



July 7, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

Re: FDASIA Health IT Report. Docket: FDA-2014-N-0339

To Whom It May Concern:

The American Health Information Management Association (AHIMA) is pleased to submit the following comments on the FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework. AHIMA represents more than 71,000 educated health information management and health informatics professionals in the United States and around the world. AHIMA is committed to promoting and advocating for high quality research, best practices and effective standards in health information and to actively contributing to the development and advancement of health information professionals worldwide. AHIMA's enduring goal is quality healthcare through quality information (www.ahima.org).

General Comments

AHIMA applauds the collaborative efforts of the Food and Drug Administration (FDA), Federal Communications Commission (FCC), and the Office of the National Coordinator for Health Information Technology (ONC) for seeking public comment on such a critical topic and appreciates efforts in seeking to “advance a framework that is relevant to current functionalities and technologies yet sufficiently flexible to accommodate the future and rapid evolution of health IT.”

Overall, we are supportive of the report and DHHS' efforts to take steps to ensure patient safety in the development, implementation, and use of health IT. We believe that a balanced approach is needed to ensure shared responsibility and accountability while allowing innovation in both technology and healthcare.

AHIMA recently formalized its endorsement of the core values of a **learning health system** (LHS) that supports an effort to share secure, high-quality data to improve patient health.



The LHS concept represents a transformative vision of data, information, and knowledge sharing to empower all stakeholders to routinely engage in virtuous cycles of continuous learning and improvement.¹

As health information technology (IT) applications and uses, including electronic health records (EHRs) and health information exchange (HIE), continue to expand, it is increasingly important to make healthcare safer by understanding and mitigating health IT hazards and safety events. AHIMA has partnered with the ECRI Institute and other stakeholders in a pilot project to promote patient safety and quality care by reducing of health IT risk and enhancing health IT innovation. The project, **the Partnership for Promoting Health IT Patient Safety**, will create a national framework to proactively identify and resolve health IT safety issues based on various HIT events and hazards.²

AHIMA's specific comments regarding the FDASIA Health IT Report are included below:

AHIMA supports the existing focus areas and strongly believes that the standardization of patient identification should be highlighted as a major and primary focus area. This would align with the FDASIA report's emphasis on flexible risk-based approach and framework.

AHIMA notes that the accuracy, quality, and completeness of data attached to or associated with an individual patient impacts quality of care, patient safety, patient privacy, medical identity theft, health information exchange, and coordination of care, all of which are critical strategic priorities for healthcare stakeholders. The accuracy of patient matching and patient identity integrity also impacts administrative and financial efficiencies, from prior authorizations to claims processing and patient billing.

AHIMA believes that until a workable solution(s) is identified, the healthcare industry will continue to experience patient safety risks and true interoperability will not be achieved. AHIMA urges that ONC work with a diverse group of stakeholders to further the work toward achieving patient identification integrity. AHIMA and its members have long-standing experience linking and matching patients to their records and to their data.

Furthermore, AHIMA has recognized that high-quality data are needed for multiple purposes such as care delivery, performance and outcomes measures, population and public health, research, and policy making. AHIMA strongly believes that additional attention, such as improved quality controls, standardization, and appropriate validation at data collection points (such as patient and specimen registration) throughout the care continuum are needed to improve the accuracy of patient matching.

¹ Rubin, Joshua C; Friedman, Charles P. "Weaving Together a Healthcare Improvement Tapestry." *Journal of AHIMA* 85, no.5 (May 2014): 38-43. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050661.hcsp?dDocName=bok1_050661

² ECRI Institute. "Partnership for Promoting Health IT Patient Safety." <https://www.ecri.org/Products/PatientSafetyQualityRiskManagement/Pages/Partnership-for-Promoting-Health-IT-Patient-Safety.aspx>



AHIMA has recently released a revised Practice Brief, “Managing the Integrity of Patient Identify in Health Information Exchange” (also see the white paper “Ensuring Data Integrity in Health Information Exchange”),^{3, 4} that we believe would be very beneficial to this important discussion. And we have compiled an annotated bibliography that was previously shared with ONC as part of the ONC Patient Identification and Matching project. For your convenience we have included the bibliography at the end of this comment letter.

As healthcare delivery systems and providers consolidate, merge, and are acquired and with the continued implementation of health information exchanges (HIEs), accurate and reliable patient matching is even more vital. However, AHIMA emphasizes that developing an algorithm or implementing a technology solution does not solve the problem. AHIMA notes that people, processes, and practices, including workflow, are absolutely critical to ensure that data collected and exchanged is accurate.

Accurate patient identification is foundational to the successful linking of patient records within care delivery sites and across the healthcare ecosystem to underpin care delivery, data exchange, analytics, and critical business and clinical processes. These goals have become increasingly important as health information exchange has evolved over the last decade, with the healthcare industry striving to reduce costs, increase interoperability, and transform to a patient-centric care delivery model.

Thank you for providing AHIMA the opportunity to provide comments on the FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework. We look forward to continuing our work with you to advance our nation’s healthcare system. If you have any comments or questions, please do not hesitate to contact Meryl Bloomrosen, AHIMA’s Vice President of Public Policy and Government Relations, at Meryl.Bloomrosen@ahima.org or at 202-659-9440.

Sincerely,

A handwritten signature in black ink, appearing to read "Lynne Gordon", is written over a horizontal line.

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
CEO

³ AHIMA. "Managing the Integrity of Patient Identity in Health Information Exchange (Updated)." *Journal of AHIMA* 85, no.5 (May 2014): 60-65. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050658.hcsp?dDocName=bok1_050658

⁴ AHIMA HIE Practice Council. "Ensuring Data Integrity in Health Information Exchange." AHIMA Thought Leadership Series. AHIMA, 2012. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_049675.pdf



Selected AHIMA Resources on Patient Identity/Matching

Articles

Altendorf, Robin L. "Establishment of a Quality Program for the Master Patient Index." *2007 AHIMA Convention Proceedings, October 2007*

This article is focused on quality programs for maintaining the MPI. The article is styled in an instructional flow with introduction, background, MPI importance with tables, MPI solutions including the quality component, and method with graphic outlining the quality process and conclusion.

Dimick, Chris. "Exposing Double Identity at Patient Registration" *Journal of AHIMA* 80, no.11 (November 2009): web extra

This article includes real-life examples of how HIM provides a feedback loop to registration and the importance of direct training.

Eramo, Lisa A. "Partnering on Patient Matching: An HIM Committee Helps Steer a RHIO's Patient Index." *Journal of AHIMA* 83, no.5 (May 2012): 28-30

This article includes real-life examples of how important the MPI is to a RHIO or HIO.

Fernandes, Lorraine, O'Connor, Michele. "Future of Patient Identification." *Journal of AHIMA* 77, no.1 (January 2006): 36-40

This article focuses on interoperability. Sections include matching, unique problems with unique identifiers, the importance of cleaning the data, concerns with privacy, usefulness, and logistics, the use of the SSN, and challenges of scale and complexity including probabilistic matching and quality data attributes. In addition, it includes a table that shows how variation in attributes can result in false-negative rates.

Landsbach, Grant; Just, Beth Haenke. "Five Risky HIE Practices that Threaten Data Integrity." *Journal of AHIMA* 84, no. 11 (November–December 2013): 40-42

This article highlights five risks in HIE: Relying on weak algorithms, failing to include HIM staff in implementing record-matching algorithms, failure to manage ongoing data integrity, lack of standard interfaces and automated processes, and establishment of weak governance processes. It concludes with the importance of data integrity.

Mendoza, Theresa; Kotyk, Steve. "EMPI Links Hospitals to Transform Data Exchange and Research in 17-County North Texas Region." *2011 AHIMA Convention Proceedings, October 2011*

This article focuses on a regional EMPI and how it aids in research efforts. Sections include matching of patient claims, identifying lag days between admissions, calculation of lost reimbursement, program implementation with graphics and sample case studies related to readmissions.

AHIMA Practice Briefs

AHIMA. "Assessing and Improving EHR Data Quality (Updated)." *Journal of AHIMA* 84, no.2 (March 2013): 48-53 [expanded online version].

This practice brief discusses the challenges of maintaining quality data in the EHR and offers best practice guidance for ensuring the integrity of the healthcare data. It also covers copy/paste, corrections and amendments and refers readers to the "Amendment Toolkit" listed below.

AHIMA. "Fundamentals for Building a Master Patient Index/Enterprise Master Patient Index (Updated)." *Journal of AHIMA* (Updated September 2010)



This practice brief includes an appendix with recommended core data elements for EMPs. It differentiates between the various algorithms. Note: This brief has been retained for “historical purposes” where percentages may be outdated.

AHIMA. "Integrity of the Healthcare Record: Best Practices for EHR Documentation." *Journal of AHIMA* 84, no.8 (August 2013): 58-62

This brief provides guidance for maintaining documentation integrity while using automated EHR functions. It touches on information governance, legal issues such as template documentation challenges, copy/paste, amendments, fraud and abuse, audit integrity and compliance education. It includes four appendices; resource list, case studies, steps to prevent fraud, and an EHR integrity checklist.

AHIMA. "Limiting the Use of the Social Security Number in Healthcare." *Journal of AHIMA* 82, no.6 (June 2011): 52-56

This practice brief outlines the importance of accurate patient identification. It also provides guidance on limiting the use of the SSN in patient identification practices and outlines the unique identifier option.

AHIMA. "Reconciling and Managing EMPs (Updated)." *Journal of AHIMA* 81, no.4 (April 2010): 52-57

This brief outlines the process for effective MPI management, including how to reconcile two MPIs. It also outlines staff roles and responsibilities for MPI management and conversions.

AHIMA Toolkits

AHIMA. Amendments in the Electronic Health Record Toolkit. (2012)

This toolkit is designed to provide guidance to HIM professionals when addressing the amendment functionality in an EHR. The authors have made the assumption that electronic signatures are used in the EHR. This toolkit defines the term “amendments” to include addendums, corrections, and deletions.

AHIMA. Health Information Management Staff Transformation Toolkit. (2012)

This toolkit is designed to support and guide HIM professionals. It outlines how information management will change and how HIM professionals and their departments can prepare for this transformation. Transformation gap analysis, skills assessment, functions assessment, and other training tools will assist the staff transformation in the HIM department.

AHIMA. Information Integrity in the Electronic Health Record Toolkit. (2012)

This toolkit explores best practices to ensure information integrity in the course of using and managing an EHR system, whether fully electronic or in a hybrid state, and covers practices for multiple processes from capturing information all the way through the continuum to sharing information. It also includes a section on managing the MPI.

White Paper/Reports

AHIMA HIE Practice Council. (2012). Ensuring Data Integrity In HIE

This white paper focuses on patient and data integrity, especially in the HIE environment. “Patient identity integrity is the accuracy, quality, and completeness of demographic data attached to or associated with an individual patient. This includes the accuracy and quality of the data as it relates to the individual, as well as the correctness of the linking or matching of all existing records for that individual within and across information



systems. There are tremendous potential benefits and cost savings within the healthcare industry contingent on accurate patient identification and interoperability. Participation in an HIE can also provide increased efficiency in the delivery of healthcare by permitting access to more complete and timely information regarding individual patients.”

AHIMA/HIMSS. Trends in Health Information Exchange Organizational Staffing. (2012).

The Healthcare Information and Management Systems Society (HIMSS) and AHIMA formed a collaborative workgroup to analyze job opportunities and skill sets required in the HIO setting. “This analysis aims to identify current environment staffing models, emerging staffing models and required skill sets to support these organizations. The results of this analysis will serve those who are seeking employment focused on data exchange or HIE activities, including those exploring opportunities in education, training and certification to enhance their knowledge and skills in this area.”