



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0406]

Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology.” FDA, the Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communication Commission (FCC) (collectively referred for the purpose of this notice as “the Agencies”<sup>1</sup>) seek broad input from stakeholders and experts on the proposed strategy and recommendations for a risk-based framework for the Food and Drug Administration Safety and Innovation Act (FDASIA) Health Information Technology (IT). The topic to be discussed is the FDASIA Health IT report that contains a proposed strategy and recommendations on an appropriate, risk-based framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.

Dates and Times: The public workshop will be held on May 13-15, 2014, from 8 a.m. to 5 p.m.

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<sup>1</sup> ONC is not an agency, but an office, within the Department of Health and Human Services.

Location: The public workshop will be held at National Institute of Standards and Technology, 100 Bureau Dr., Building 101, Red Auditorium, Gaithersburg, MD 20899-1070.

Contact Person: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993, 301-796-5528, email: [Bakul.patel@fda.hhs.gov](mailto:Bakul.patel@fda.hhs.gov).

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on May 2, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration on the day of the public workshop will not be available.

If you need special accommodations due to a disability, please contact Susan Monahan, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring MD 20993, 301-796-5661, email: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than April 29, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see special accommodations contact). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by May 2, 2014, 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after May 5, 2014. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Requests for Public Comment: This public workshop will include public comment sessions and topic-focused sessions. The Agencies have included topics for comment in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments. The Agencies will post additional details on the meeting Web page.

Comments: The Agencies are holding this public workshop to seek broad input from stakeholders and experts on the FDASIA Health IT Report that contains a proposed strategy and recommendations on an appropriate, risk-based framework pertaining to health information technology. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is June 12, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov><http://www.regulations.gov/>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

(Select this public workshop from the posted events list).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 618 of FDASIA (Pub. L. 112-144), requires that FDA, in consultation with ONC and FCC, develop and post on their respective Web sites “a report that contains a proposed strategy and recommendations on an appropriate, risk-based framework pertaining to health IT,

including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.” To assist the Agencies’ efforts in developing this report, FDA in collaboration with ONC and FCC formed a new workgroup, referred to as the FDASIA Workgroup, under ONC’s Health Information Technology Policy Committee (HITPC) to help HITPC provide appropriate input and recommendations to FDA, ONC, and FCC as suggested by section 618(b) of FDASIA. The “Proposed Strategy and Recommendations for a Risk-Based Framework for FDASIA Health IT” report is available at FDA’s Web site, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm> or ONC’s Web site, [www.healthit.gov/FDASIA](http://www.healthit.gov/FDASIA).

The proposed strategy and recommendations in the report reflect the Agencies’ understanding that risks to patient safety and steps to promote innovation can occur at all stages of the health IT product life cycle and must consider the complex sociotechnical ecosystem in which these products are developed, implemented, and used. The Agencies believe a limited, narrowly-tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities is prudent. The Agencies’ proposed strategy identifies three categories of health IT: (1) administrative health IT functions, (2) health management health IT functions, and (3) medical device health IT functions. The Agencies proposed strategy and recommendations focus primarily on a risk-based framework for clinical health IT functionalities. Four key proposed priority areas are identified in the report for a risk-based framework for health management health IT functionality:

- Promote the use of quality management principles;
- identify, develop, and adopt standards and best practices;
- leverage conformity assessment tools; and

- create an environment of learning and continual improvement.

The Agencies also recommend the creation of a Health IT Safety Center that includes broad representation from public and private sector stakeholders. This public-private entity would be created by ONC, in collaboration with FDA, FCC, and the Agency for Healthcare Research and Quality (AHRQ), with involvement of other Federal Agencies, and other health IT stakeholders. The Health IT Safety Center would convene stakeholders in activities that promote health IT as an integral part of patient safety with the goal of assisting in the creation of a sustainable, integrated health IT learning system that avoids duplication and leverages and complements existing and ongoing efforts.

## II. Topics for Discussion at the Public Workshop

Public comment is sought on the following topics: The Agencies' proposed strategy identifies three categories of health IT: (1) administrative health IT functions, (2) health management health IT functions, and (3) medical device health IT functions. The Agencies seek input on these three categories of health IT.

### A. Promote the Use of Quality Management Principles

The Agencies seek input on the following questions related to promoting the use of quality management principles in health IT:

1. What essential quality management principles should apply to health IT? How should they apply to different stakeholders and at different stages of the health IT product lifecycle?
2. How do we assure stakeholder accountability for adoption of quality management principles? Is there a role for a non-governmental, independent program to assess stakeholder adherence to quality management principles? Is there a role for government?

### B. Identify, Develop, and Adopt Standards and Best Practices

The Agencies seek input on the following questions related to identification, development, and adoption of standards and best practices in health IT:

1. Are the identified priority areas for standards and best practices the proper areas of focus? If not, what areas should be prioritized?
2. How can the private sector help facilitate the development and adoption of applicable health IT standards and best practices? Is there a role for a non-governmental, independent program to assess product and stakeholder adherence to standards and best practices? Is there a role for government?

### C. Leverage Conformity Assessment Tools

The Agencies seek input on the following questions related to clarifying the value and role of conformity assessment tools in health IT:

1. What conformity assessment tools, if any, should be incorporated into a risk-based health IT framework? How should they apply to different stakeholders and at different stages of the health IT product lifecycle? How can adoption of and adherence to conformity assessment programs be promoted?
2. Should interoperability be tested? How should tests to validate interoperability be conducted? Should interoperability standard(s) be adopted and used for conformity assessments (i.e. develop a functional standard that specifies interoperability characteristics that could be used for conformity assessment)?
3. How should the intended user (e.g. health care provider, consumer, etc.) affect the type of conformity assessment performed?
4. How should conformance assessment results be communicated to stakeholders?

5. Is there a role for a non-governmental, independent health IT conformity assessment program? Is there a role for government? Should the ONC Health IT Certification Program be leveraged to protect patient safety through the use of conformity assessment tools?

D. Create an Environment of Learning and Continual Improvement

The Agencies seek public input on the following questions related to creating an environment of learning and continual improvement:

1. What should be the governance structure and functions of the Health IT Safety Center, in order for it to serve as a central point for a learning environment, complement existing systems, facilitate reporting, and promote transparent sharing of adverse events, near misses, lessons learned, and best practices?
2. How can comparative user experiences with health IT be captured and made available to the health IT community and other members of the public to promote learning?
3. How can the private sector help facilitate the development of a non-governmental process for listing selected health IT products? What types of products and information should be included? Should the results of conformity assessments, such as conformance with certain clinical or privacy and security standards, be included?
4. In terms of risk management, what type of safety-related surveillance is appropriate for health IT products categorized as health management functionality? What continued or expanded role(s), if any, should the ONC Health IT Certification Program play in the safety-related surveillance of health IT products?
5. What role should government play in creating an environment of learning and continual improvement for health IT?

### E. Clinical Decision Support

The Agencies seek public input on the following questions related to clinical decision support (CDS):

1. What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?
2. How should the following priority areas identified in the health management health IT framework be applied to CDS categorized as health management health IT functionality?
  - a. Quality management principles.
  - b. Standards and best practices.
  - c. Conformity assessments.
  - d. Learning environment and continual improvement.
3. Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?
4. Does the certification of CDS functionalities, such as those functionalities currently certified under the ONC Health IT Certification Program, sufficiently balance patient safety and the promotion of innovation?
5. How can the private sector help assure the facilitation of the development, application and adoption of high quality CDS with health management health IT functionality in lieu of a regulatory approach? What role, if any, should government play?

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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