-based Marketplace eligibility, redetermination, and appeals systems store certain eligibility and enrollment records in order to fulfill specific functions, including helping a consumer with an application or eligibility problem. This limited data storage is similar to what private issuers and the Medicare and Medicaid programs currently use to determine eligibility, enroll applicants into health coverage, process appeals, and perform customer service, as well as prevent fraud, waste, and abuse. Approximately 300 virtual servers (including Presentation, Application and Data servers) are used for hosting, and 16 large memory Marklogic Databases are used for storing data. Please note these figures will change as we add more servers as dictated by program or performance needs.

3. **Does your current system for healthcare.gov keep detailed error logs that can be referenced when difficulties with the website occur? If yes, will you please provide the committee a copy of these logs?**

Answer: CMS uses a variety of monitoring platforms to support HealthCare.gov. Earlier in October, the tech team put into place enhanced monitoring tools for HealthCare.gov, providing us with the data that enables us to get a high level picture of what's going on in the marketplace application and enrollment system. Thanks to this work, we are now better able to see how quickly pages are responding, and measure how changes improve a user experience on the site.

4. **CGI was first awarded a contract to work on this project in December of 2011. Do you know why they did not begin to write code until spring of 2013?**

Answer: The development and coding of the Federally-facilitated Marketplace began well before spring 2013. On September 30, 2011, CMS awarded a contract to CGI Federal to help build and support the information technology systems of the Federally-facilitated Marketplaces. With that contract, CGI was given a list of deliverables that began as early as 5 calendar days after the effective date of the contract and covered such items as the architectural diagrams, system design documents, data models, test cases, testing results, and other technical deliverables.

5. **How many rules or regulations pertaining to the ACA were issued between September 1 and November of 2012?**

Answer: CMS issued nine final and proposed rules pertaining to the Affordable Care Act during that time.

6. **As I am sure you know, unprotected passing of personal information—name, address, date of birth, social security number—is illegal under the Privacy Act of 1974 and a very serious concern of many people regarding information input into the healthcare.gov data hub. What processes are in place to prevent this information passing and protect consumer's right to privacy?**

Answer: CMS follows Federal law, government-wide security processes, and standard business practices to ensure stringent security and privacy protections, whether they apply on Healthcare.gov, through the FFM Call Center, with the paper application, or with the help of an in-person assister. Access to data provided to or obtained by the Marketplace during the application process is limited to authorized personnel through passwords, encryptions, firewalls, and secured systems. All personnel, including call center workers, people who handle paper applications and in-person assisters are trained in Privacy Act requirements.

7. **Has any or all party of healthcare.gov been audited to ensure compliance with the HIPAA Privacy, Security, and Breach Notification Rules?**

Answer: The Marketplace application on HealthCare.gov never asks for personal health information beyond what is normally asked for in Medicaid eligibility applications. This is due to the provisions in the Affordable Care Act, which prohibit issuers from denying applicants insurance based on pre-existing conditions or charging more based on health status. Consumers in the Marketplace do not need to disclose details of their medical history as they might have had to do to apply for health coverage in the past.

<u>The Honorable John D. Dingell</u>

1. **In New Hampshire, which has a state-federal partnership and only one insurer, HHS has accepted without question the state's signoff on the insurer's rates, deductibles, and network adequacy. This decision allowed one insurer, Anthem Blue Cross Blue Shield, to decide which hospitals and doctors will be included in the exchange. New Hampshire has very weak insurance regulations, especially with regards to network adequacy. And this one insurer now has a monopoly on the New Hampshire exchange and is offering a very narrow network. The network has gotten national attention because it drops ten of the states twenty six hospitals, impacting patients and the doctors who treat them. For example, some pregnant women in Congresswoman Carol Shea-Porter's district will have to drive more than an hour, past a doctor and hospital that have been excluded from the network, for routine prenatal care. Why did HHS fail to exercise its regulatory authority with regards to network adequacy and instead adopt a policy of deferring to state regulators in states like New Hampshire?**

Answer: Federal regulations at 45 CFR 156.230(a)(2) require a qualified health plan (QHP) issuer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible without unreasonable delay. When CMS evaluated applications for QHP certification for the 2014 coverage year, they relied on state analyses and recommendations from states like New Hampshire, which have the authority and means to assess issuer network adequacy. The states are the traditional regulator of health insurance issuers, and have authority to require additions to networks if requirements of state law are not met. In this case, the New Hampshire Department of Insurance approved the network as adequate, and CMS will work with the Department to monitor adequacy during the benefit year.

<u>The Honorable Joseph R. Pitts</u>

1. **Please explain the steps a healthcare.gov user should take to determine whether the plans they are considering include abortion as a covered benefit?**
2. **In 1303(b)(3)(A) the Affordable Care Act specifies that "A qualified health plan that provides for coverage of the services described in paragraph (1)(B)(i) [abortion in cases other than rape, incest or to save the life of the mother], shall provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage." Please describe how this notice is provided to individuals purchasing plans through the federally facilitated exchange website.**
3. **Rep. Chris Smith (R-NJ) has introduced a bill called the "Abortion Insurance Full Disclosure Act" (H.R. 3279). The bill would require the exchange to prominently display whether each plan includes abortion coverage. It also says if a plan includes abortion (and thus charges an abortion surcharge), the surcharge should be displayed anywhere the price is displayed. Do you support this legislation?**
4. **Please provide a list of all plans sold in each state on the federally facilitated exchange. For each plan please indicate whether the plan includes abortion as a covered benefit. If the plan includes abortion, please indicate the circumstances in which abortion is a covered benefit (e.g. all cases, cases of rape and incest, to save the life of the mother, etc.) In addition, for each plan that includes abortion in cases other than rape, incest or to save the life of the mother, please list the amount of the abortion surcharge described in 1303(b)(2)(i)(II) of the ACA.**

Answer to #s 1-4: CMS has not fully examined the legislation you mention, and cannot offer comment at this time. CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the Qualified Health Plans (QHPs) available to them. The Affordable Care Act requires that each plan in the Marketplace include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. The Affordable Care Act requires plans in the Marketplace to cover the ten essential health benefits. It is up to the issuer to determine which additional services they cover, and consumers may always contact issuers with any questions.

CMS did not separately collect information about issuers' estimates of the actuarial value of coverage of abortion services for which public funding is prohibited. Rather, issuers were directed to include the costs attributable to abortion services for which public funding is prohibited with costs attributable to non-essential health benefits to facilitate the accurate display of premium information. Consistent with section 1303(b)(3)(B) of the Affordable Care Act, specified information including any advertising used by the issuer with respect to the plan and any information provided by the Marketplace must specify only the total amount of the combined charges for coverage of abortion services for which public funding is prohibited and for all other coverage provided by the plan.

5. **According to CRS report R41137, "In certain instances, the [premium tax credit] amount may cover the entire premium and the tax filer pays nothing toward the premium." In such cases where the plan purchaser receives a 100% subsidy how does the insurance company collect the abortion surcharge described in 1303(b)(2)(i)(II) of the ACA?**

Answer: The premium tax credit established under section 36B of the Internal Revenue Code may be used only to cover or reduce the costs of essential health benefits covered by a QHP. Further, the tax credit may not be used to cover the costs of abortion services for which Federal funding is prohibited, consistent with section 1303(b)(2)(A) of the Affordable Care Act.

As described at 45 CFR 156.470, CMS implemented these requirements by collecting from issuers the portion of the total rate that is attributable to essential health benefits, excluding any costs attributable to coverage of services that are not essential health benefits, including abortion services for which Federal funding is prohibited. This amount is then used to calculate advance payments of the premium tax credit. Pursuant to sections 1303(b)(2)(B)(i) and 1303(b)(2)(D)(ii)(III) of the Affordable Care Act, the issuer of a qualified health plan that provides coverage for abortion services for which Federal funding is prohibited must collect a separate, non-subsidized payment from each enrollee of an amount equal to the actuarial value of these services, which the issuer may not estimate to be less than one dollar per enrollee per month. Therefore, it is not possible for a consumer to have no out-of-pocket premium responsibility for a qualified health plan that covers abortion services for which Federal funding is prohibited.

Example: An issuer charges a rate of $100 per month for a particular qualified health plan, of which one dollar is attributable to abortion services for which Federal funding is prohibited and four dollars are attributable to other non-essential health benefits. The premium tax credit eligible portion of the premium is $95, meaning that the maximum amount of premium tax credit a consumer could apply to the plan, if eligible, is $95 per month. Even if the consumer were eligible for a tax credit of $97 per month, the consumer remains directly responsible for five dollars per month. On the Federally-facilitated Marketplace website, the consumer would be advised of his or her out-of-pocket responsibility (in this example, five dollars) during plan shopping.

6. For individuals who are eligible for cost-sharing credits, how will plans ensure compliance with section 1303(b)(2)(A)(ii)?

Answer: As discussed at 45 CFR 156.430 and finalized in the HHS Notice of Benefit and Payment Parameters for 2014, HHS will provide to QHP issuers advance payments and reconciliation payments based on cost-sharing reductions provided for essential health benefits, which do not include abortion services for which Federal funding is prohibited, *see* 45 CFR 156.280(d)(1). Further, in accordance with 45 CFR 156.280(e)(1)(ii), issuers must not use any cost-sharing reductions or advance payments thereof to pay for abortion services for which Federal funds are prohibited. Instead, claims for such abortion services must be paid out of the separate allocation account established for this purpose, *see* 45 CFR 156.280(e)(3).

7. Is abortion ever classified as a "preventive service" in plans sold on the federally facilitated exchanges?

Answer: No.

8. The Affordable Care Act (ACA) departs from the principles of the Hyde Amendment by allowing federal funding of Exchange plans that cover abortion on demand. Moreover, these abortion-covering plans will charge a mandatory abortion surcharge. ACA Section 1303 requires the issuer of an Exchange plan to collect "separate payments" from "each enrollee in the plan:" a "separate payment" in an amount equal of the actuarial value of the abortions for which public funding is prohibited, and a separate payment in an amount equal to the portion of the premium to be paid by the enrollee for all other services. Again, from a pro-life perspective, it is very disturbing that even enrollees who oppose abortion on moral or religious grounds must make such "separate payments," but nevertheless the law is the law until the Congress amends the statute, and the law must be enforced. Moreover, to do otherwise would leave the "abortion surcharge" as a hidden fee that the enrollee pays without the enrollee's knowledge.

a. **With regards to the "Establishment of Allocation Accounts" requirement set forth in Sec. 1303(b)(2)(B), what guidance has HHS given issuers of plans that will participate in the individual market in the Federally-facilitated Exchanges for how to comply with this "separate payment" requirement? Note, this question does not pertain to the "segregation of funds" requirement set forth in Sec. 1303(b)(2)(C), but rather it pertains to the "Establishment of Allocation Accounts" requirement for "separate payments" set forth in Sec. 1303(b)(2)(B). What guidance has HHS given to state Exchanges with regards to issuers of plans in the respective state Exchange's individual market with regards to this "separate payments" statutory requirement? How does HHS intend to monitor and enforce this "separate payments" statutory requirement?**

Answer: Generally, HHS has sought to maximize the flexibility and discretion afforded to State-based Marketplaces within the parameters established by the Affordable Care Act. Consistent with this overall approach, HHS has not published specific guidance outlining how State-based Marketplaces should administer or oversee this specific statutory requirement. However, HHS has specified requirements in 45 CFR 156.280, which apply to issuers of all QHPs, including those in State-based Marketplaces. Additionally, 45 CFR 156.280(e)(2) specifically implements the "separate payments" requirement. State-based Marketplaces could provide additional direction to their QHP issuers if desired, provided that such direction is consistent with the statute and implementing regulations. Similarly, HHS recognizes that QHP issuers participating in the Federally-facilitated Marketplaces may take any of several potential approaches to collecting these separate payments based on their administrative and business practices, also provided that such approaches are consistent with the statute and implementing regulations.

b. **Again, within ACA Sec. 1303(b)(2)(B), "Establishment of Allocation Accounts," the ACA states: "In the case of an enrollee whose premium for coverage under the plan is paid through employee payroll deposit, the separate payments required under this subparagraph shall each be paid by a separate deposit." How does HHS intend to enforce this statutory requirement in the Federally-facilitated SHOP Exchanges? How does HHS intend to monitor and enforce this statutory requirement in the state Exchanges?**

Answer: Because the requirement to collect separate payments and to establish allocation accounts hinges on the presence of the premium tax credit and cost-sharing reductions, neither of which is available for coverage purchased through a SHOP Marketplace, the requirements established in section 1303(b)(2) of the Affordable Care Act and implementing regulations in 45 CFR 156.280 regarding separate payments and allocation accounts do not apply to issuers with respect to their offering of QHPs through a SHOP Marketplace. With respect to the separate payroll deposit, oversight and enforcement of this provision will be consistent with oversight and enforcement for the segregation of funds requirement, with which section 1303(b)(2)(E) of the Affordable Care Act charges state health insurance commissioners.

c. **With regards to the "Segregation of Funds" requirement set forth in ACA Section 1303(b)(2)(C), HHS stated in its "Pre-Regulatory Model Guidelines Under Section 1303 of the Affordable Care Act" that "[p]rior to establishment of the Exchanges, the OMB Circular A-133 Compliance Supplement will be amended to include guidance to assist auditors of State governments regarding compliance with Section 1303." Has such guidance been issued? If not, please explain why.**

Answer: The regulation at 45 CFR 156.280 specifies segregation of funds requirements for issuers to follow. While separate guidance has not been issued, this regulation serves as a guide for state regulators.

d. 45 CFR 156.280(e)(5)(iii) requires: "Each QHP issuer participating in the Exchange must provide to the State insurance commissioner an annual assurance statement attesting that the plan has complied with section 1303 of the Affordable Care Act and applicable regulations." The "Pre-Regulatory Model Guidelines Under Section 1303 of the Affordable Care Act" state that the term "State health insurance commissioner" includes "the relevant federal official in a given State that does not establish an Exchange."

i. For purposes of the Federally facilitated Exchanges, how does HHS intend to monitor that QHP issuers have made a truthful attestation to the U.S. Government that they have complied with all of Section 1303, including the "separate payments" requirement set forth in Sec. 1303(b)(2)(B), "Establishment of Allocation Accounts"?

Answer: HHS expects to employ a number of strategies to ensure that issuers of QHPs in the Federally-facilitated Marketplaces remain in compliance with QHP certification and other applicable standards, including applicable requirements in section 1303 of the Affordable Care Act. These strategies include, but are not limited to, post-certification monitoring, audits, consumer complaints, and technical consultation and assistance provided by CMS regional office account managers.

ii. For purposes of the state Exchanges, how does HHS intend to instruct the state health insurance commissioners to monitor that QHP issuers have made a truthful attestation to the state that they have complied with all of Section 1303, including the "separate payments" requirement set forth in Sec. 1303(b)(2)(B), "Establishment of Allocation Accounts"?

Answer: Consistent with section 1303(b)(2)(E) of the Affordable Care Act, state health insurance commissioners, or the appropriate state regulators, are responsible for collecting and reviewing issuers' plans related to segregation of funds. HHS does not plan to direct state insurance commissioners or other state officials in their efforts to enforce the requirements of section 1303.

iii. According to a Politifact report (http://www.politifact.com/rhode-island/statements/2013/oct/23/barth-bracy/anti-abortion-activist-barth-bracy-says-people-who/), "'The customer is not billed a separate fee,' Dara Chadwick, spokeswoman for HealthSource RI said in an email. The way the system is set up, the issuer of each plan (an insurance company such as Blue Cross) does not bill the customer directly. HealthSource RI does. She asserted that another portion of the law, subsection b(3), prohibits separate billing because abortions can only be mentioned in the summary of benefits when the person is enrolled." Based on this information is HealthSource RI in compliance with the separate payment requirement? Has your department had any interaction with HealthSource RI regarding the separate payment requirement?

Answer: CMS does not interfere with decisions undertaken by State-based Marketplaces as long as they do not violate the Affordable Care Act or its implementing regulations.

9. **HHS indicated that it tends to propose in the future rulemaking to exempt self-insured, self-administered plans from the reinsurance fee in 2014 and 2015. This would include but not be limited to multiple employer plans. What is the justification for this carve out? Is it correct that self-insured plans of any kind currently must pay the $63 fee to the reinsurance program but do not receive any benefit from the program? Why only exempt a small segment of self-insured plans from the fee?**

Answer: Section 1341(b)(1)(A) of the Affordable Care Act provides that "health insurance issuers and third party administrators on behalf of group health plans" make contributions. We believe an appropriate interpretation of this provision is that self-funded plans that do not use third-party administrators for core functions such as claims processing are exempt. We intend to propose to modify the definition of "contributing entity" in future regulations to reflect our revised interpretation.

10. **Please identify the dates on which you, your designee, or representatives from HHS, CMS, or CCIIO discussed healthcare.gov or any of its supporting systems with President Obama or any other White House official and identify those officials.**

Answer: HHS and CMS officials meet and speak regularly with executive branch entities, including the White House and the Office of Management and Budget.

11. **Please provide any materials created or used by you, your designee, or representatives from HHS, CMS, or CCIIO to brief or discuss healthcare.gov or any of its supporting systems with President Obama or any other White House official.**

    Answer: The Department received a document request concerning the development of HealthCare.gov from the Committee on October 10, 2013, and has been working to provide appropriate documents to the Committee.

12. **Please identify the dates where you or Department officials discussed with the President the work and progress related to the creation and building of healthcare.gov, the data hub, exchange subsidy eligibility systems, and related work.**

Answer: I frequently attend White House meetings on the implementation of the Affordable Care Act, including dozens with the President in the last year alone. HHS and CMS officials meet with speak regularly with executive branch entities, including the White House and the Office of Management and Budget.

The Honorable Greg Walden

1. **On August 6 of this year, I sent you along with Secretary Perez a letter regarding a local Multiple Employer Welfare Arrangement (MEWA) plan offered by the Chamber of Commerce in Bend, Oregon. This health plan, which is fully insured and meets all state and federal laws, including those contained in the Affordable Care Act, serves 2,000 employees in my home District. However, the plan still has not been approved by the federal government as a multiple employer organization. With that background, I will make the same request I made in my still unanswered letter from three months ago: please inform me of the action you plan on taking to protect this plan or any other similar association health plan, offered to employees by local businesses in Oregon.**

Answer: As you know, all health insurance issuers must comply with rating reforms in the Affordable Care Act. CMS has provided guidance on how the Public Health Service Act views these arrangements, and depending on the group size, the issuer will need to comply with Fair Health Insurance Premiums (Public Health Service Act section 2701) and the single risk pool (Affordable Care Act section 1312(c)). The issuer can still differentiate this product, for example, by using administrative costs as a "plan-level modifier" in its pricing calculation. Premiums can be lower, reflecting low administrative costs, passing savings on to the consumers and keeping premiums down. Although the guaranteed availability requirement of the Affordable Care Act means that any person who wishes to purchase this product must be able to do so, the product may be sold exclusively via certain agents. In addition, the issuer may continue to use target marketing to certain members. By using these flexibilities, a fully-insured MEWA plan can continue while still complying with the single risk pool requirement of the Affordable Care Act.

2. **In a similar situation, the employees of a company in my District are members of a Teamsters union. Their union uses the Oregon Processors Employees Trust for their medical benefits. Although the trust's medical benefits for year-round, "Regular status" employees comply with the Affordable Care Act, their coverage for seasonal employees does not meet the ACA requirements. The union has informed this employer that they are not going to bring the plan up to the minimum requirements to comply with the Affordable Care Act. This scenario puts the business in a difficult situation: violate their union contract or violate the Affordable Care Act. With 80 seasonal employees who would be forced to purchase insurance through the exchange, the business would be facing tens of thousands of dollars in fines. What recourse do you suggest I offer to this business so that they are not forced to violate either union contract or the health care law?**

Answer: As you may know, on July 9, 2013, the Internal Revenue Service (IRS) published Notice 2013-45 providing for transition relief from sections 6055, 6056 and 4980H of the Internal Revenue Code. These provisions relate to information reporting for employers and issuers and employer shared responsibility. Pursuant to that notice, both the information reporting and the Employer Shared Responsibility Provisions will be fully effective for 2015. In addition, on December 28, 2012, IRS issued proposed regulations on "Shared Responsibility for Employers Regarding Health Coverage".[5] That regulation included proposed rules related to how seasonal employees would be counted for purposes of the employer shared responsibility provision. If you have additional questions about the application of employer responsibility provisions, I suggest that you reach directly to the IRS, as they are the Agency responsible for implementing those provisions.

[5] http://www.irs.gov/pub/newsroom/reg-138006-12.pdf

The Honorable Michael C. Burgess

1. **While we have heard a lot about the front end problems—like creating an account—isn't it true we may not even know the depth of other problems that may come as consumers continue upstream? What problems would you anticipate in the next few months as more users access the website and attempt to actually sign-up for plans?**

Answer: Unfortunately, the experience on HealthCare.gov has been frustrating for many Americans. The initial consumer experience of HealthCare.gov has not lived up to the expectations of the American people and is not acceptable. We are committed to fixing these problems as soon as possible. As part of our efforts to improve HealthCare.gov, we've established a new management structure, led by a general contractor, QSSI. This nerve center for technical operations is diagnosing problems and making quick decisions with developers and vendors to analyze, troubleshoot, prioritize and resolve issues in real time.

This team has put in place enhanced monitoring and instrumentation tools for HealthCare.gov -- providing us with data that enables us to get a high level picture of what's going on in the Marketplace application and enrollment process. We are now better able to see how quickly pages are responding, and measure how changes improve a user's experience on the site. We're also getting information on which parts of the application are causing the most errors--enabling us to prioritize what we fix next. We expect the vast majority of users will be able to successfully enroll through HealthCare.gov by the end of November.

2. **We have heard that various companies, contractors, insurers and others had daily contact with CMS just prior to launch (including conference calls)—were you involved in any of these calls? If so, who was on these calls and were White House staff involved?**

Answer: While I understand that CMS staff worked closely with contractors and issuers, I did not participate in daily operational calls.

3. **When did your pre-launch testing occur as integrated systems? (Also referred to as end-to-end testing)?**

Answer: The FFM eligibility and enrollment system consists of numerous modules. Each module of this system was tested for functionality. Each interface with our business partners and other Federal agencies was also tested. Numerous test cases were used to exercise the end-to-end functionality of the system, and through those tests, CMS was able to identify problems and address them. We know now that we underestimated the volume of users who would attempt to log onto the system at the same time, and therefore our testing did not include performance testing at the volume we experienced at launch.

We are encouraged that the Hub is working as intended, and that the framework for a better-functioning FFM eligibility and enrollment system is in place. By enlisting additional technical help, aggressively monitoring for errors, testing to prevent new issues from cropping up, and regularly deploying fixes to the site, we have already made significant improvements to the performance and functionality of the system.

4. **When healthcare.gov launched on October 1, it required people to set up an account, submit an application, and verify their identity prior to viewing their choice of health plans and costs. However, we have received word from the contractors involved in creating the website that there was originally a browsing feature available, but it was turned off prior to October 1. Who made this decision? Did you or someone in your office make the decision to turn off the browsing feature? If not, were you aware that the contractors were told to turn off the browsing feature?**

Answer: Marilyn Tavenner, as the Administrator of CMS, made the decision to disable the anonymous shopper function in September because the application had performance problems and deficiencies.

5. **Do you have a "Plan C" or contingency plan in place if the website is not fixed by November 30?**

Answer: Based on our analysis we will have it fully functioning by the end of November. We expect that the vast majority of users will be able to successfully enroll through HealthCare.gov. However, there will always be people who don't want to use the website, who would prefer to use a paper application, who need to speak with a call center or need additional in-person assistance.

We've always assumed that, based on Massachusetts' experience, the initial sign-up would be slow. And in fact, consumers have until December 15th to enroll for coverage beginning January 1. So while we don't like the problems we had in October, we do not think it will impact the timeline, because we have a six-month enrollment, so individuals will still have four months to apply for coverage by the end of March.

6. **Section 1303 of the ACA sets up a system in which those who enroll in plans that include abortion will pay an abortion surcharge. Since many Americans do not want to pay such a surcharge, it is important that consumers are able to ascertain which plans will charge the abortion surcharge and which will not. I have received reports that consumers are not able to obtain this information on the healthcare.gov website. What steps are you taking to make sure consumers can access information about abortion coverage and the possible surcharges?**

Answer: CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. The Affordable Care Act requires that each plan in the Marketplace include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. The Affordable Care Act requires plans in the Marketplace to cover the ten essential health benefits. It is up to the issuer to determine which additional services they cover, and consumers may always contact issuers with any questions.

The Honorable Steve Scalise

1. **How can an individual in Louisiana determine if a health insurance plan includes abortion coverage? No American should be put in a position where they have to violate their conscience with respect to their religious beliefs just to comply with the health care law. Will people be able to determine in a clear way on the federal website healthcare.gov whether or not a plan they are considering includes coverage for abortion services?**

Answer: Because Louisiana has enacted a state law consistent with section 1303(a)(1) of the Affordable Care Act, no qualified health plan certified to offer Marketplace coverage in Louisiana covers abortion services for which Federal funding is prohibited. Generally, CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. The Affordable Care Act requires that each plan in the Marketplace include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. The Affordable Care Act requires plans in the Marketplace to cover the ten essential health benefits. It is up to the issuer to determine which additional services they cover, and consumers may always contact issuers with any questions.

2. **Is an issuer permitted to deny or refuse to effectuate enrollment in a qualified health plan when a qualified individual or employer has been assisted with the submission of an application and plan selection to a federal facilitated marketplace by an insurance producer if (1) the state allows insurance producers to enroll applicants through an exchange and (2) the producer has completed the FFM certification and registration process? If so, why are issuers permitted to take such action?**

Answer: The Affordable Care Act requires issuers to accept all individual market applicants within the open enrollment period. The small and large group markets are guaranteed issue all year round with certain exceptions. If a consumer is refused enrollment into a QHP, please have the constituent contact the state Department of Insurance or CMS.

The Honorable Bruce Braley

1. **On April 29, 2013, the Center for Consumer Information and Insurance Oversight (CCIIO) published Set 15 of its ACA Implementation FAQs, which included a section on provider non-discrimination and Section 2706(a). Unfortunately, the FAQ includes information that is misleading and inaccurate and that I believe would change the meaning of the law. The ACA establishes many important patient protections, and provider non-discrimination is one of these protections of access to care. However, the misleading information in this FAQ only serves to undermine our efforts to improve access to care, and is contrary to both the language and the intent of this section of the ACA. Can you please explain why CCIIO appears to have weakened its provision that improves access to care by protecting our nation's doctors, nurses, and other licensed or certified caregivers from discrimination?**

Answer: The statutory language of section 2706(a) of the Public Health Service Act is applicable to non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

Until any further guidance is issued, group health plans and health insurance issuers offering group or individual coverage are expected to implement the requirements of section 2706(a) using a good faith, reasonable interpretation of the law.

The Departments will work together with employers, plans, issuers, states, providers, and other stakeholders to help them come into compliance with the provider nondiscrimination provision and will work with families and individuals to help them understand the law and benefit from it as intended.

The Honorable Bill Cassidy

1. **Numerous actuaries and health care policy analysts have expressed concern that the new health insurance premiums will be far more expensive for young and healthy individuals than paying the individual mandate tax/penalty. This could dissuade them from not going on the Obamacare exchanges. Now that the majority of the individual market has been eliminated due to the new mandates and requirements of the health care law, many of these people will have no place to get health insurance policies if the health policies become unaffordable on the exchanges. Given the challenges Obamacare has faced since its rollout, it is disingenuous to argue that there is not a possibility of adverse selection in the exchanges. Therefore, what is the Administration's plan to provide health insurance to individuals if there is adverse selection in the exchanges and the health care policies become unaffordable?**

Answer: One of the things we've learned since the start of Open Enrollment on October 1 is that the demand for affordable health coverage is very, very high. And, in fact, a new Commonwealth Fund survey confirms just how eager Americans are to purchase coverage through the new Health Insurance Marketplace. The survey found that Americans across our country are aware of the Marketplace and plan to shop for affordable coverage. Some of those who are the most eager to purchase affordable coverage happen to be young, healthy adults. In fact, according to this study, one in five visitors to the Marketplace during the first month was age 19 to 29. A majority of all survey respondents (nearly 60 percent) say they are committed to shopping some more for a plan in the Marketplace and checking out their eligibility for financial help.

The Honorable Gus Bilirakis

1. **The Affordable Care Act has cost-sharing limits that are designed to protect consumers, including limits on deductibles of $2,000 for an individual and $4,000 for a family, in addition to the annual out of pocket maximum. Unfortunately, regulatory guidance issued by CMS has allowed insurance companies to ignore these statutory limits in order to meet the actuarial values of the metal tiers. As a result, we have seen many deductibles at the bronze and silver levels of more than $5,000, which as you know create barriers to accessing care. Could you please share why HHS is allowing these plans to ignore the deductible limits set forth by the law?**

Answer: Deductible limits apply to the small group market only. The HHS Final Regulation on standards related to essential health benefits implements the deductible provisions described in section 1302(c)(2) of the Affordable Care Act for non-grandfathered health insurance coverage and qualified health plans offered in the small group market, including a provision implementing section 1302(c)(2)(C) so that such small group market health insurance coverage may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (metal tier) without exceeding the deductible limit. As you

know, there is often a tradeoff between deductibles and premiums, and higher deductible plans tend to have lower premiums, making them more affordable for consumers.

2. **Individuals suffering from rare diseases or complex medical conditions need plans that provide a comprehensive provider network that includes multiple specialists required to manage and treat these conditions. These patients need to be able to easily search the Marketplace to find plans based with these in-network specialists. Explain the actions you are taking to ensure that enrollees have the necessary search tools to easily review a plan's network offerings and identify the providers included in that network?**

Answer: HealthCare.gov includes a function that allows consumers to preview plans without creating an account. Consumers can simply click and see the qualified health plan's summary of benefits and coverage, the online issuer provider network, and a list of covered prescription drugs. CMS will continue to post additional consumer materials on appeals and other consumer rights created by the Affordable Care Act in the future.

We encourage consumers to be informed shoppers, and to shop for the coverage that best fits their needs. In addition to shopping online through HealthCare.gov, consumers can seek the assistance of agents and brokers or a Navigator to assist with network questions.

3. **I hear of reports of Exchange networks being narrower than traditional commercial insurance. Does the Administration have data on how many doctors and hospitals are included in a typical plan? What are the minimal requirements for the provider network?**

Answer: Federal regulations at 45 CFR 155.1050 and 45 CFR 156.230 set forth network adequacy requirements for all Marketplaces. A QHP issuer must maintain a network that is sufficient in number and types of providers, to assure that all services will be accessible without unreasonable delay.

4. **Can you comment on a NY Times article highlighting how many Americans in rural communities have few options in the Exchange? In my home state of Florida there are only one or two insurance companies participating in the Exchange in 57% of our counties. Nearly a third of our counties have only one option available.**

Answer: The problem of rural and medically-underserved areas is a long-standing issue. We recognize the unique concerns of rural America, and the Affordable Care Act is working to help. Rural areas have fewer potential customers, fewer providers, and fewer issuers. This can result in limited competition. The Affordable Care Act has specific policies designed to encourage competition and lower premiums for Americans across the Nation, including Americans in rural areas.

First, the Marketplace encourage competition and choice by allowing Americans to easily shop and compare plans based on premiums, benefits, and cost-sharing. Many insurers are competing to offer plans in the Marketplace because they are interested in insuring new customers who are drawn to the lower-cost plans thanks to the premium tax credit.

Overall, about a quarter of the insurers proposing to offer individual plans in the Federally-facilitated Marketplace are new to the individual market. On average, consumers can choose from about 50 health plans in the Federally-facilitated Marketplace and 95 percent of Americans live in areas where there are at least two insurance companies in the Marketplace. We expect the number of insurers participating in the

Marketplaces will continue to grow over the next several years as consumers and the country become accustomed to the Marketplaces.

Second, CO-OPs, which are operating in 22 states, are offering new, consumer-oriented competition. For example, in their CO-OPs, they have provided consumers with a third choice in insurance companies. In Maine, the CO-OP provides Mainers with a second option in a market with very few issuers. In Nevada, the CO-OP provided a fourth choice.

The Affordable Care Act also calls for multi-state plans, administered by the Office of Personnel Management, to expand consumer choice in markets. Over 150 Multi-State Plan options are available through the Marketplace in 30 states and the District of Columbia.

The combined effect of the Affordable Care Act has increased competition and has helped premiums be about 16 percent lower than the premium level implied by earlier CBO estimates.[6]

Finally, besides increasing competition, there are many parts of the law that help lower premium rates for every American, including the rate review and medical loss ratio programs.

5. When Arkansas submitted its waiver for Medicaid expansion, the budget neutrality agreement that you approved says it would cost exactly the same amount to cover someone under Medicaid as under an Exchange plan. But the waiver says it will show improved access because rates are higher for Exchange plans that for Medicaid.

a. Could you explain the process of finding this waiver budget neutral?

Answer: Because these individuals could otherwise be eligible for Medicaid absent the demonstration, we examined the best available data to estimate a reasonable per member cost for individuals in the demonstration. This is consistent with how we determine budget neutrality for other Medicaid section 1115 demonstrations. We do not allow the state to accrue or spend any savings attributable to this population.

b. Did CMS actuaries run any analyses of this waiver?

Answer: Consistent with the process used for section 1115 demonstrations, the demonstration proposal was reviewed by a Federal Review Team with reviewers from various entities within Federal Government. The Office of the Actuary does not serve on the Federal Review Team.

c. GAO has previously questioned HHS's budget neutrality agreements as actually increasing federal costs. Can you explain what steps were taken to ensure this, unlike other waiver approvals, won't increase costs on federal taxpayers?

Answer: As indicated in our response to GAO's latest report on this issue, we believe our budget neutrality methodology is appropriate. Our review of the Arkansas waiver was consistent with how we have determined budget neutrality for other Medicaid section 1115 waivers covering the new adult group.

[6] http://aspe.hhs.gov/health/reports/2013/MarketplacePremiums/ib_marketplace_premiums.cfm#_ftnref18.

d. **How did CMS reconcile the fact that Arkansas originally projected Medicaid expansion under FFS to cost $3,900 per person, but says in the waiver that now it will cost $5,666 per person.**

Answer: We are not familiar with the $3,900 analysis, but the estimates used in the budget neutrality analysis for the demonstration were developed in a way that is consistent with how we determine budget neutrality in other Medicaid section 1115 waivers.

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide information for the record. For your convenience, relevant excerpts from the hearing transcript regarding these requests are provided below.

The Honorable Marsha Blackburn

1. **Would you please submit a detailed accounting of exactly what has been spent on healthcare.gov?**

Answer: From enactment of the Affordable Care Act through September 30, 2013, HHS has obligated $490 million for Marketplace IT, and of that amount has spent $230 million. This includes the Healthcare.gov website, and all of the systems and services that support enrollment through the Marketplaces, such as the data services hub and the Federally-facilitated Marketplace IT systems. During that same time period, HHS has obligated approximately $175 million in other IT costs necessary to support the Marketplace IT systems, such as cloud computing and enterprise identity management.

The Honorable John D. Dingell

1. **What can we do about insurance companies that are cancelling policies?**

Answer: The Affordable Care Act provided an opportunity for insurance companies to maintain grandfathered plans as long as they want to in the future. These grandfathered plans may, but do not have to, comply with many of the market reforms included in the Affordable Care Act. Since enactment of the Affordable Care Act in 2010, many issuers have continued to renew employers' grandfathered plans under this provision. Additionally, issuers that renew plans prior to January 1, 2014, are generally able to renew those plans without having them comply with the new protections that take effect for plan or policy years beginning on or after January 1, 2014.

We encourage individuals who do receive a notice that their policy will be discontinued to shop on the Marketplace and review their coverage options. Some individuals may find they qualify for tax credits and/or cost-sharing help to make coverage more affordable.

The Honorable Ralph Hall

1. **How much has the Administration spent on the exchanges in total; not just healthcare.gov but all of the exchanges?**

   Answer: From enactment of the Affordable Care Act through September 30, 2013, HHS has obligated approximately two billion dollars on Marketplaces, and of that amount has outlaid $741 million.

The Honorable John Shimkus

1. **Who made the decision to quote anyone 49 years old and younger to be quoted as a 27 year old and anyone 50 years and older to be quoted as a 50 year old? When was this decision made?**

Answer: We had always envisioned window shopping as a tool that would be a part of HealthCare.gov at some point, however we chose to prioritize other functionality in order to be ready for an October 1 launch. We did include a list of plans and pre-tax credit examples of premiums on the homepage of HealthCare.gov day the site launched, and later rolled out our plan preview tool that allows consumers to see this information by entering some basic information about themselves and the coverage they are looking for. Consumers visiting the site are told that their rates may differ based on their individual circumstances and can call the Marketplace for more specific information. We plan to enhance this window shopping functionality in the coming months to provide consumers with additional information.

2. **When you go on the Federal Exchange, will an individual be able to determine if a plan includes abortion coverage or not? Can you provide for the committee the list of insurers in the Federal Exchange who do not offer abortion coverage as part of their package?**

Answer: CMS is committed to ensuring that HealthCare.gov provides the key information consumers need to make an informed selection from among the QHPs available to them. The Affordable Care Act requires that each plan in the Marketplace include a Summary of Benefits and Coverage and a link to the plan brochure, where consumers can learn more about which services are covered. The Affordable Care Act requires plans in the Marketplace to cover the ten essential health benefits. It is up to the issuer to determine which additional services they cover, and consumers may always contact issuers with any questions.

The Honorable Joseph R. Pitts

1. **In the Washington Post, on October 21, there was an article that said about a month before the exchange opened, a testing group of 10 insurers urged agency officials not to launch the site, because it was riddled with problems. Please provide the names of those that these insurers spoke to. Did HHS respond to the insurers' recommendation to delay the launch?**

Answer: As we stated even before HealthCare.gov launched, this is a complex project, and as with any large scale IT project, we expected there to be bumps in the road at launch. However, we did not anticipate the degree of problems with the system. Given the initial user experience, we now know that we underestimated the volume of users who would attempt to log onto the system at the same time, and therefore our testing did not include performance testing at the volume we experienced at launch.

Additionally, the Federal Marketplace is comprised of distinct pieces of functionality that, together, make up the full integrated system--plan management, eligibility and enrollment, and financial management. CMS prioritized essential functionality to be live on October 1 to ensure that consumers would be able to apply for eligibility and select a plan. Other functionality will come online over time. This is a complex project with a short timeline -- and as such issues were prioritized to meet the October 1 launch date.

The Honorable Lee Terry

1. **Do you have data on how many people in the United States have tried to enroll in a plan through healthcare.gov? Do you have any data on how people have tried to enroll but, because of the problems, have not been able to accomplish that?**

2. **I have reached out to our State insurance commissioner and Governor and found out they have no data about Nebraskans who have either tried to enroll or have enrolled. Would you please provide those numbers?**

Answer #1 and #2: We will be releasing enrollment numbers for the Federally-facilitated Marketplace and the state-based Marketplaces once a month for the preceding month.

The Honorable Mike Rogers

1. **Has any end-to-end security testing been conducted since healthcare.gov went live on October 1? Are there end-to-end security tests run after every new piece of code is put in?**

Answer: CMS protects the FFM through intensive and stringent security testing. CMS conducts continuous anti-virus and malware scans, and monitors data flow and protects against threats by denying access to known bad internet protocols and actors. Additionally, we conduct two separate types of penetration testing on a weekly basis. The most recent penetration testing showed no significant findings. Also on a weekly basis, CMS reviews the operation system, infrastructure, and the application software to be sure that these systems are compliant and do not have vulnerabilities. Vulnerabilities are often mitigated immediately on-site, and re-tested to ensure the strength of our systems' security. Vulnerabilities that cannot be mitigated immediately are tracked using the system's plan of action and milestones which provides a process for assigning responsibility, allocating resources, and identifying specific milestones and completion dates. For the FFM, we conduct Security Control Assessments on a quarterly basis, which is beyond FISMA requirements.

The Honorable Michael C. Burgess

1. **Would you please provide us with the number of people who have been able to enroll on the telephone?**

Answer: There are four ways to enroll in the Marketplace: online, using in-person assistance, a paper application, or over the phone. Consumers who wish to apply by phone can call our call center 24 hours a day, seven days a week. Customer service representatives can work with them to fill out there application, receive their eligibility determination, talk through plan options, and enroll in a plan. Consumers have flexibility on how they would like to complete the application

and enrollment process. For example, they could choose to start their application on the phone and finish their application online at a later time or start with a paper application and then enroll in a plan through the call center. Because many consumers may ultimately use more than one of the four pathways to enroll, it is difficult to classify an enrollment as having occurred only over the telephone.

The Honorable Gregg Harper

1. **During the hearing, we shared a copy of a CGI slideshow from October 11, discussing technical issues that must be addressed within the Website. On page 8 of that slideshow, CGI recommended that CGI and CMS have a review board to agree on which issues can technically be solved and which should be politically solved. Will you find out for us if such a review board was done and if any decisions were made on political reasons or any other reasons?**

Answer: Yes. An existing CMS Change Control Board (CCB), which was established early in the program for managing system change requests, was streamlined to be an integrated Marketplace CCB that addressed both operations management and systems changes. This CCB has been instrumental in prioritizing and determining which set of issues (i.e., change requests) should be worked on and become part of the system defects resolution process and enhancement implementations. In addition, the QSSI general contractor has instituted daily reviews with CMS and CGI since they were brought on board to drive the prioritization, resolution, and release scheduling for critical defects.

The Honorable Adam Kinzinger

1. **Where is HHS getting the money to pay for these fixes? Is it coming from other HHS accounts? Have you used your transfer authority to move money from non-ACA programs to pay for the cost of implementing the President's health care program? If so, from which programs have you drawn money to help with the fix that's not ACA-related?**

Answer: Currently, CMS is funding Marketplace efforts through its appropriation for Program Management and the Nonrecurring Expenses Fund. In Fiscal Year (FY) 2013, HHS used a number of resources at its disposal to ensure sufficient funding for implementation of Marketplaces, including the Secretary's Transfer Authority. The Department notified Congress on its use of the Secretary's transfer authority, which is similar to authority existing in other agencies, and allows for transfer of funds appropriated in an appropriations act for unanticipated needs. For instance, the Department also used the Secretary's transfer authority to provide CMS funding for the 1-800 Medicare call center when call volumes increased significantly under Medicare Part D implementation. The Department has also used the authority in previous years to fund programs such as the Ryan White AIDS Drug Assistance Program and the Administration for Children and Families Office of Refugee Resettlement assistance for unaccompanied alien children.

<u>The Honorable Gus Bilirakis</u>

1. **The New York Times wrote the following: "Project managers at the Department of Health and Human Services assured the White House that any remaining problems could be worked out once the web site went live, but other senior officials predicted serious trouble and advised delaying the rollout." Please provide the names of the officials that gave you the advice that there were serious problems.**

Answer: While HHS officials did expect there might be glitches in HealthCare.gov's operations on October 1, I was not advised to delay the rollout of HealthCare.gov. CMS Administrator Tavenner decided in September that certain functions of the website, such as the Spanish language website, the SHOP website, and the window shopping feature, not go live on October 1. The hope was that delaying these functions to focus on the core functions of HealthCare.gov would alleviate some of the anticipated glitches upon launch. HHS staff did not anticipate the magnitude of the functional and capacity problems seen upon HealthCare.gov's October 1 launch.