DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the National Coordinator
for Health Information Technology
Washington, D.C. 20201

July 8, 2014

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
2183 Rayburn House Office Building
Washington, DC 20515-2206

Dear Mr. Chairman:

Thank you for your recent letter regarding the Office of the National Coordinator for Health Information Technology's (ONC's) responsibilities under the Health Information Technology for Economic and Clinical Health (HITECH) Act.[1] In addition, you asked about recommendations contained in the draft report required by section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA).[2] I am pleased to address both issues as well as specific questions posed.

While health IT presents many new opportunities to improve patient care and safety, poorly designed health IT can also create new potential hazards.[5] For example, poor user interface design or unclear information displays can contribute to clinician errors.[6] Health IT can only fulfill its enormous potential to improve patient safety if the risks associated with its use are identified, if there is a coordinated effort to mitigate those risks, and if it is used to make care safer.

As noted in your letter, ONC, the Food and Drug Administration (FDA), and the Federal Communications Commission (FCC) published a draft report as required by FDASIA in April 2014. The report is open for public comment containing a proposed strategy and recommendations on a risk-based regulatory framework for health IT that seeks to promote innovation, protect patient safety, and avoid regulatory duplication.[3] The public comment period for the draft report closes on July 7, 2014. Prior to issuing the draft report, a "FDASIA Workgroup" was established under ONC's Health IT Policy Committee (HITPC),[4] which provided expert input to ONC's HITPC to inform the development of this report. The FDASIA Workgroup was comprised of a wide range of stakeholders and conducted in a transparent manner with ample opportunity for public comment. The workgroup gave its final

---

[1] Pub. L. 111-5, 123 Stat. 115, Division A, Title XIII, & Division B, Title IV.
[2] Pub. L. 112-144, 126 Stat. 993.
[3] *See* http://www.healthit.gov/FDASIA
[4] *See* FCC, "Membership Applications Sought for FDA Safety Innovation Act Workgroup," available at *http://www.fcc.gov/membership-applications-sought-fda-safety-innovation-act-workgroup*. The Workgroup was formed under the ONC's HITPC, a Federal advisory committee established by the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of the American Recovery and Reinvestment Act, Public Law 111-5 (123 Stat. 115) (Feb. 17, 2009) (available at *http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf*).

recommendations in early September 2013, which the Health IT Policy Committee adopted. ONC, FDA, and FCC relied on these recommendations to produce the draft report.

The report did not propose that the Health IT Safety Center would have the authority to regulate health IT. The draft report recommends that no new or additional areas of FDA oversight are needed.[5] Instead, the draft report promotes flexibility and recommends "a limited, narrowly tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities."[6] The draft strategy proposes the creation of an environment of learning and continual improvement including transparent reporting, aggregation, and analysis of safety issues. ONC, FDA, and FCC believe this is central to a health IT framework that promotes innovation and protects patient safety. To that end, in the draft FDASIA report, ONC, FDA and FCC recommend the "creation of a Health IT Safety Center that includes broad representation from public and private stakeholders to establish a governance structure for the creation of a sustainable, integrated health IT learning system that avoids regulatory duplication and leverages and complements existing and ongoing efforts."[7]

As separately noted in your letter, the President's Fiscal Year (FY) 2014 Budget for ONC included a proposal that would have authorized the Secretary to assess user fees to provide ONC with a dedicated and predictable funding stream for administering the ONC Certification Program. The proposal ultimately was not enacted; the President's FY 2015 budget did not include a user fee proposal.

To address your questions regarding our responsibilities under the HITECH Act and how we expect our role to evolve in the future, I would note first that the statutory authorities for the Medicare and Medicaid EHR Incentive Programs are separate from ONC's authorities. CMS administers these incentive programs, which provide incentives through 2016 for Medicare and 2021 for Medicaid. Payment adjustments through Medicare begin in 2015 and continue indefinitely.

Through the HITECH Act, Congress established ONC by statute, and in PHSA section 3001(b), charged the National Coordinator to perform a broad range of duties "in a manner consistent with the development of a nationwide health information technology infrastructure" that among other things, protects and promotes patient safety and "promotes a more effective marketplace, greater competition, greater systems analysis…."

ONC's statutory authority includes, but is not limited to, PHSA section 3001(c)(5), which authorizes the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, to establish programs for the voluntary certification of health IT.[8] In addition, PHSA section 3004 authorizes the Secretary to adopt standards, implementation specifications, and certification criteria for health IT through rulemaking.

---

[5] *Id.*

[6] FDA, "FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework" (April 2014), at 3 (available at http://www.healthit.gov/sites/default/files/fdasia_healthitreport_final.pdf).

[7] *Id.* at 16.

[8] PHSA section 3000(5) defines "Health Information Technology" broadly as "hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information."

In addition, PHSA section 3011 (subsequently delegated to ONC by the Secretary) authorizes investments in "the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States…." That section authorizes the investment of funds to support the "[d]evelopment and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act for the adoption of such records."

Our recent regulatory activities are consistent with the authorities discussed above, and we remain focused on coordinating and promoting health information technology certification criteria related to interoperability, privacy and security, and quality reporting. Our 2015 Edition NPRM proposed voluntary, iterative improvements to the existing 2014 Edition certification criteria to more efficiently respond to stakeholder feedback and enhance interoperability. It was also intended to provide all stakeholders with an opportunity to give early feedback on potential future interoperability updates and greater visibility into ONC's direction.

Going forward, we believe that for health IT to achieve its potential to make care safer, the public and private sectors must work together to integrate health IT fully into a culture of safety in health care that includes shared responsibility, learning, and continuous improvement. ONC expects to continue leading and convening our key public partners (including FDA, AHRQ and FCC) and private stakeholders with respect to health IT safety and interoperability as we implement our HITECH Act responsibilities. We also expect to continue to certify EHR technology as additional health care providers adopt and use EHRs and other technology to support improvements in health and health care.

ONC was first established in 2004 by Executive Order during the Bush Administration and was established by legislation in 2009, with the enactment of the HITECH Act, part of the Recovery Act. Last month, ONC marked its 10-year anniversary and has accomplished a great deal in the advancement of a health IT infrastructure that can help improve care, lower cost, and improve the health of all Americans.

As we enter our second decade, ONC plans to focus on developing and implementing an interoperability roadmap, supporting care transformation, and establishing a framework to support appropriate use of health data to further meaningful consumer engagement, system-level quality and safety of care, improvements in the public's health, and advancements in science.

The Health IT Policy Committee and Health IT Standards Committee (ONC's Federal Advisory Committees) play an important role in ONC's policy making process, and we fully consider recommendations issued by each committee. As noted earlier, the Health IT Policy Committee provided recommendations concerning the draft FDASIA report. In response to stakeholder feedback, ONC is currently restructuring the workgroups of the Health IT Policy Committee (HITPC) and Health IT Standards Committee (HITSC). This effort is aimed at ensuring the work of the committees guides and aligns with ONC's strategic direction and policy priorities into the next decade. It also serves as an opportunity to support collaboration across the committees and to build on the workgroups' diverse membership. The committees provide ONC with public input and in depth discussion of issues. ONC is not obligated to

adopt recommendations from either committee; however, we have implemented the majority of their recommendations.

I appreciate your interest in the work of ONC. I would welcome the opportunity to discuss these issues with you in person. We will also provide this response to the co-signers of your letter.

Sincerely,

Karen B. DeSalvo, MD, MPH, MSc