DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice of public meeting and request for comments

SUMMARY: The Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), and Federal Communication Commission (FCC) seek broad input from stakeholders and experts on the elements we should consider as we develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. To that end, we are requesting comments on the topics identified in Section III.

DATES: This Docket on regulations.gov will remain open for public comments until 11:59pm Eastern Time, August 31, 2013.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health IT, 202-690-7151.

SUPPLEMENTARY INFORMATION:

I. The Food and Drug Administration Safety and Innovation Act Workgroup under ONC's HIT Policy Committee

Section 618(a) of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Public Law 112-144) directs the Secretary of the Department of Health and

Human Services (HHS), acting through the Commissioner of the Food and Drug Administration (FDA), and in consultation with the HHS Office of the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC), to publish a report that will offer a proposed strategy and recommendations for an appropriate risk-based Health IT regulatory framework that would include mobile medical applications and promotes innovation, protects patient safety, and avoids regulatory duplication.

To assist the agencies' efforts in developing this report, the FDA in collaboration with ONC and FCC formed a new workgroup, referred to as the FDASIA Workgroup, under ONC's HIT Policy Committee to help the HIT Policy Committee provide appropriate input and recommendations to FDA, ONC, and FCC as suggested by section 618(b) of FDASIA. Accordingly, the FDASIA Workgroup is charged with providing input on issues relevant to the report FDA, ONC, and FCC will develop, which include:

- Types of risk that may be posed by health IT that impact patient safety, the likelihood that these risks will be realized, and the impact of these considerations on a risk-based approach;
- Factors or approaches that could be included in a risk-based regulatory approach for health IT that also promote innovation and protect patient safety; and
- Approaches to avoid duplicative or overlapping regulatory requirements.

The workgroup's membership includes agency officials and representatives from a wide range of stakeholders, including patients, consumers, health care providers, startup companies, health plans and other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, and employers.

Through this request for comments, FDA, ONC, and FCC would like to provide an opportunity for broad public input on section 618 of FDASIA. Timely submitted written comments will inform the new FDASIA Workgroup's deliberations on the input it will provide

to the HIT Policy Committee regarding the report required by section 618 of FDASIA. We seek input on a number of specific topics identified in Section III, but welcome any other pertinent information stakeholders wish to share. For commenters that wish to have their comments considered by the FDASIA Workgroup, we encourage you to submit your comments as early as possible and preferably before June 30, 2013.

FDASIA Workgroup In-Person Meeting

On May 30 and 31, 2013, in Washington, D.C., the FDASIA Workgroup will hold an in-person meeting which will also be webcast. Persons interested in attending the in-person meeting or viewing the webcast can access information about doing so at this URL:

http://www.healthit.gov/policy-researchers-implementers/policy-fdasia-1

Interested parties may submit electronic comments to http://www.regulations.gov. Submit written comments to Office of the National Coordinator for Health Information Technology, Attention: FDASIA Report Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201.

II. Background

Health IT is being rapidly adopted by the health care industry and there is a growing need for the Federal government to develop a coordinated approach to its oversight of health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. FDA, FCC, and ONC each have important roles with respect to the development and use of health IT that significantly impacts public health and welfare. Congress recognized the importance of a coordinated regulatory approach and through FDASIA, specifically tasked the FDA, ONC, and FCC with creating a report that includes a proposed strategy and recommendations for an appropriate, risk-based regulatory framework for health IT. To inform the report required by FDASIA, FDA, ONC, and FCC, in addition to receiving input from the HIT Policy Committee, intend to provide multiple opportunities, as appropriate, for input from other stakeholders at

different stages throughout the report's development, including, if feasible, feedback on the draft framework prior to finalizing the report.

III. Topics for Discussion

Public comment is sought on any or all of the following topics below.

1. Taxonomy

    a. What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

2. Risk and Innovation

    a. What are the risks to patient safety posed by health IT and what is the likelihood of these risks?

    b. What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?

3. Regulation

    a. Are there **current** areas of regulatory overlap among FDA, ONC, and/or FCC and if so, what are they? Please be specific if possible.

    b. If there are areas of regulatory overlap, what, if any, actions should the agencies take to minimize this overlap? How can further duplication be avoided?

Dated: _May 23, 2013_

Jodi Daniel,

Director, Office of Policy and Planning

Office of the National Coordinator for Health IT

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