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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

June 3, 2014

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services

Dear Dr. DeSalvo:

The efficient and effective deployment of health information technology has been a priority for the House Committee on Energy and Commerce, with various legislative initiatives and oversight conducted in recent years to improve the regulation of new technologies that can improve health outcomes for patients. Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA) required that the Food and Drug Administration (FDA), acting in consultation with your office and the Federal Communications Commission, produce a report on a "proposed risk-based regulatory framework pertaining to health information technology (Health IT), including mobile medical applications."

That report, released in April 2014, suggests that the Office of the National Coordinator (ONC) for Health Information Technology would, among other things, create a Health IT Safety Center for the purposes of regulating software and other Health IT products. In addition, the ONC 2014 budget suggests it will impose a new user fee on Health IT vendors and developers to support ONC's certification and standardization activities.

Public Law 111-5 established the ONC within the Department of Health and Human Services to perform duties "consistent with the development of a nationwide health information technology infrastructure." However, it is not clear to us under what statutory authority ONC is now pursuing these enhanced regulatory activities, including the levying of new user fees, on Health IT.

So that we can better understand your perspective on ONCs role moving forward, we request responses to the following questions:

- When the authorization for the Medicare and Medicaid Incentive program expires, under what statutory authority does ONC believe it is able to regulate Health IT and electronic health records, particularly in (but not limited to) non-Meaningful Use areas?

- The FDA is provided with the authority to regulate medical devices by the Federal Food, Drug, and Cosmetic Act. What similar authority does ONC point to, going forward, to participate in regulatory activities in coordination with the FDA and the FCC?

- To what extent does ONC's NPRM on 2015 Edition EHR Certification represent a broader shift in focus from coordinating and promoting efforts related to interoperability, privacy and security, and quality reporting criteria, to the regulation of data collection, functionality requirements, and other areas where market forces are more likely to promote innovation and efficiency?

- What role does ONC plan to play moving forward on issues including, but not limited to, Health IT safety and EHR certification requirements? How will the recommendations of ONC's Federal Advisory Committees guide these plans? Will ONC's role be limited to the scope of these recommendations?

Thank you for your attention to these concerns. If you have any questions about this request, please contact Robert Horne of the committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Joseph R. Pitts
Chairman
Subcommittee on Health

Marsha Blackburn
Vice Chairman

Greg Walden
Chairman
Subcommittee on Communications and Technology

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Frank Pallone, Ranking Member
Subcommittee on Health

The Honorable Anna Eshoo, Ranking Member
Subcommittee on Communications and Technology