



The Office of the National Coordinator for  
Health Information Technology



# FDASIA Health IT Report Webinar

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**Jodi Daniel, ONC**  
**Bakul Patel, FDA**  
**Matt Quinn, FCC**

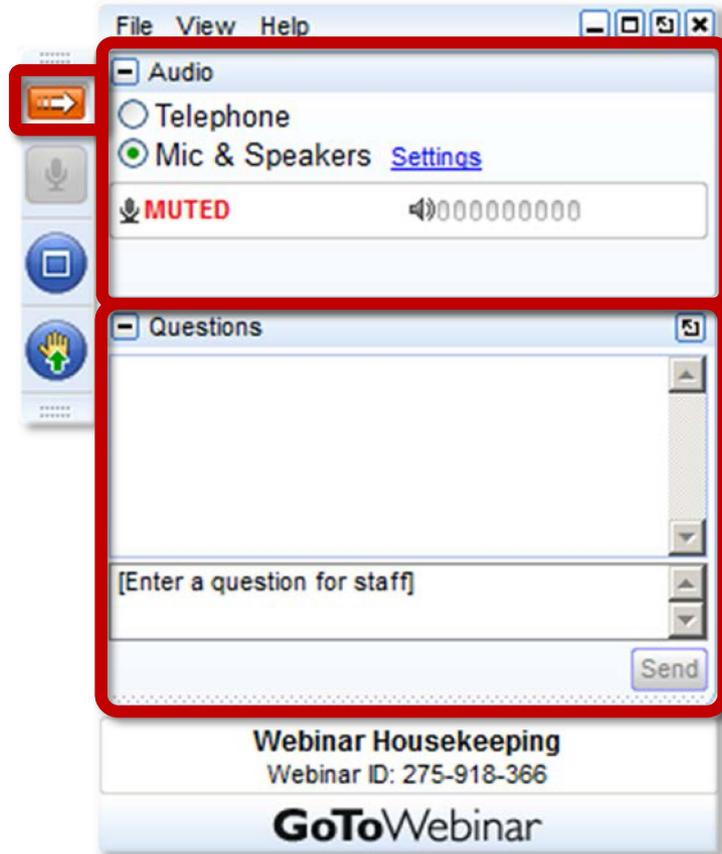
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HealthIT.gov

# Welcome to the FDASIA Health IT Report Webinar!

- Congratulations, you have logged in successfully!



## Your Participation

Open and close your control panel

Join audio:

- Choose “Mic & Speakers” to use VoIP
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Submit questions and comments via the Questions panel

**Note:** Today’s presentation is being recorded and will be provided within 48 hours.

Will I be able to get a copy of these slides after the event?

**Yes**



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Director of Healthcare Initiatives,  
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- Health IT can offer tremendous benefits:\*

  - Prevention of medical errors
  - Improved efficiency and health care quality
  - Reduced costs
  - Increased consumer engagement

- Health IT can pose risks to patients if it is not designed, developed, implemented, maintained, or used properly.\*

*\* Institute of Medicine. 2012. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press.*

- Charged FDA, in consultation with ONC and FCC, to develop and post on their respective websites:
  - *“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.”*
- Permitted the convening of external stakeholders and experts for input.

- **ONC Health IT Policy Committee - FDASIA Workgroup**
  - 28 members + Agency ex-officio members (FDA, FCC, and ONC)
  - experts representing patients, consumers, health care providers, startup companies, health plans, venture capitalists, IT and health IT vendors, small businesses, purchasers, and employers
- **More than 28 Workgroup meetings (open to public)**
  - **Subgroups:**
    - Taxonomy
    - Risk & Innovation
    - Regulations
- **Federal Register docket**
- **Recommendations as input to the framework**

- Employ a risk-based approach to appropriately mitigate patient safety risks while avoiding unnecessary regulatory oversight;
- Leverage private sector knowledge, experience, and expertise;
- Facilitate, rather than impede, innovation;
- Promote transparency on product performance and safety; and
- Create/support an environment of learning and continual improvement.

# Categories of Health IT Functionality

Administrative Functionality*	Health Management Functionality*	Medical Device Functionality*
<ul style="list-style-type: none"> <li>• Admissions;</li> <li>• Billing and claims processing;</li> <li>• Practice and inventory management;</li> <li>• Scheduling;</li> <li>• General purpose communications;</li> <li>• Analysis of historical claims data;</li> <li>• Determination of health benefit eligibility;</li> <li>• Reporting communicable diseases;</li> <li>• Reporting on quality.</li> </ul>	<ul style="list-style-type: none"> <li>• Health information and data management;</li> <li>• Data capture and encounter documentation;</li> <li>• Electronic access to clinical results;</li> <li>• Some clinical decision support;</li> <li>• Medication management;</li> <li>• Electronic communication (e.g. provider-patient, provider-provider, etc.);</li> <li>• Provider order entry;</li> <li>• Knowledge management;</li> <li>• Patient ID and matching.</li> </ul>	<ul style="list-style-type: none"> <li>• Computer aided detection software;</li> <li>• Remote display or notification of real-time alarms from bedside monitors;</li> <li>• Radiation treatment therapy planning software;</li> <li>• Arrhythmia detection.</li> </ul> <p style="text-align: center;">* Examples provided. Not intended to be an exhaustive list of functionalities.</p>
No Additional Oversight	Primary Focus of Proposed Health IT Framework	Primarily FDA Oversight

**Promote the Use of Quality Management Principles**

**Identify, Develop, and Adopt Standards and Best Practices**

**Leverage Conformity Assessment Tools**

**Create an Environment of Learning and Continual Improvement**

## **Health IT Safety Center**

- **Promote the Use of Quality Management Principles**

- Conclusion: The application of quality management principles, including a quality systems approach by health IT stakeholders, is necessary for the safe design, development, implementation, customization, and use of health IT.

- **Identify, Develop, and Adopt Standards and Best Practices**

- Conclusion: The identification, development, and adoption of applicable health IT standards and best practices can help to deliver consistently high-quality health IT products and services to consumers.

- **Leverage Conformity Assessment Tools**

- Conclusion: These tools should be used and applied in a risk-based manner to distinguish high-quality products, developers, vendors, and organizations from those that fail to meet a specified level of quality, safety, or performance.

- **Create an Environment of Learning and Continual Improvement**

- Conclusion: The public and private sector must work together to develop a culture of safety, transparency, learning, continual improvement, and shared responsibility with better-defined accountability.

# Feedback from the public workshop



ONC

FDA

FCC

# DISCUSSION

## *Questions:*

- *Does the focus on functionality make sense?*
- *Are the three categories of functionality logical?*
- *Are there areas where the Agencies can be more clear about how functionalities fall within the bucket?*

## Questions:

- *What conformity assessment tools, if any, should be used? How should they apply to different stakeholders? How can adoption of and adherence to conformity assessment programs be promoted?*
- *Should interoperability be tested? How should tests to validate interoperability be conducted?*
- *How should the intended user (e.g. health care provider, consumer, etc.) affect the type of conformity assessment performed?*
- *How should conformance assessment results be communicated to stakeholders?*
- *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?*

- CDS: Encompasses tools intended to enhance, inform, and influence health care decisions.
- Most CDS functionalities would be health management health IT.

## Health Management Functionality

- Clinician order sets;
- Drug-drug interactions and drug-allergy contraindication alerts;
- Drug dosing calculations;
- Drug formulary guidelines;
- Reminders for preventative care;
- Access to treatment guidelines;
- Calculation of prediction rules.

## Medical Device Functionality<sup>2</sup>

- Computer aided detection/diagnostic software;
- Remote display or notification of real-time alarms from bedside monitors;
- Radiation treatment planning;
- Robotic surgical planning and control;
- Electrocardiography analytical software.

- FDA:
  - does not intend to focus its oversight on Health Management Functionality
  - will continue to focus on Medical Device Functionality
  - will work with federal and private stakeholders to clarify the types of medical device clinical decision support that should be the focus of FDA's oversight.

## Questions:

- *What types of CDS functionality should be the focus of FDA oversight?*
- *How should the priority areas be applied to CDS categorized as health management health IT?*
- *Are there additional safeguards for CDS, such as greater transparency with respect to CDS knowledge base and decision model that are needed to appropriately balance patient safety and the promotion of innovation?*
- *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?*
- *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?*

- Public-private entity would be created by ONC, in collaboration with relevant agencies and other stakeholders
- Serve as a trusted convener of health IT stakeholders
- Focus
  - Education
  - Engagement
  - Evidence

## Questions:

- *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?*
- *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?*
- *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 be included?*
- *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?*

- 90-day Comment Period
- Ends July 7
  
- For the report and more information:  
<http://www.healthit.gov/FDASIA>