ONC Fact Sheet:
Health Information Technology
Patient Safety Action & Surveillance Plan
for Public Comment
FY2013 – 2015

Background

Health IT has the potential to greatly improve patient safety; however, its full potential can only be realized if all interested parties, including the government and private sectors, recognize that patient safety is a shared responsibility.

The *Health IT Patient Safety Action and Surveillance Plan* (Health IT Safety Plan) places the role of health IT within HHS's overall commitment to patient safety and builds upon the recommendations made in the 2011 Institute of Medicine Report, *Health IT and Patient Safety: Building Safer Systems for Better Care*.

Summary of Plan

The Health IT Safety Plan's goal is to "*Inspire Confidence and Trust in Health IT and Health Information Exchange,*" by taking steps to:
1. Use health IT to make care safer
2. Continuously improve the safety of health IT

As discussed in the Health IT Safety Plan, ONC will leverage existing federal agencies' authorities and private sector safety programs to increase knowledge about health IT safety among health care professionals and improve how health IT makes care safer. The Health IT Safety Plan, issued on December 21, 2012, covers fiscal years 2013 through 2015. Public comments to the plan are due by February 4, 2013, 11:59 pm EST, to ONC.Policy@hhs.gov.

Plan Strategies

The draft plan prescribes a list of actions that are organized under three strategies:

A. **Learn**: Increase the quantity and quality of data and knowledge about health IT safety
B. **Improve**: Target resources and corrective actions to improve health IT safety and patient safety
C. **Lead:** Promote a culture of safety related to health IT

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Plan Highlights

1. <u>**Continuously improve the safety of health IT products:**</u>
   - Code of conduct: ONC will work with developers on a code of conduct that commits developers to:
     o Work with Patient Safety Organizations (PSOs) — or similar entities — to report, aggregate, and analyze health IT – related safety events
     o Support providers in reporting safety events
     o Collaborate with private sector efforts to make comparative user experience with different EHR systems more available
   - ONC-Authorize Accrediting Bodies' (ONC-ACB's) surveillance and ONC certification:
     o ONC will leverage ONC-ACB surveillance and live testing to ensure safety features are functional in live environments and that developers address safety complaints
     o ONC will continue to incorporate safety into its standards and certification criteria
   - Manufacturer and User Facility Device Experience: ONC will monitor health IT adverse event reports to the FDA's MAUDE database

2. <u>**Improve understanding of health IT and patient safety:**</u>
   - AHRQ Common Formats to enhance provider reporting: The Agency for Healthcare Research and Quality (AHRQ) and ONC will work with providers and PSOs to incorporate AHRQ Common Formats into providers' health IT and reporting systems. AHRQ Common Formats allow for easy, real-time reporting and aggregation of patient safety events and risks
   - PSOs and AHRQ to collect, aggregate and analyze patient safety reports: AHRQ, in collaboration with ONC, will work with PSOs, providers, and developers to add a focus of health IT to their collection, aggregation, analysis, and mitigation of providers' adverse event reports. AHRQ will also provide guidance to PSOs on how they can work with providers to use health IT to improve reporting and mitigate health IT risks

3. <u>**Promote safe use of health IT as part of a culture of safety among providers:**</u> Align Centers for Medicare & Medicaid Services' (CMS') safety standards for health care facilities, its interpretive guidance, and surveyor trainings to add a focus on health IT and patient safety

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4. **Incorporate safety requirements into Meaningful Use**: CMS Medicare and Medicaid EHR Incentive Programs and ONC's Standards and Certification Criteria rulemakings have been and will continue to be used to improve patient safety

5. **Establish Priority Areas:**
    - ONC plans to lead a public-private process to identify health IT safety priority areas, measures, and targets – building from current research to develop health IT safety guides and assess effectiveness of health IT safety interventions
    - HHS plans to support research and development of tools and guidance for using health IT to improve safety and mitigate health IT safety risks

6. **Establish the ONC Safety Program**:
    - Coordinate the implementation of the Health IT Safety Plan
    - Comprehensively analyze data from identified reporting programs
    - Eliminate or significantly reduce inefficiencies across the programs
    - Develop policies and procedures to establish an ad hoc HHS multi-agency committee to address major health IT safety issues

7. **Evaluate and monitor approaches:**
    - During implementation, ONC will continually evaluate the effectiveness of the Health IT Safety Plan and determine whether additional actions are required to better capitalize on health IT's potential to improve patient safety
    - ONC will collaborate with FDA and the Federal Communications Commission (FCC), to produce a report that proposes a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT which promotes safety and innovation

Next Steps in publishing the Health IT Patient Safety Plan

ONC has released the Health IT Safety Plan for public comments on December 21, 2012. Public comments will be accepted for 45 days, February 4, 2013, 1:59 pm EST and can be emailed to ONC.Policy@hhs.gov. Based on the public input, ONC will publish the final Health IT Safety Plan.

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