ONC Health Information Technology Patient Safety Action & Surveillance Plan

Summary

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Background

In November 2011, the Institute of Medicine published an ONC-funded report “Health IT and Patient Safety: Building Safer Systems for Better Care” which included recommendations for HHS action to reduce HIT-related adverse events. In response to the report, ONC published “Health Information Technology Patient Safety Action & Surveillance Plan” which announced a series of initiatives designed to improve reporting and data collection of HIT-related adverse events through:

- Voluntary reporting using AHRQ’s Common Data Format
- HIT Certification including adverse event reporting functionality using AHRQ Common Data Format, coupled with patient safety audits by ONC Certification bodies.
- Launch of new monitoring initiatives by AHRQ, FDA, and CMS.

ONC has requested public comments on the Health IT Safety Plan. Public comments will be accepted through February 4, 2013. Comments should be submitted to ONC.Policy@hhs.gov.

Health IT Action Plan

- ONC will propose using certification criteria to ensure that EHR technology can facilitate reporting of safety events in AHRQ’s Common Format.
- Within 12 months of release ONC will work with EHRA, EHR developers, and professional groups to develop a code of conduct that is aligned with a credible mechanism for holding EHR developers accountable. The code will:
  - Ensure business practices are in place to promote the usability and safety of HIT products and adverse event reporting.
  - HIT developers should collaborate with PSOs and provide safety information related to their product.
  - Support provider reporting of safety events. (contractual nondisclosure clauses and intellectual property protections) and other factors that may inhibit the free exchange of information re: patient safety and transparency.
  - Ensure developers cooperate with efforts to compare user experiences across different EHR systems. (Comparative User Experience)
- Provide support to Patient Safety Organizations (PSOs) to identify, aggregate, and analyze health IT safety event and hazard reports.
  - AHRQ will provide technical assistance on using Common Formats, rendering patient safety event data non-identifiable (as needed) and making health IT – related patient safety reports available in the Network of Patient Safety Databases (NPSD).
  - AHRQ will issue guidance on how stakeholders can incorporate health IT expertise and collaborate for the purposes of analyzing and correcting health IT – related adverse events, trends, and risks.
• Incorporate HIT safety in post-market surveillance of certified EHR technology through ONC-Authorized Certification Bodies (ONC-ACBs).
  o ONC will provide guidance regarding:
    ▪ Developers keeping a record of complaints;
    ▪ Making complaint records available to the certification body upon request;
    ▪ Taking appropriate action with respect to complaints; and
    ▪ Documenting actions taken.
  o ONC will provide guidance to ONC-ACBs on reviewing complaints, safety issues related to capabilities for which certification is required, and information included in the annual surveillance report submitted to ONC.
• CMS plans to align its health and safety standards for providers/suppliers and its interpretive guidance consistent with the HIT Safety Plan. CMS surveyors will be trained accordingly. Surveyors will also monitor hospitals for use of the AHRQ Common Format.
• AHRQ will launch QSRS (Quality, Safety, and Review System), a voluntary adverse event reporting system, in 2014 to replace Medicare Patient Safety Monitoring System (MPSMS). In the meantime, AHRQ will use MPSMS and support research to better estimate adverse event occurrence.
• ONC will monitor health IT adverse event reports to the FDA Manufacturer and User Facility Device Experience (MAUDE) database.

**ONC Patient Safety Program**

In order to accomplish these goals, ONC will launch the ONC Safety Program to coordinate the HIT Patient Safety Plan.

• Coordinate the implementation of the Health IT Safety Plan by
  o Ensuring all actors are fulfilling their responsibilities under the Plan; and
  o Collaborating with actors to incorporate health IT and patient safety in their organizations.

• Comprehensively analyze data from the data streams, which includes
  o Collecting and aggregating data among the different data streams;
  o Identifying trends in patient safety and health IT;
  o Providing feedback to developers and providers; and
  o Submitting policy recommendations to government agencies and Congress.

• Eliminate or significantly reduce inefficiencies across the programs by
  o Identifying any unnecessary overlap that occurs when implementing the Health IT Safety Plan;
  o Evaluating the outcomes and effectiveness of the Health IT Safety Plan as it is implemented; and
  o Determining from the outcomes what actions are beneficial.