High Time for Information Governance, Standards, and Streamlined Certification

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By AHIMA's Advocacy and Policy Team

As healthcare organizations implement electronic health records (EHRs), and as new care delivery and financing mechanisms such as accountable care organizations proliferate, there are increasing demands for the accountability, reliability, and security of data and information. It has become apparent that now is the time for healthcare organizations, including providers, payers, and clearinghouses, to develop and implement information governance programs.

>AHIMA leaders were featured at the CMS eHealth Summit in Washington, DC in May, where healthcare industry leaders met to discuss important eHealth topics such as administrative simplification initiatives, information governance, health IT and its impact on care delivery and payment reform, and quality initiatives and the impact they have on primary care.

>An AHIMA panel presented a forum on information governance at the summit, moderated by Margarita Valdez, AHIMA's director of congressional relations. The panel discussed AHIMA's efforts to advance information governance leadership through publishing white papers, convening an expert advisory panel, developing a maturity model, developing self-assessment tools, and developing resources to operationalize information governance as well as provide references, webinars, and forums to raise information governance awareness.

Government Entities Unite on Health IT Regulatory Framework

>Last month's column discussed the FDASIA Health IT Report "Proposed Strategy and Recommendations for a Risk-Based Framework," which was released by the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), and the Office of the National Coordinator for Health IT (ONC). The report 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." As a follow-up to their effort, the FDA, FCC, and ONC hosted a three-day workshop at the National Institute of Standards and Technology (NIST) to discuss elements of the report and potential actions for moving forward.

>The workshop format included six panels of health IT policy experts from the public and private sectors. Each panel addressed two distinct issues included in the FDASIA report.

Panel A was moderated by the FDA's Senior Policy Advisor to the Director of the Center for Devices and Radiological Health, Bakul Patel, and addressed the risk-based framework and categories of health information technology.

Panel B was moderated by the FCC's Director of Healthcare Initiatives, Matthew Quinn, and covered promoting quality management and best practices.

Panel C was moderated by the FDA's Deputy Center Director for Science for the Center for Devices and Radiological Health, William Maisel, MD, and discussed clinical decision support.

Panel D was moderated by ONC's Federal Policy Division Director, Steve Posnack, and addressed standards and interoperability and conformity assessment.

Panel E was moderated by ONC's Office of Policy and Planning Director, Jodi Daniel, JD, MPH, and discussed the environment of learning and continual improvement and the reporting of patient safety data.

Panel F was also moderated by Daniel and addressed the value proposition and evidence, education, and dissemination issues of a Health IT Safety Center.

Many discussion points were raised in the panels, including the need for:

- Interoperability
- A Health IT Safety Center to serve as an information- gathering and dissemination group to encourage discussion regarding safety issues
- Developing a way to ensure that requirements are not duplicative from agency to agency, thereby eliminating a requirement for multiple approvals

Further information on the workshops is available at www.healthit.gov/FDASIA.

Workgroups Recommend Streamlined Certification Process

On May 7 and May 8, ONC staff and the ONC Health IT Standards Committee, Health IT Policy Committee, and Health IT Policy Committee Workgroups for Certification and Adoption, Meaningful Use, and Implementation all met to review and potentially develop recommendations to improve the "meaningful use" EHR Incentive Program certification process. After two days of discussion, the group forwarded recommendations to the Health IT Policy Committee to hold a formal "Kaizen event" to review and improve the certification process and consider short-term tweaks, long-term enhancements, and a continuous improvement program. The group also recommend certification be limited to three primary areas: interoperability, clinical quality measures, and privacy and security.

The Kaizen event, which is a method for holding a sustained and focused meeting to streamline a process, is expected to include a wide swath of players such as health information exchanges, testing bodies, certifiers, surveillance entities, the National Institute of Standards and Technology, downstream auditors, healthcare providers, regulators, trainers, end-users, public health, behavioral health, long-term and post-acute care, and health information service providers. ONC is expected to lead the Kaizen effort.

Following an ONC overview of the Health IT Certification Program, the proceedings on May 7 included testimony from providers and health information exchange organizations, vendors, certification/accreditation bodies, and various private sector representatives.

The testimony from each group was largely consistent, expressing a high level of frustration with the current certification process including tight timelines, using immature standards before having a full assessment, and conflicts with other initiatives and timelines. Ultimately discussion dug down to the program's scope, the time allotted to get it done, and the resources needed to comply. On May 8 the workgroups met to discuss the testimony and to pass the above recommendations on to the full Health IT Policy Committee.

Harnessing the Power of Data Provenance

The Standards and Interoperability (S&I) Framework, a forum for healthcare stakeholders to focus on solving real-world interoperability challenges, launched a new initiative on data provenance in April. The S&I Framework is an approach adopted by ONC's Office of Standards and Interoperability to enable interoperability specifications that support national health outcomes and healthcare priorities such as the meaningful use program, more effective care, improved population health monitoring, and cost reduction. The S&I Framework empowers healthcare stakeholders to establish standards, specifications, and other implementation guidance to facilitate effective healthcare information exchange.

The Data Provenance Initiative aims to establish a standardized way of capturing, retaining, and exchanging the provenance of health information including inbound, system generated, and outbound provenance. The term "provenance" in the context of health information technology refers to evidence and attributes that describe the origin of health information at the time of capture in a health system. As the exchange of health data increases, so does the demand to track the provenance of data over time. Confidence in the authenticity, trustworthiness, and reliability of the data being shared is fundamental to the privacy, security, safety, and accuracy of health information exchange. While there have been efforts to address data provenance, there is no existing authoritative specification, standard, or model for provenance that has been universally adopted within the context of health IT. This S&I initiative has also established a Tiger Team to work with standards development organizations (SDOs) in support of the initiative with the specific task of accelerating the standards analysis activity and providing recommendations back to the initiative.

HL7 is also working on a project on data provenance in addition to the S&I Framework to build a Draft Standard for Technical Use, which is a type of normative standard to instruct users of the clinical document architecture on implementation and use of that standard.

The HL7 Data Provenance project will develop a specification that describes the constraints on CDA which are necessary to convey data provenance. The project scope will include broad perspectives of provenance including security, privacy, medical records, patient safety, and other stakeholders. Much of this information has already been developed by HL7 and exists in multiple artifacts.

Knowing the provenance of information will help users of health information make informed decisions based on the quality, reliability, trust, and confidence in the source of that information. AHIMA is actively involved on this Tiger Team and is a committed member. More information is available at http://wiki.siframework.org/Data+Provenance+Initiative.

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

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