AHIMA Helping Set the Standards for Health IT

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By AHIMA's Advocacy and Policy Team

Standards development for health IT and healthcare has become an increasingly important part of AHIMA's work over the last several years. Now, through the association's recent work with both national and international standards groups, AHIMA staff and members are playing a deciding role in just what standards are implemented, and just how they will improve local and global healthcare.

AHIMA Advancing International Standards Work

AHIMA's role in standards development was evident in April when the United States Technical Advisory Group (US TAG) to ISO/Technical Committee 215 on Health Informatics (ISO/TC215) met in Arlington, VA to discuss projects and standards that work to improve compatibility and promote interoperability between EHRs, PHRs, medical devices, and other healthcare systems.

The International Organization for Standardization (ISO) is a network of national standards bodies that represent ISO in their respective countries. In the United States, the American National Standards Institute (ANSI) is the national standard body representing ISO and has immediate access to the standards development processes. ANSI coordinates the US voluntary consensus standards system, and AHIMA serves as the ANSI-appointed Secretariat to ISO/TC215 and as Administrator of the US TAG, the delegation representing the US to ISO/TC215.

AHIMA is responsible for the administrative organization and management of the work of ISO/TC215. The dual roles of AHIMA are important components of AHIMA's vision and strategic work to advance health information management and health informatics to greatly enhance the delivery of efficient, safe, and quality healthcare. Standardization in the field of health informatics aims to improve consistency for health information and data, as well as to reduce duplication of effort and redundancies in areas such as healthcare delivery, disease prevention and wellness promotion, public health and surveillance, and clinical research related to health service.

The meeting was held at the headquarters of the Association for the Advancement of Medical Instrumentation (AAMI). Members of working groups of ISO/TC215 discussed current standards in various stages of development within the following areas: architecture, frameworks and models; systems and device interoperability; semantic content; security, safety and privacy; pharmacy and medicines business; application of risk management for IT networks incorporating medical devices; and informatics aspects of traditional Chinese medicine.

Subject matter experts and stakeholders from government, industry, academic and research institutions, providers, payers, professional associations and individuals participated in the quarterly meeting. US government agencies represented included the Department of Veterans Affairs, the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health IT (ONC). Generous benefactors supporting the operations of the US TAG include the Mayo Clinic, American Dental Association (ADA), AAMI, Kaiser Permanente, Siemens, and ONC. For more information about ISO/TC215 and the US TAG visit www.ahima.org/about/global?tabid=ISO.

AHIMA Engaging Several Regulatory Fronts

The Washington, DC spring was filled with the emergence of issues and initiatives intended to move forward the adoption and use of health IT (HIT). These activities require AHIMA to be active and engaged with developments by being prepared and willing to share the association's health information management (HIM) expertise in order to assist with shaping the ultimate policies that are adopted. Two of the major issues that have received AHIMA's attention are the FDASIA Health IT Report and the February 26 proposed rule on Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements.

FDA Safety and Innovation Act (FDASIA)

On April 3 the FDA, the Federal Communications Commission (FCC), and ONC cooperated on the development of the FDASIA Health IT Report "Proposed Strategy and Recommendations for a Risk-Based Framework." This report was required by Section 618 of the FDA Safety and Innovation Act (FDASIA), Public Law 112-144, and called for the FDA, FCC, and ONC to develop and post on their websites a report "that contains a proposed strategy and recommendations on an appropriate risk-based regulatory framework pertaining to health information technology, including mobile applications, that promotes innovations, protects patient safety, and avoids regulatory duplication."

According to the report, the proposed strategy and recommendations are based on the premise that risk and corresponding controls should focus on HIT functionality and not the platform(s) on which such functionality resides or the product name/description of which it is a part. Additionally, the proposed strategy and recommendations look to advance a framework that is relevant to current functionalities and technologies and be flexible to accommodate the future and rapid evolution of HIT.

The proposed strategy outlined in the report identifies three categories of HIT—administrative HIT functions; health management HIT functions; and medical device HIT functions.

Because the administrative HIT functions and the health management HIT functions pose little or very low risk to patient safety, they will not likely receive oversight focus from the FDA. As the report states, the FDA will likely "focus its attention and oversight on medical device HIT functionality, such as computer aided detection software, remote display or notification of real-time alarms from bedside monitors, and robotic surgical planning and control."

Finally the report identifies four key priority areas for advancing, and benefitting from, HIT:

1. Promote the use of quality management principles
2. Identify, develop, and adopt standards/best practices
3. Leverage conformity assessment tools
4. Create an environment of learning and continual improvement

AHIMA staff and member volunteers are developing comments on the FDASIA report and plan to submit them to the FDA. The general public is also encouraged to submit comments on the report. Comments are due to the FDA no later than July 7, 2014 and can be submitted at http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0339-0001.

Voluntary 2015 Edition EHR Certification Criteria;
Interoperability Updates and Regulatory Improvements

On April 28 AHIMA submitted comments on ONC's Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements proposed rule. The preface states that "the proposed rule proposes new, revised, and unchanged certification criteria that can be used to support the CMS Medicare and Medicaid EHR Incentive Programs. It also includes proposals and requests for public comment that offer insights into ONC's potential regulatory direction for the future. The proposed rule affects certification criteria only and does not impact meaningful use (MU) objectives and measures."

AHIMA formed a team of staff and association members to develop comments on this proposed rule. The comments can be found on AHIMA's Advocacy Page at www.ahima.org/about/advocacy. AHIMA's comments focused on specific areas of the proposed rule, including:

- Implementing drug-drug and drug-allergy interaction checks
- Recording electronic notes in patient records
- Transitions of care
- Clinical Quality Measures—Electronically Processing eMeasures
- Clinical Quality Measures—Functions and Standards for CQM Certification
- Clinical Quality Measures—Capture and Export
- Audit reports

- View, download, transmit to a third party
- Duplicate patient records
- Disaster preparedness

In each of these areas, ONC was specifically seeking comment and provided questions and guidance. AHIMA's breadth of HIM expertise provided the ability to postively contribute to this process.

Hard at Work Revamping Healthcare

AHIMA is working hard to represent its membership to help improve the nation's healthcare system, as evident by AHIMA's involvement with ISO, the regulatory process, and its ICD-10-CM/PCS advocacy efforts over the past several months. In the coming months and years, expect a high level of activity to continue in these areas, as AHIMA will be an integral part of the action in Washington DC and beyond.

The AHIMA Advocacy and Policy Team (advocacyandpolicy@ahima.org) is based in Washington, DC.

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