



## Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

February 20, 2014

Karen DeSalvo, MD  
National Coordinator for Health Information Technology  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Dr. DeSalvo:

This transmittal letter presents the recommendations of the Health IT Policy Committee as approved on September 4, 2013. These recommendations are a result of the work of the Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup and deliberations of the Health IT Policy Committee.

### **FDASIA Workgroup Charge**

The FDASIA Workgroup was charged with providing expert input on issues and concepts identified by the Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communications Commission (FCC) to inform the development of a report on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication.

### **Background**

Section 618 of the FDASIA, enacted by Congress, requires that the FDA, in consultation with ONC and the FCC, develop and post “a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.” Section 618(b) of the FDASIA permits the Secretary of the Department of Health and Human Services to convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations that are included in the report. In response to this, the Secretary convened the FDASIA Workgroup under the Health IT Policy Committee.

The FDASIA Workgroup consisted of 28 public members and an ex officio representing each of the three agencies (FDA, ONC and the FCC). The FDASIA Workgroup convened its first meeting on April 29, 2013. The workgroup divided itself into the following 3 subgroups: taxonomy of health IT; health IT risk assessment and innovation; and health IT regulations. The workgroup held an in-person meeting on May 30-31, 2013. The workgroup (and its subgroups) held dozens of subsequent virtual meetings that culminated in its presentations to the Health IT Policy Committee.

## **Recommendations**

The FDASIA workgroup presented draft recommendations to the Health IT Policy Committee on August 7, 2013, and final recommendations on September 4, 2013. The FDASIA Workgroup recommendations were accepted and adopted as recommendations of the Health IT Policy Committee at the September 4, 2013 meeting. These recommendations are embodied in the attached PowerPoint presentation, with supplemental notes and subgroup summaries.

We appreciate the opportunity to provide these recommendations to inform the development of the report required by Section 618 of the FDASIA.

Sincerely yours,

/s/

Paul Tang  
Vice Chair, HIT Policy Committee

Attachments: FDASIA PowerPoint Presentation (w/ recommendations)  
Notes for FDASIA Recommendations  
FDASIA Taxonomy Summary  
FDASIA Promoting Innovation Summary  
FDASIA Regulations Summary