

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

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](mailto: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?
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.
  - b. Please explain how this assessment factored into the agency’s decision to propose this rule.
  - 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.
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?
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.

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?
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.
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?
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?
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?

**The Honorable Marsha Blackburn**

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?
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?
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?
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?

5. How many rules or regulations pertaining to the ACA were issued between September 1 and November of 2012?
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?
7. Has any or all party of healthcare.gov been audited to ensure compliance with the HIPAA Privacy, Security, and Breach Notification Rules?

**The Honorable John D. Dingell**

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?

**The Honorable Joseph R. Pitts**

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.
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?

6. For individuals who are eligible for cost-sharing credits, how will plans ensure compliance with section 1303(b)(2)(A)(ii)?
7. Is abortion ever classified as a “preventive service” in plans sold on the federally facilitated exchanges?
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?
  - 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?
  - 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.
  - 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”?
  - 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”?
  - 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?
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?
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.
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.
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.

**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.

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?

#### **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?
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?
3. When did your pre-launch testing occur as integrated systems? (Also referred to as end-to-end testing)?
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?
5. Do you have a "Plan C" or contingency plan in place if the website is not fixed by November 30?
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?

#### **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?

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?

**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?

**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?

**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?
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?
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?



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.
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 than for Medicaid.
  - a. Could you explain the process of finding this waiver budget neutral?
  - b. Did CMS actuaries run any analyses of this waiver?
  - 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?
  - 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.

## **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?

### **The Honorable John D. Dingell**

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

### **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?

### **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?
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?

### **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?

### **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?

### **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?

**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?

**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?

**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?

**The Honorable Gus Bilirakis**

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.