Congress of the United States
Washington, DC 20515

July 18, 2016

The Honorable Karen DeSalvo
National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St S.W.
Floor 7
Washington, DC 20024

Dear Dr. DeSalvo:

We write to request clarifications to the "Office of the National Coordinator (ONC) Health IT Certification Program: Enhanced Oversight and Accountability" proposed rule issued on March 1, 2016. Currently, certification bodies authorized by ONC are responsible for the review of certified health information technology. The Enhanced Oversight and Accountability proposed rule seeks to expand the current scope of ONC's review by implementing "direct review" of tehnology by ONC. Because the provisions included in the proposed rule would mark a significant change in the certification process, we have questions related to ONC's authorities and the implementation of these policies should they be finalized. As evidenced in the work produced by our committees, we share the interest of achieving interoperability and improving patient care, including patient safety. It is important, however, that federal regulations do not overstep authorities provided by Congress or have unintended consequences, such as impeding advances in technology and patient outcomes or hindering the ability to deliver care.

Therefore, we request that you provide the following information:

1. What issues or problems would be solved under these proposed changes?

2. New oversight authority in the proposed rule states it "would extend to the interaction of certified and uncertified capabilities within the certified health IT and to the interaction of a certified Health IT's capabilities with other products" through the "direct review" process.
    - Where does this authority originate in statute?
    - What is the intended impact on products outside the scope of certification?

3. The proposed rule states that Authorized Certification Bodies (ACBs) do not currently have expertise beyond determining compliance with certification criteria.
    - What will be conducted through the "direct review" process that is not already being done by ACBs?
    - Does the ONC have this expertise?

- If not, will it be hiring personnel with this expertise?

4. Would taking a more direct role in oversight of certified health IT products diminish the abilities of the ONC to fulfill other obligations required by statute?

5. The "Enhanced Oversight" rule proposes to "publicly post identifiable surveillance results." Does ONC have security protections in place to protect privacy as well as intellectual property for such disclosures and sharing of information?

6. What other agencies or entities does the ONC anticipate sharing disclosures with during the "fact-finding" portions of "direct reviews?"
   - Does ONC anticipate generating regulatory action at other agencies through this process? If so, what type?

7. How would "direct review" be structured?
   - How would interaction between ACBs and ONC change?
   - Would ONC directly review technology before an ACB is able to review?
   - Will specific technologies be targeted for "direct review?"
   - Is there a trigger that will start the "direct review" process?

8. Providers would be required to attest that they will comply with "direct review" under the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models proposed rule. If finalized:
   - What can providers expect from "direct review?"
   - Will there be guidelines available for providers?
   - What resources can providers anticipate will be needed to comply with "direct review?"

If you have any questions regarding this request, please contact the majority committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate

Joe Barton
Chairman Emeritus
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Michael B. Enzi
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Marsha Blackburn
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