Integrating the Healthcare Enterprise



IHE IT Infrastructure (ITI)

White Paper

10 Health IT Standards for Health Information Management (HIM) Practices

Draft for Public Comment Revision 1.0

20 Date: June 19, 2015 Author: ITI Planning Committee Email: iti@ihe.net

Please verify you have the most recent version of this document. See <u>here</u> for Published versions and <u>here</u> for Public Comment versions.

Copyright © 2015: IHE International, Inc.

25

15

Foreword

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and

30 effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE Profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Frameworks.

This white paper is published on June 19, 2015 for public comment. Comments are invited and can be submitted at <u>http://www.ihe.net/ITI_Public_Comments</u>. In order to be considered in development of the subsequent version of the document, comments must be received by July 19, 2015.

40 201

35

For on-going development work, see http://wiki.ihe.net/index.php?title=HIT_Standards_for_HIM_Practices

General information about IHE can be found at: http://ihe.net.

45 Information about the IHE IT Infrastructure domain can be found at: <u>http://ihe.net/IHE_Domains</u>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <u>http://ihe.net/IHE_Process</u> and <u>http://ihe.net/Profiles</u>.

50 The current version of the IHE IT Infrastructure Technical Framework can be found at: <u>http://ihe.net/Resources/Technical_Frameworks</u>.

CONTENTS

55

	1	Acknowledgement	
	2	Introduction	
		2.1 Need, Goal and Objectives, Scope and Outcome	
		2.2 Intended Audience	
60	3	Methodology	. 10
		3.1 Method	
		3.2 Project Participants	
		3.3 Project Tasks, Timeline and Deliverables	
	4	Overview of Health Information Management	. 14
65		4.1 HIM Professionals (Actors)	
		4.2 HIM Practices (Actions)	. 15
		4.3 Health Information (Products)	. 16
		4.4 Information Governance	. 18
		4.4.1 Principle of Information Availability: Business Requirements	. 21
70		4.4.2 Principle of Information Integrity: Business Requirements	. 22
		4.4.3 Principle of Information Protection: Business Requirements	. 23
		4.5 HIM Practice CheckList	. 24
		4.6 HIM Practice Use Cases	. 24
		4.7 Glossary	
75	5	Gap Analysis of HIT Standards to Support HIM Practices	. 25
		Recommendations	
	7	Roadmap	. 30
	A	ppendix A: HIM Practice Checklist	. 32
	A	ppendix B: HIM Practice Use Cases	. 39
80		B.1 Use Case A1.1: All documents are accounted for within a specific time period post	
		completion of the episode of care	. 39
		B.2 Use Case A1.2: Record is closed as complete within a specific time period post	
		completion of the episode of care	. 43
		B.3 Use Case A2.1: Documents within the record can be viewed by or released to the exter	nal
85		requestor	. 45
		B.4 Use Case A3.1: An audit log of the episode of care record	. 47
		B.5 Use Case A3.2: An audit log of requests for release of information and accounting of	
		disclosures	. 48
	A	ppendix C: Glossary	. 49
90	A	ppendix D: HIT Standards for HIM Practices	. 54

1 Acknowledgement

This White Paper was developed with the support from the American Health Information
Management Association (AHIMA) - the not-for-profit membership-based healthcare association representing more than 101,000 health information management (HIM) and informatics professionals who work in more than 40 different types of entities related to our nation's public health and healthcare industry.

This White Paper was developed as a part of a new globally-focused AHIMA initiative on
 Information Governance (IG)¹ – an organization-wide framework for managing information
 throughout its lifecycle and supporting the organization's strategy, operations, regulatory, legal,
 risk, and environmental requirements.² This IG Initiative is a key component of AHIMA's overall strategy to develop guidelines, operating rules and standards for healthcare documentation practices.

105 AHIMA formed a Task Force of HIM professionals – subject matter experts (SMEs) – to provide expertise for aligning HIM practices and capabilities of health information systems through health information technology (HIT) standards. Their work was facilitated by the AHIMA Standards Team. Table 1 presents the list of the Task Force members.

Name	Affiliation
Kathleen Addison	Alberta Health Services
Linda Bailey-Woods	HIMagine Solutions
Kevin Baldwin	UCLA
Alane Combs	Coastal Healthcare
Funmilola Daniel	Quest Diagnostics
Vicki Delgado	Kindred Hospital Albuquerque
Elisa Gorton	St. Vincent's Medical Center
Sandra Huyck	Beaumont Health System
Satyendra Kaith	Kaplan Higher Education Group
Susan Lucci	Just Associates
Amber Martinez	Precyse

Table 1: AHIMA-IHE White Paper Task Force Members

¹ Cohasset Associates | American Health Information Management Association (AHIMA). Information Governance in Healthcare: Benchmarking White Paper. 2014. URL:

http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsP&lang=0&data=

(NOTE: You need to fill out AHIMA brief IG survey to access this document.)

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

² American Health Information Management Association (AHIMA). Information Governance. Glossary. URL: <u>http://www.ahima.org/topics/infogovernance/ig-glossary</u>

Name	Affiliation
Lori McNeil Tolley	Boston Children's Hospital
Denese Miller	Kennestone Regional Medical Center
Megan Munns	Just Associates
Neysa Noreen	Children's Hospitals and Clinics of Minnesota
Michael Nusbaum	M.H. Nusbaum & Associates Ltd.
Deane Stillar	Alberta Health Services
DeAnn Tucker	Owensboro Health
Lee Wise	Summit Medical Center

2 Introduction

115 This document, the IHE Information Technology Infrastructure (ITI) White Paper "HIT Standards for HIM Practices," describes the need for, value and an approach for aligning HIM business practices (HIM practices) with capabilities of standards-based HIT products to support information governance in healthcare.

The White Paper provides:

- 120 1. An overview of HIM practices related to information governance
 - 2. Detailed analysis of HIM business requirements and best practices checklist related to information availability, integrity and protection three of the information governance principles selected out of a total of eight principles³,⁴
 - 3. Five Use Cases derived from these business requirements and best practices for the information availability in order to guide the development of the functional requirements for HIT standards
 - 4. Definitions of terms, participants (actors), processes (actions) and outcomes of HIM practices related to the Use Cases
 - 5. An initial gap analysis of existing HIT standards to support HIM business requirements and
 - 6. Recommendations for HIM community and standards development organizations (SDOs) for further standardization of both HIM practices as well as capabilities of HIT products to support these practices.

The White Paper describes an approach (methodology) and a roadmap for expanding the list of Use Cases to support business requirements for HIM practices under other information governance principles in the future.

2.1 Need, Goal and Objectives, Scope and Outcome

Need. In the past decade HIM professionals have been working on implementing health information systems (HIS) – Electronic Health Record Systems (EHRS), Laboratory Information Management Systems (LIMS) and other information and communication technology (ICT)

140

125

130

http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data= (NOTE: You need to fill out AHIMA brief IG survey to access this document.)

³ Cohasset Associates | American Health Information Management Association (AHIMA). Information Governance in Healthcare: Benchmarking White Paper. 2014. URL:

⁴ American Health Information Management Association (AHIMA). Information Governance Principles in Healthcare (IGPHC). 2014. URL: <u>http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data</u>= (*NOTE: You need to fill out AHIMA brief IG survey to access this document.*)

products – in healthcare and public health organizations. Based on the their experience the following challenges were identified with ICT adoption: ^{5,6,7,8,9,10,11,12}

- 1. EHR System Design Flaws
- 2. Poor System Usability and Improper System Use
- 5 3. Inappropriate Documentation Capture
 - 4. Errors Related to Use of Clinical Decision Support Systems
 - 5. Errors Related to Faulty HIM Practices in Health IT Systems
 - 6. Inadequate Training

To address challenges that HIM professionals documented while transitioning from the paperbased to an electronic environment, there is a need to establish cross-collaboration between HIM

150 based to an electronic environment, there is a need to establish cross-collaboration between HIM professionals, standards developers and HIT vendors focusing on the following three efforts to assure that:

Effort 1: Functional requirements for HIM practices have been communicated to standards developers for creating HIT standards;

155 Effort 2: Standards are adopted in the HIT products; and

http://search.proquest.com.library.capella.edu/docview/1399741170?pq-origsite=summon

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

⁵ Bowman, S. Impact of electronic health record systems on information integrity: Quality and safety implications. Perspectives in Health Information Management. 2013. URL: <u>http://perspectives.ahima.org/impact-of-electronic-health-record-systems-on-information-integrity-quality-and-safety-implications/#.VU00LPm6e00</u>

⁶ Nguyen, L, Bellucci, E, & Nguyen, LT Electronic health records implementation: An evaluation of information system impact and contingency factors. International Journal of Medical Informatics. 2014. 83(11): 779-796.

⁷ Kuhn, T, Basch, P, Barr, M, & Yackel, T. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. Annals of Internal Medicine. 2015. URL; <u>http://scholar.google.com/scholar?hl=en&q=Clinical+Documentation+in+the+21st+Century%3A+Executive+Summary+of+a+Policy+Position+Paper+From+the+American+College+of+Physicians&btnG=&as_sdt=1%2C14&as_sdt p=</u>

 ^{p=}
 ⁸ Bouamrane, M, & Mair, FS A study of general practitioners' perspectives on electronic medical records systems in NHS Scotland. BMC Medical Informatics and Decision Making. 2013. 13, 58URL:

⁹ Walker, JM, Carayon, P, Leveson, etal. EHR safety: the way forward to safe and effective systems. JAMA. 2008, 15(3): 272-277. URL: <u>http://jamia.oxfordjournals.org/content/15/3/272.short</u>

¹⁰ Health Level Seven (HL7). Electronic Health Records System Usability Conformance Criteria, Release 1. 2015. Health Level Seven (HL7) Comment-only Ballot. URL: <u>http://wiki.hl7.org/index.php?title=EHR_USABILITY</u>

¹¹ Terry AL, Thorpe CF, Giles G, etal. Implementing electronic health records. Key factors in primary care. Canadian Family Physician. 2008, 54(5):730–736. URL: <u>http://www.cfp.ca/content/54/5/730.short</u>

¹² Holroyd-Leduc, JM, Lorenzetti, D, Straus, SE, etal. The impact of the electronic medical record on structure, process, and outcomes within primary care: a systematic review of the evidence. JAMA. 2011. 18(6): 732-737. URL:http://scholar.google.com/scholar?hl=en&q=The+impact+of+the+electronic+medical+record+on+structure%2 C+process%2C+and+outcomes+within+primary+care%3A+a+systematic+review+of+the+evidence.&btnG=&as_sd t=1%2C14&as_sdtp=

Effort 3: Standards-based HIT products support HIM practices.

<u>Goals and Objectives</u>. The goals of the White Paper are two-fold: (a) inform HIT standards developers about HIM practices; and (b) to outline a methodology for aligning HIM practices with the capabilities of HIT products through standards.

The following are the White Paper objectives:

- 1. Demonstrate the alignment between HIM practices (business requirements, practice checklists, use cases), and capabilities of HIT products to support these practices
- 2. Inform IHE development process by defining Profile Specifier checklist aligned with the HIM practice checklist
- 3. Inform the development of national and international HIT interoperability standards for HIT products for identified HIM practices and
- 4. Create the roadmap for the development of these standards.
- 170 <u>SCOPE</u>. The White Paper is focused on HIM practices related to electronic health information capture, management, sharing and use. This year (Year 1), we developed a methodology for cross-collaboration between HIM professionals and HIT standards developers concentrating on Effort 1 a systematic approach for specifying functional requirements for HIM practices via use cases in order to validate existing HIT standards and to guide the development of new standards.
- 175 In the future, we anticipate working with the IHE community on expanding our approach to focus on HIT standards adoption in HIT products (Effort 2) and providing a feedback on capabilities of standards-based HIT products to support HIM practices as needed (Effort 3).

We focused on the three information governance principles: information availability, integrity and protection. This White Paper presents:

- 180 1. HIM business requirements under the three principles
 - 2. Results of literature review for the best HIM practices under these three principles aligned with the business requirements and
 - 3. Five Use Cases that are focused on three HIM practices for information availability.

In the future, we anticipate continuing the development of additional Use Cases under information availability as well as other IG principles.

<u>OUTCOME</u>. We established methodology (a systematic approach) for continuing collaboration between HIM professionals and standards developers via specifying (a) business requirements for information governance principles, (b) HIM practice checklist based on the analysis of the business requirements and HIM practices documented in the literature; and (c) Use Cases and functional requirements to support HIM practices in HIT products. This methodology is

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

165

190

described in details in the correspondent section below. Six specific deliverables listed in the Introduction section above are also described in details in the White Paper.

2.2 Intended Audience

195

The intended audience of the White Paper includes HIM professionals, HIM educators, standards developers, HIT and ICT vendors for all types of clinical, public health and research information systems and products, and other stakeholders involved in current or planned implementation of HIT/ICT in healthcare, public health and research organizations.

3 Methodology

200 **3.1 Method**

In this project, we deployed requirement elicitation methodology to specify HIM needs for the standard-based HIT products. Figure 1 presents high level overview of methodology deployed.

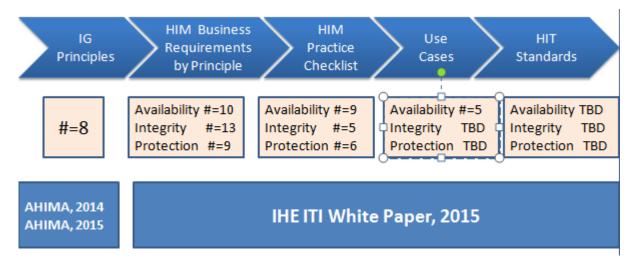


Figure	1:	Project	Methodology
--------	----	---------	-------------

Derived from the on-going AHIMA work on the information governance principles in healthcare, ^{13,14,15} we specified HIM business requirements under information availability,

210 integrity and protection principles. Further we conducted literature review on the HIM best practices supporting these business requirements and developed HIM checklists by principle. Drawn from the checklist's items, we developed Use Cases to specify functional requirements for HIT standards. Numbers (#=XX) on Figure 1 show the number of items developed by each step of the project.

215

205

http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data=

(NOTE: You need to fill out AHIMA brief IG survey to access this document.)

¹⁴ American Health Information Management Association (AHIMA). Information Governance Principles in Healthcare (IGPHC). 2014. URL: <u>http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data</u>= (*NOTE: You need to fill out AHIMA brief IG survey to access this document.*)

¹³ Cohasset Associates | American Health Information Management Association (AHIMA). Information Governance in Healthcare: Benchmarking White Paper. 2014. URL:

¹⁵ American Health Information Management Association (AHIMA). Information Governance in Healthcare. Pilot Projects. Work in progress. 2015.

3.2 **Project Participants**

The project was conducted under the IHE ITI Planning Committee. HIM professionals – subject matter experts - were recruited via the Call for Participation¹⁶ among those serving on AHIMA volunteer initiatives as follows:

- 220 1. AHIMA Enterprise Information Management Practice Council (EIMPC)
 - 2. Health Information Exchange Practice Council (HIEPC)
 - 3. Privacy/Security Practice Council (PSPC)
 - 4. Data and Information Analysis Task Force (DIATF)
 - 5. Clinical Documentation Improvement Task Force (CDITF)
 - 6. Coordination of Care Task Force (CCTF)
 - 7. Consumer Engagement Task Force (CETF)
 - 8. AHIMA IG Advisory Group

A total of 19 HIM SMEs were recruited (Table 1). Table 2 describes types of organizations and HIM roles of volunteers participated in the Task Force.

230

Organization	HIM Role	Number of Volunteers
Hospital	Senior Provincial Director	1
	Director, Enterprise Information Management	1
	Director/Manager/Assistant Director	3
	Director/Assistant Director Privacy	2
	Data Integrity & Applications Manager	1
	Compliance Audit Specialist	1
	HIM Consultant	2
Consultant Entity	HIM Consultant	3
Higher Education	Faculty	1
Laboratory	Senior Customer Service Representative	1
Vendor	Associate Identity Manager	1
	Consultant, Chief Privacy Officer	1
	Consultant, Sr. Information System	1

Table 2: Task Force Members: Organizations and Roles

¹⁶ Integrating the Healthcare Enterprise (IHE). Information Technology Infrastructure (ITI) Planning Committee. HIT Standards for HIM Practices White Paper. Call for Participation. January 15, 2015

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

The overall work on the project was facilitated by the AHIMA Standards Team.

3.3 Project Tasks, Timeline and Deliverables

This project was conducted during September 2014 – September 2015. Table 3 describes 235 projects tasks, timeline and deliverables. Project activities were conducted via biweekly conference calls of the HIM Task Force members. Representatives from the Task Force and AHIMA Staff also participated in the biweekly meeting of the IHE ITI Planning Committee to review and critique Use Cases and functional requirements for HIT standards developed by the HIM volunteers.

240

The AHIMA staff attended 3 in-person IHE meetings (November 2014, April and July 2015) to provide progress reports on the project activities.

Task	Timeframe	Deliverable
Develop and defend proposal to the IHE ITI Committee	SeptNov.2014	Proposal for the 2014-15 IHE development cycle
Develop Project Infrastructure	Dec. 2014	Wiki Pages
Assemble AHIMA HIM SME Task Force	Jan. 2015	Call for Participation
Develop project methodology	Jan. 2015	Methodology
Document business requirements and HIM best practices by selected IG principle: availability, protection and integrity	JanApril2015	Business Requirements Literature Review HIM Practice Checklist
Define Use Cases for selected HIM best practices	FebApril 2015	HIM Use Case List
Conduct gap analysis of HIT standards to assess their relevance to supporting HIM practice	MarApr.2015	Standards Gap Analysis Table
Develop recommendations and roadmap for addressing identified gaps in HIM practices and HITstandards	MarApr.2015	Recommendations and Roadmap
Publish draft White Paper for public comments	May 2015	Draft White Paper
Publish final White Paper	Aug. 2015	Final White Paper
Communication, outreach and marketing	May-Sept. 2015	Spotlight in HIMSS Media Article in Journal of AHIMA Presentation at AHIMA Convention
Develop proposal for the IHE 2015-16 development cycle	Sept. 2015	Proposal for the 2015-16 IHE development cycle

Table 3: Tasks, Timeline and Deliverables

245

Figure 2 presents summary of the project activities.

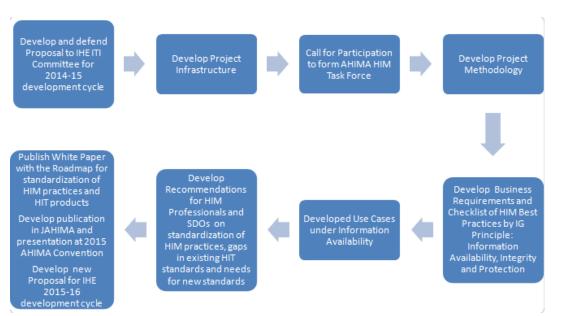


Figure 2: Project Activities

250

4 Overview of Health Information Management

4.1 HIM Professionals (Actors)

HIM Professionals are responsible for ensuring the availability, accuracy, and protection of information that is needed to deliver healthcare services and to make appropriate healthcare-related decisions.¹⁷ Table 4 presents current roles of HIM professionals in healthcare organizations.

255

HIM Roles				
Data	Capture, Validation, and Mainten	ance		
Chart correction analyst	Data architect	ICD-10 implementation specialist		
Classification editor and exchange expert	Data capture design specialist	Information workflow designer		
Clinical coding validator	Data dictionary manager	Patient identity manager		
Clinical content manager	Data integrity and transition specialist/auditor	Registrar (birth, cancer, device, bone marrow, tissue)		
Clinical documentation improvement specialist/supervisor	Data mapper/translator	Research coordinator/associate		
Coder Data quality manager/analyst Research data abstractor		Research data abstractor		
Coding compliance coordinator/supervisor/manager	Documentations/EHR trainer	Terminology asset manager		
Computer-assisted coding validation practice leader	EHR content manager	Voice capture specialist		
Chart correction analyst	Enterprise patient master index, data integrity analyst			
Data/Information Analysis, Decision Support and Informatics				
Business analyst/data analyst	Data integration manager/analyst	Decision support officer		
Claims data analyst	Data integrity and transactions specialist/auditor	Health data analyst/manager/director		
Clinical content analyst Data quality manager/analyst		Health Data statistician		
Data abstractor/coordinator Data repository architect/manager/analyst		Health outcomes analyst		
Data architect Decision support analyst Health data quality engineer		Health data quality engineer		

Table 4: Roles of HIM Professionals in Healthcare Organizations¹⁸

260 The emerging roles for HIM professionals in the new interoperable electronic data sharing environment include Standard setters, Educators, Consumer advocates, Brokers of information.¹⁹

 ¹⁷ LaTour, K. et al, Health Information Management. Chicago, IL: AHIMA Press, 2013, p.50.
 ¹⁸ Ibid

4.2 HIM Practices (Actions)

HIM practices are focused on collecting health information, ensuring complete documentation, maintaining health data, and appropriately sharing authorized information though electronic as well as paper-based release of information.20 Thus HIM practices include various activities aimed to support basic HIM functions: Capture, Process, Use, Store, and Dispose health information. Table 5 presents HIM activities under these functions.²¹

			•	
Capture	Process	Use	Store	Dispose
Create	Classify	Code	Store	Delete
Enter	Validate	Examine	Preserve	Deprecate
Record	Analyze	Analytics	Archive	Destroy
Dictate	QC/QA	Business Intelligence		Permanent Store
Write	Compliance	Release		Discover
Receive	Interface	Discover		Permanent Archive
Interface	Integrate	Hold		Transition
		Retain		
		Export		
		Transmit		
		Exchange		
		Share		

	Table 5: HIM	Activities b	y HIM	Function
--	--------------	--------------	-------	----------

270

265

Figure 3 present HIM view of the high level functions to support information lifecycle.

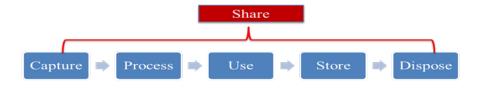


Figure 3: HIM Functions to Support Information Lifecycle

¹⁹ Van Dolan, P. "Reframing Roles". American Health Information Management Association (AHIMA) LeadershipSymposium, July 11-12, 2014.

²⁰ LaTour, K. et al, Health Information Management. Chicago, IL: AHIMA Press, 2013, p.50.

²¹ American Health Information Management Association (AHIMA). Information Governance in Healthcare. Maturity Model. Work in Progress. 2015

4.3 Health Information (Products)

Health information is a product of HIM activities. It is comprised of all types of health data generated in the process of care delivery within an episode of care and assembled/presented/stored/exchanged in **records** that include documents/data quires/screens/readings, etc. (i.e., all that describes the episode of care). Relevant paper-based

280 documents provided by patient, caregiver and/or clinicians during the episode of care can be scanned and become part of the record of the episode of care.

An episode of care consists of various functions, e.g., registration, triage, assessment, testing, care plan, etc. The order of performing these functions is determined by the type of encounter and specified by organizational or jurisdictional policies.

285 Each of these functions is associated with capturing/producing/sharing/using specific information in the records. Table 6 shows the examples of episode of care's functions and correspondent information.

290

	Necolu
Episode of Care's Functions*	Examples of Information in the Record
Visit Registration/Admission	Patient and Facility Demographics, Billing, Consent for Information Exchange (opt-out/opt-in)
Triage	Triage Notes and Vital Signs
Assessment	History & Physical, Problem List, Medication Reconciliation, Preliminary Diagnosis and Care Plan
Laboratory and Diagnostic Testing	Consent for Procedure Test Orders and Test Result Reports
Diagnosis and Care Plan	Confirmed Diagnosis and Updated Care Plan
Prescription	Medication Order and Dispense Report
Summary of Care	Transfer Summary or Discharge Summary
Discharge/Transfer/Disposition (ADT)	ADT Record

Table 6: Functions of the Episode of Care and Examples of Health Information in the Record

Figure 4 presents the hierarchy of the records such as:

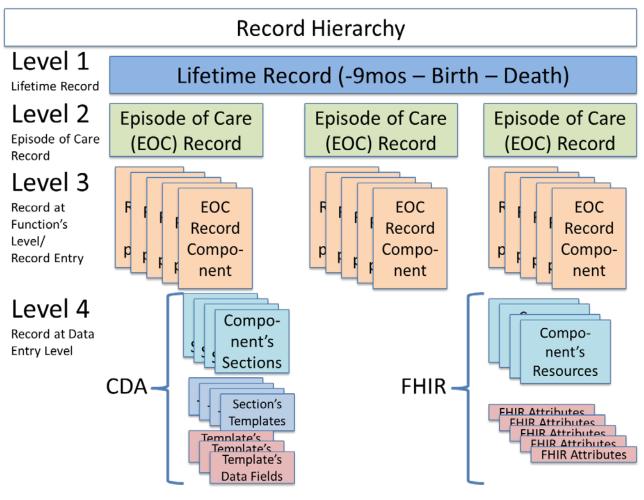
Level 1 – Lifetime Record (prenatal care – birth – life – death)

Level 2 – Episode of Care record consists of multiple information components generated during a specific function as shown in Table 6

Level 3 – Function's record component, i.e., admission record, test order record, test result reports record, etc.

300

Level 4 – Record at data entry level is associated with the standards-based representation of data in a record, (e.g., using Health Level Seven (HL7) Clinical Document Architecture (CDA) standard²²; HL7 Fast Health Interchange Resource (FHIR) standard²³; and/or other information content standards).



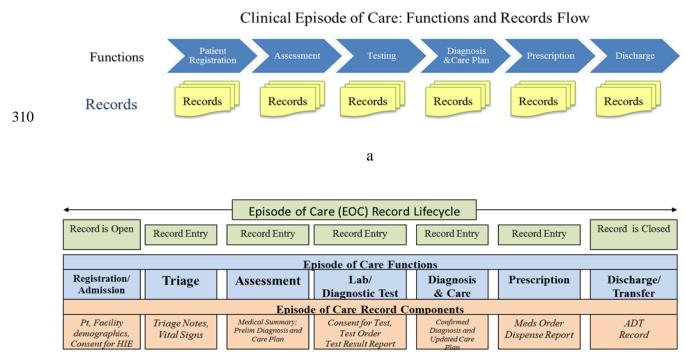
305

Figure 4: Record Hierarchy

Figure 5 presents the examples of the Episode of Care's functions and record components generated at a specific function in the process of care.

²² Health Level 7 (HL7). Clinical Documentation Architecture (CDA) Release 2. 2005. URL: http://wiki.hl7.org/index.php?title=Structured_Documents

²³ Health Level 7 (HL7). Fast Healthcare Interoperability Resources (FHIR). 2014. http://www.hl7.org/fhir/



315

b Figure 5: Examples of Episode of Care/Encounter's Functions and Records/Documents:

a – High level view of the episode of care functions and documentation;

b - Detailed view of episode of care functions and documentation

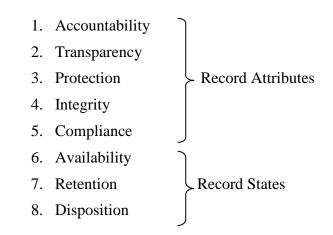
4.4 Information Governance 320

Information governance is described as an accountability framework that "includes the processes, roles, standards, and metrics that ensure the effective and efficient use of information in enabling an organization to achieve its goals."²⁴ In short, information governance defines the rules imposed on the information as a product. According to the American Record Management

Association (ARMA), generally accepted recordkeeping principles include: 325

330

²⁴ American Record Management Association (ARMA). Generally Accepted Recordkeeping Principles. Information Governance Maturity Model. 2013. URL; http://www.arma.org/principles



Please note that principles 1-5 represent the attributes of the record, principles 6-8 represent the 340 states of the record lifecycle.

In 2014 AHIMA launched Information Governance Initiative to adopt these IG principles for healthcare - IGPHC²⁵ – and conducted the first survey of the healthcare stakeholders on the state of information governance.²⁶ As the result of the survey, AHIMA developed the IG Maturity Model that is currently piloted in healthcare and health information exchange (HIE)

organizations.²⁷

335

345

Figure 6 presents AHIMA framework for information governance that enables organizational policies and processes to support information lifecycle.²⁸

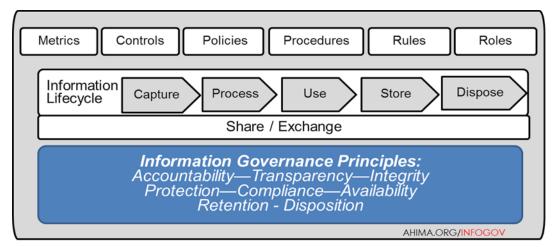
http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data=

²⁵ American Health Information Management Association (AHIMA). Information Governance Principles in Healthcare (IGPHC). 2014. URL: http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data= (NOTE: You need to fill out AHIMA brief IG survey to access this document.)

²⁶ Cohasset Associates | American Health Information Management Association (AHIMA). Information Governance in Healthcare: Benchmarking White Paper. 2014. URL:

⁽*NOTE: You need to fill out AHIMA brief IG survey to access this document.*)²⁷ American Health Information Management Association (AHIMA). Information Governance Maturity Model: Pilot Projects. Work in Progress. 2015

²⁸ Green D. AHIMA:Information Governance Update. Presentation at the Health Information Management and Systems Society (HIMSS) Annual Convention. Chicago IL, April 12-16, 2015



350

Figure 6: AHIMA Information Governance Framework: Organizational Policies and Processes for Information Lifecycle

The authority on establishing organizational policies and processes as well as specific documentation generated via these policies and processes and/or mandated by regulatory bodies falls on a Committee comprised of representatives from clinical, business and technology departments within the facility.^{29,30}

These representatives may include:

- Patient care providers
- 360
- Clinicians (MDs, PA, RNs, residents, other credentialed providers) and
- Staff who supports ancillary services (laboratory, radiology, pharmacy, etc.)
- Practice administrators (physician's assistants, medical group administration)
- Health information services directors/medical informatics (CMIO)
- Health information technology department (CIO)
- Health information directors (HIM, CDI, ROI)
 - Compliance officers (legal and regulatory support) (CLO, Audit)
 - Purchasing and financial managers (CFO) and
 - Vendors (scanning, imaging, EHR, laboratory, etc.) and
 - Other.

370

²⁹ Forms Management. Hospital Policy. University of Vanderbilt, Nashville TN. June 12, 2000

³⁰ Quinsey CA. Managing forms and legal electronic health records. JAHIMA, July 2007, p.58-59

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

Please note that this Committee may have various titles (Form Management Committee, HIT Committee, etc.) and carry out different responsibilities in different organizations. Further efforts are needed to assure standardization of Committee's efforts in defining HIM practices and documentation when implementing information governance within an organization. This is

375 specifically important because in the interoperable, electronic information sharing environment, a lack of sound organizational policies and practices on HIM may compromise shared data, information and knowledge. Our suggestions regarding standardization of the Committee's efforts are presented in the Recommendation section below.

To carry out project activities, in Year 1 we selected 3 information governance principles
(information availability, integrity and protection). Sections that follow provide definitions and business requirements for the selected principles.

4.4.1 Principle of Information Availability: Business Requirements

Information Availability is defined as the ability of an organization to maintain information in a manner that ensures *timely, accurate, and efficient* retrieval of information by authorized entity,³¹ i.e., information shall be availability upon request of authorized entity.

This information may be used by:

- The healthcare team, patients, and other caregivers
- Authorized members of the workforce and others authorized users consistent with regulations
- Legal and compliance authorities for discovery and regulatory review purposes and
 - Internal and external reviewers for purposes including but not limited to payer audit, financial audit, case management, and quality assurance.

Table 7 presents HIM business requirements under **Principle of Information Availability** to retrieve, use, audit, and manage information.

395

Table 7: HIM Business Practices: Information Availability

Information Availability: Business Requirements
1. Maintain information in a manner that ensures timely, accurate, and efficient retrieval.
2. Enable trust of requestor in information by ability to ensure the timeliness, accuracy (completeness and correctness), and efficiency of information availability.
3. Ability to identify, locate, and retrieve the information required to support organization's ongoing activities via queries and access to data across various systems.
4. Ability to address multiple demands for having the right information available at the right time for the right requestor

³¹ American Health Information Management Association (AHIMA). Information Governance Principles in Healthcare (IGPHC). 2014. URL: <u>http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data</u>= (*NOTE: You need to fill out AHIMA brief IG survey to access this document.*)

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

390

Information Availability: Business Requirements

5. Ability to search for information in continually expanding volumes of information and multiple systems including multiple electronic and manual systems.

6. Ability to assemble information from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.

7. Ability to access information created with legacy hardware and software systems. In case of impending system obsolescence, information with organizational value should be migrated to currently supported hardware and/or converted into a machine-readable format.

8. Ability to maintain metadata services across all participating systems assigning structural and descriptive characteristics to information including data provenance information, e.g., authors and dates of creation, modification, sending, receipt, access, etc.

9. Ability to manage both vendor relationships and employee turnover to maintain the workforce capabilities on the most current methods to access information.

10. To ensure levels of redundancy, failover, contingencies and other risk management practices to minimize risks of nonavailability of information due to a disaster, system malfunction, or data corruption.

We further used these business requirements to identify HIM best practices Checklist via literature review, developing Use Cases to specify functional requirements for HIT standards, and conducting gap analysis of existing standards supporting these business requirements (please

400

and conducting gap analysis of existing standards supporting these business requiremen see below Appendices A, B and D, respectively).

4.4.2 Principle of Information Integrity: Business Requirements

Information integrity – the state of being whole or unimpaired – is defined as the ability of data to maintain its structure and attributes to assure representation of intended content and meaning.³²

405

Table 8 presents HIM business requirements under Principle of Information Integrity.

Table 0. This business i factices. Information integrity
Information Integrity: Business Requirements
1. Maintain information in a manner that ensures confidence in its authenticity, timeliness, accuracy, and completeness.
2. Ability to maintain integrity of information to comply with safety, quality of care, and compliance with applicable voluntary, regulatory and legal requirements.
3. Ability to maintain integrity of information in adherence to the organization's policies and procedures.
4. Ability to provide appropriate workforce training on information management and governance to support integrity of information.
5. Enable trust of requestor in the integrity of information by ability to ensure the authenticity, timeliness, accuracy, and completeness, admissibility of records for litigation purposes

Table 8: HIM Business Practices:	Information	Integrity
---	-------------	-----------

³² In formulating this definition we revised the original definition of information integrity in AHIMA Pocket Glossary, 2013. We will work to update AHIMA definition in the future as needed.

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

Information Integrity: Business Requirements

6. Ability to ensure integrity of information through reliable system controls that support the organization's ongoing activities across various systems.

7. Ability to classify and manage information received from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.

8. Ability to demonstrate oversight by senior management of adherence to approved policies and procedures necessary to maintain reliability of information.

9. Ability to ensure reliability of data and information based on the nature and type of healthcare organization processes and systems for creation and capture, processing, and other applicable stages of the information's lifecycle.

10. Ability to implement ongoing quality control measures include field-specific data edits built into systems/applications; monitoring and correction of vendor identity errors and patient identity errors; monitoring and correction of documentation completeness and data accuracy; and ongoing data quality controls.

11. Ability to prove reliability and integrity of the information through the employment of audit trails that are acceptable and verifiable.

12. Ability to monitor hardware, network infrastructure, software, storage, and other system components for reliability of performance

13. Maintain formal change control processes as part of a reliable information environment. That incomplete required testing of functionality, and validation of data and all appropriate metadata.

410 **4.4.3** Principle of Information Protection: Business Requirements

Information Protection is defined as "(1) guarding against inappropriate acquisition, access, disclosure or use of protected health information as well as (2) guarding against loss, tampering, and corruption of health information."³³ Thus part 1 of this definition relates to protection of Information Availability when part 2 - to protection of Information Integrity.

415 Table 9 presents HIM business requirements under **Principle of Information Protection**.

Table 9: HIM Business Practices: Information Protection

Information Protection: Business Requirements
1. Ability to ensure appropriate levels of protection from breach, corruption and loss are provided for information that is private, confidential, secret, classified, essential to business continuity, or otherwise requires protection.
2. Ability to consistently apply and enforce levels of protection to information, regardless of medium, from the moment the information is created until the moment it reaches or exceeds its retention period and is appropriately disposed.
3. Ability to manage and balance compliance with the varying degrees of protection, mandated by laws, regulations, and/or organizational policies for information generated and managed by an organization.
4. Ability to provide security, business continuity, and disaster recovery processes that will ensure continued operation and continued protection, during and after periods of failure or disruption.
5. Ability to assign and manage appropriate levels of information access and security clearance to all members of the workforce and other authorized parties relevant to their roles or duties.

³³ American Health Information Management Association (AHIMA) Pocket Glossary of Health Information Management and Technology. 2014. p.xx

Information Protection: Business Requirements

6. Maintain appropriate security safeguards, clearly defined and enforced by organizational policies, designed to protect electronic information from being inappropriately viewed, e-mailed, downloaded, uploaded, or otherwise proliferated—intentionally or inadvertently, even by individuals with legitimate access to the system.

7. Ability to provide physical security safeguards of computing and access devices or any equipment containing private, secret, or confidential information or intellectual property of the organization.

8. Adhere to security, privacy and confidentiality requirements (rules, regulations, policies) when determining a method for the final disposition of information, regardless of source or media. Whether that disposition is archival, transfer to another organization, preservation for permanent storage, or destruction.

9. Ability to establish an audit program that defines a clear process for verifying whether sensitive secure information is being handled in accordance with the organization's policies and procedures, and compliant with applicable laws and business practices.

4.5 HIM Practice CheckList

420 Based on the literature review we developed HIM Practices Checklist of best practices used in HIM for information availability, integrity and protection. We aligned this Checklist with the business requirements described in Tables 7-9. Appendix A presents the HIM Practice Checklist by business requirements under selected information governance principles: availability, integrity and protection.

425 **4.6 HIM Practice Use Cases**

We further used the HIM Practices Checklist (Appendix A) to develop five Use Cases utilizing an iterative development, vetting and validation working both with the HIM SMEs and IHE ITI experts. Detail description of the Use Cases is provided in Appendix B.

4.7 Glossary

430 To assure the use of consistent terms and definitions across Use Cases we developed a Glossary of terms and concepts used in HIM practices (Appendix C). In some cases we use definitions from the AHIMA HIM Glossary;³⁴ in other, we developed our own definition. This Glossary has to be validated via broader HIM community. After validation, we anticipate updating the AHIMA HIM Glossary by revising current definitions and/or adding new definitions as needed.

³⁴ American Health Information Management Association (AHIMA) Pocket Glossary of Health Information Management and Technology. 2014

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

5 Gap Analysis of HIT Standards to Support HIM Practices

Based on the business requirements, we conducted a high level analysis of HIT standards developed by standards development organizations which may be applicable to HIM practices. Specifically, we focused on identifying standards from the following SDOs:

- International Organization for Standardization (ISO)
- American Society for Testing and Materials (ASTM) and
 - Health Level Seven (HL7).

440

Appendix D presents the framework for the gap analysis of HIT standards that we will be conducting in the future. It contains examples of ISO, ASTM and HL7 standards by HIM
business requirements under the selected three IG principles. We anticipate carrying out the detailed analysis of these and other standards in the future by Use Case. This analysis will specifically include the detail review and selection of IHE standards (integration and content profiles) for a specific Use Case.

Please note that Appendix D contains only the standard's identification number (ID) from the correspondent SDO not the title of the standard or its description. On the project wiki pages, we developed supporting table that contains the ID, title and abstract for the standards listed in Appendix (URL: <u>ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr13-2015-</u> <u>2016/Planning_Cmte/WorkItems/HIM_Practices/Standards_Table_0507/</u>).</u>

455 **6 Recommendations**

Working on the analysis of the HIM business requirements (Tables 79), HIM Practices Checklist (Appendix A) and Use Cases (Appendix B), we identified gaps in both HIM as well as standards development practices. Table 10 presents our recommendations for affected stakeholders to better align HIM practices and capabilities of HIT product through standards.

460

Table 10: Recommendation to HIM Professionals and SDOs

Table 10: Recommendation to HIM Protessionals and SDOS			
HIM Professionals			
A. Standardize Policies for Organizations' Form Management Committee ³⁵ including			
1. Standardize/harmonize scope and operations of the Committee in accordance with the information governance principles			
2. Harmonize existing policies across healthcare organizations			
3. Develop a template organizational policy related to documentation development and management			
4. Define standardized set of documentation for the Episode of Care			
5. Get samples of all possible documents that HIM must have for the Episode of Care			
a. Define policies on the Open and Closed Records and the processes and timeliness of the record completion. This includes finalizing definitions on Open records - former terms must be harmonized and eliminated, (e.g., Incomplete, Lost, Delinquent, Cancelled etc.)			
b. Define policy that outlines how clinicians are notified of open and closed records when			
i. Procedures ordered but not performed			
ii. Documentation components are missing, or			
iii. Signatures are missing. ³⁶			
6. Define a minimum set of content to be analyzed for timeliness and completeness in the legal record			
B. Designate HIM representatives to participate at HL7 Working Groups including			
1. HL7 Community-based Collaborative Care (CBCC) Workgroup			
a. Review Patient Friendly Consent Directive ³⁷			
i. Review CBCC documentation in wiki (URL: <u>http://wiki.hl7.org/index.php?title=Community-Based_Collaborative_Care</u>			
a. Review Data Provenance Model:			
i. Research - where the provenance of provenance and research processes are key concerns			

ii. Clinical – where a Clinician or a Clinical Decision Support system need to evaluate confidence/authenticity/reliability

³⁵ Please see note in the Information Governance section above that the name of this Committee may vary in different organizations.

³⁶ American Health Information Management Association (AHIMA) Pocket Glossary of Health Information Management and Technology. 2014. p.77

³⁷ Health Level Seven (HL7). Patient Friendly Consent Directive. URL:

 $http://wiki.hl7.org/index.php?title=HL7_Patient_Friendly_Consent_Directive_Project$

of information for clinical decision-making

- iii. Records Management and Evidentiary Support where the medico-legal issues related to provenance are key concerns, and
- iv. Security where the focus is on audit, accounting of disclosure, and provenance related access control are of key concern [e.g., only the author can access an unattested record entry].³⁸

2. EHR Workgroup

a. Normalize definitions for records/document lifecycle.

Specific examples of statements from the HL7 EHR Functional Model standard³⁹ are provided in italic below. Yellow highlights indicate statements in questions and blue - proposed revisions as follows:

"Record Infrastructure RI. 1.4, Function; Record Completeness, Conformance Criteria:

Statement: Manage Record Completeness.

Description: The EHR-S must provide support the ability for an organization to define minimum elements and timeframes for completion at the report level and at the record level."

EHR system will not define minimum elements and timeframes. This is the work of the Form Management Committee (see above).

1. Discuss and define the use of terms: minimum element, report level, record level

2. Propose to change "provide" to "support".

"Provide a report that identifies completion and timeliness status by patient/ health record number or other specified parameters."

Is this Audit trail report?

"Prior to disclosure for legal proceedings or other official purposes, an organization analyzes the health record for completeness. EHR systems must provide the ability to *define* capture a minimum set of content to

³⁸ Health Level Seven (HL7). HL7 Data provenance Project Space. URL: http://wiki.hl7.org/index.php?title=HL7_Data_Provenance_Project_Space

³⁹ Health Level Seven (HL7). Electronic Health Record Functional Model Release 2. 2014. URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

be analyzed for timeliness and completeness and provide a report of the status."40

EHR system will not define a minimum set of content prior to release of information (ROI). This is the work of the Form Management Committee (see above).

- 1. Propose to change "define" to "capture".
- 2. Define a report of status?

"Care Provision Support (CPS) 3.3.12: The system SHOULD provide the ability to render an indicator that a patient record is incomplete (e.g., not finalized or authenticated/signed) when a discharge or transfer order is entered into the system.⁴¹

Harmonize terms for "incomplete" with terms "open" and "closed" records. We suggest that the term "incomplete" will be replaced with the "open" throughout the standard.

C. Review documentation on Provenance from the World Wide Web Consortium (W3C).^{42,43}

1. Review W3C documents addressing Provenance that can be summarized as follows:

"Provenance of a resource is a record that describes entities and processes involved in producing and delivering or otherwise influencing that resource. Provenance provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility. Provenance assertions are a form of contextual metadata and can themselves become important records with their own provenance."

Standards Development Organizations

A. Health Level Seven (HL7)

1. HL7 Community-based Collaborative Care (CBCC) Workgroup

a. Enable review of the Patient Friendly Consent Directive⁴⁴ with HIM professionals.

http://wiki.hl7.org/index.php?title=HL7 Patient Friendly Consent Directive Project

⁴⁰Health Level Seven (HL7) Electronic Health Record Functional Model Release 2. 2014. URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

⁴¹Health Level Seven (HL7) Electronic Health Record Functional Model Release 2. 2014. URL:

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

⁴² World Wide Web Consortium (W3C). Provenance. URL: <u>http://www.w3.org/standards/techs/provenance</u>

⁴³ World Wide Web Consortium (W3C). Provenance XG Final Report. URL: http://www.w3.org/2005/Incubator/prov/XGR-prov-20101214/

⁴⁴ Health Level Seven (HL7). Patient Friendly Consent Directive. URL:

	 a. Enable review of EHR System Functional Model - Record Lifecycle Events Implementation Guide ballot⁴⁵ with HIM professionals.
	"Record Amendment" should be replaced with "Record Retraction" that includes Record Amendment and Record Addendum.
3.	EHR Workgroup a. Enable review of the HL7 EHR Functional Model standard to incorporate recommendation from HIM professionals.
B.	Integrating the Healthcare Enterprise
	Enable review of the IHE profiles with HIM professionals.

C. Other SDO (to be determined)

⁴⁵ Health Level Seven (HL7).Electronic Health Record System Functional Model - Record Lifecycle Events Implementation Guide. URL: <u>http://hl7-fhir.github.io/ehrs-rle.html</u>

7 Roadmap

The ultimate goal of our efforts described in this White Paper was to have the HIM Principles and Practices included in the portfolio of standards (technical frameworks) that could work together to support data exchanges. The HIM Principles and Practices represents a missing component in the collaboration between HIT vendors, professional associations, and governmental entity efforts to craft an interoperable electronic document sharing portfolio of standards. We believe that we demonstrated that our work fills this missing component.

- 470 The deliverables presented in this White paper Business requirements for Information Availability, Integrity and Protection (Tables 7-9), HIM Practice Checklist (Appendix A), Use Cases (Appendix B) and examples of HIT standard gap analysis by business requirements (Appendix D) – as well as the consensus-based process employed to develop these deliverables outline the overall methodology (how and what) for aligning the HIM practices needs with the
- 475 capabilities of HIT products to support these needs. Through this effort we built the foundation for the amalgamation of the HIM and HIT universes (Figure 7).

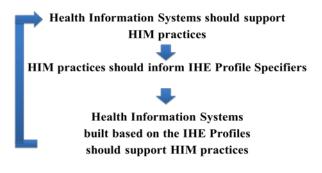


Figure 7: Amalgamation of HIM and HIT Universes

480

Based on our productive experience of HIM professionals working together with IHE experts we are determined to continue this effort in the future. We will focus on the following efforts for our future collaboration:

2015-2016

- Continue to elicit business requirements for additional 5 information governance principles using the format of Tables 7-9: Accountability, Transparency, Compliance, Retention and Disposition
 - 2. Continue to populate HIM Practice Checklist for additional principles based on the literature review of the best HIM practices (Appendix A),

- 4903. Continue to develop Use Cases for the HIM practices under Information Availability, Integrity and Protection (Appendix B)
 - 4. Undertake detailed gap analysis of HIT standards by Use Case starting with those developed in Year 1 based on the preliminary analysis conducted for the business requirements (Appendix D)
- 495 5. Define the timeline for the completion of the development of the HIM practice Use Cases based on the experience from Years 1 and 2
 - 6. Define the maintenance process for developed Use Cases and
 - 7. Identify automated tools to assist in the development and maintenance of the Use Cases.

Based on the outcomes from efforts I-VII, we anticipate developing a comprehensive Roadmap (milestones, partners, outcomes, metrics for success, supporting infrastructure (automated tools) and training) for enabling standardization of HIM practices and HIT products to support these practices.

We will further work with IHE to transition from our current *Effort 1: functional requirements* for HIM practices have been communicated to standards developers for creating HIT standards;

505 to launching activities in support of the Effort 2: standards are adopted in the HIT products; and Effort 3: standards-based HIT products support HIM practices.

Business Requirements	HIM Practice Checklist ⁴⁶	Use Case
	Information Availability (A)	
1. Maintain information in a manner that ensures <i>timely, accurate, and</i> <i>efficient</i> retrieval.	A1. All documents can be accounted for and the record closed as complete within a specific time period post patient discharge in accordance with governmental regulations, accreditation organizations, or organizational policy.	 A1.1. All documents can be accounted for within a specific time period post completion episode of care/encounter. A1.2. Record is closed as complete within a specific time period post completion of the episode of care/encounter.
2. Enable trust of requestor in information by ability to ensure the timeliness, accuracy (completeness and correctness), and efficiency of information availability.	A1. All documents can be accounted for and the record closed as complete within a specific time period post patient discharge in accordance with governmental regulations, accreditation organizations, or organizational policy.	A1.1 and A1.2 (above)
3. Ability to identify, locate, and retrieve the information required to support organization's ongoing activities via queries and access to data across various systems.	A2.Single or multiple groups of documents within the electronic medical record can be viewed by or released to the requestor .	 A2.1. Single and multiple (submission sets) documents within the electronic medical record can be viewed by or released to the requestor for treatment, payment, and healthcare operations use and disclosure. A2.2. Single and multiple
		(submission sets) groups of documents within the electronic medical record can be viewed by or released to the requestor for use and disclosure requiring a signed authorization.
4. Ability to address multiple demands having the right information available at the right time for the right requestor.	A2. Single or multiple groups of documents within the electronic medical record can be viewed by or released to the requestor.	A2.1 and A2.2 (above)
5. Ability to search for information in continually expanding volumes of information and multiple systems including multiple electronic and manual systems.	A2.Single or multiple groups of documents within the electronic medical record can be viewed by or released to the requestor.	A2.1 and A2.2 (above)
6. Ability to assemble information from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.	A2. Single or multiple groups of documents within the electronic medical record can be viewed by or released to the requestor.	A2.1 and A2.2 (above)

510 Appendix A: HIM Practice Checklist

⁴⁶ Grzybowski, D. Strategies for Electronic Document and Health Record Management. AHIMA, Chicago, IL. 2014, pp. 31, 40, 47, 159

7. Ability to access information created with legacy hardware and software systems. In case of impending system obsolescence, information with organizational value should be migrated to currently supported hardware and/or converted into a machine-readable format.	A2.Single or multiple groups of documents within the electronic medical record can be viewed by or released to the requestor.	A2.1 and A2.2 (above)
8. Ability to maintain metadata services across all participating systems assigning structural and descriptive characteristics to information including data provenance information, e.g., authors and dates of creation, modification, sending, receipt, access, etc.	To be developed (TBD)	TBD
9. Ability to manage both vendor relationships and employee turnover to maintain the workforce capabilities on the most current methods to access information.	TBD	TBD
10. To ensure levels of redundancy, failover, contingencies and other risk management practices to minimize risks of non-availability of information due to a disaster, system malfunction, or data corruption.	TBD	TBD
11.	A3. A log of all requests and accounting of disclosures is kept as an audit trail and can be referenced as needed.	
12.	A5. Maintenance of an inventory of discontinued (retired), archived, and disposed, revised, current forms according to governmental regulations. Maintaining an inventory that is complete, accurate and continually updated based on the organizational policy. Legal health record definition, and records retention policy.	
13.	A8. Current trends toward system interoperability and integration require that information quality and service quality be added as a new health information dimension. Key considerations become accuracy and completeness of data, excellent information access, continued availability of data, supported overall by privacy and security safeguards.	
14.	A9. Disclosing of records require written authorization by the patient and approval by the compliance officer if not otherwise allowed by law. A written record is kept by the compliance officer and available for audits.	

Information Integrity ⁴⁷ (I)		
1. Maintain information in a manner that ensures confidence in its authenticity, timeliness, accuracy, and completeness.	A4. Full chart management functionality (i.e., Record Lifecycle Management) to verify the identification of location of the source of the release, completeness of the documents being released, and destination for the release or review are available in the release of information software.	TBD
2. Ability to maintain integrity of information to comply with safety, quality of care, and compliance with applicable voluntary, regulatory and legal requirements.	A6. Accurate capture of patient data by electronic health record system. Reduction of medical errors that cause inaccurate recording of patients' allergies and medications, compromising quality of care and patient safety.	TBD
3. Ability to maintain integrity of information in adherence to the organization's policies and procedures.	I1. Performance of a daily duplicate medical record number and account number validity checking process in place. Enterprise-wide process exists for notification of duplications. Process of merging paper and electronic records. ⁴⁸	TBD
4. Ability to provide appropriate workforce training on information management and governance to support integrity of information.	I2 . Proper training and support of system user is paramount to preventing system errors that can potentially contribute to suboptimal healthcare quality.	TBD
5. Enable trust of requestor in the integrity of information by ability to ensure the authenticity, timeliness, accuracy, and completeness, admissibility of records for litigation purposes.	A1 . All documents can be accounted for and the record closed as complete within a specific time period post patient discharge in accordance with State and Federal regulations, accreditation organizations (e.g., Joint Commission, Det Norske Veritas Healthcare - ISO 9000), or organizational policy.	 A1.1. All documents can be accounted for within a specific time period post completion episode of care/encounter. A1.2. Record is closed as complete within a specific time period post completion of the episode of care/encounter.
6. Ability to ensure integrity of information through reliable system controls that support the organization's ongoing activities across various systems.	TBD	TBD

⁴⁷ Bowman, S. Impact of electronic health record systems on information integrity: Quality and safety implications. Perspectives in Health Information Management, 2013, pp.2, 3, 7. URL: <u>http://perspectives.ahima.org/impact-of-</u> <u>electronic-health-record-systems-on-information-integrity-quality-and-safety-implications/#.VU00LPm6e00</u>. ⁴⁸ Grzybowski, D. Strategies for Electronic Document and Health Record management.. AHIMA, Chicago, IL.

^{2014,} pp. 31, 40, 47, 159

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

7. Ability to classifying and manage information received from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.	 A6. Standard and complete capture of patient data by electronic health record system. For example; normal laboratory results with a normal reference range, 24 hour clock, pain scale with reference, with appropriate references (case definitions) for all results, findings, interpretations, care plans, standards of care (clinical pathways) allergies, and medications. To ensure integrity of patient data (prevent inaccurate recording of patients data and protect against compromising quality of care, and patient safety), see reference to integrity. A7. Operate (maintain, monitor, test, update, verify, validate) timely system interfaces that ensure accurate interchange of data using a validated (trusted) information exchange system (sender-receiver interfaces). System interface problems can lead to poor decisions, delays, data loss, errors, unnecessary testing, and system downtime. 	TBD
8. Ability to demonstrate oversight by senior management of adherence to approved policies and procedures necessary to maintain reliability of information.	I3. Improved information quality (integrity) is perceived by providers as a result of electronic health record implementation; demonstrated by the following attributes, accuracy, timeliness, accessibility to current data, and availability. ⁴⁹	TBD

⁴⁹ Nguyen, L, Bellucci, E, & Nguyen, LT Electronic health records implementation: An evaluation of information system impact and contingency factors. International Journal of Medical Informatics. 2014. 83(11): 779-796.

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

9. Ability to ensure reliability of data and information based on the nature and type of healthcare organization processes and systems for creation and capture, processing, and other applicable stages of the information's lifecycle.	 A6. Standard and complete capture of patient data by electronic health record system. For example; normal laboratory results with a normal reference range, 24 hour clock, pain scale with reference, with appropriate references (case definitions) for all results, findings, interpretations, care plans, standards of care (clinical pathways) allergies, and medications. To ensure integrity of patient data (prevent inaccurate recording of patients data and protect against compromising quality of care, and patient safety), see reference to integrity. A7. Operate (maintain, monitor, test, update, verify, validate) timely system interfaces that ensure accurate interchange of data using a validated (trusted) information exchange system (sender-receiver interfaces). System interface problems can lead to poor decisions, delays, data loss, errors, unnecessary testing, and system downtime. 	TBD
10. Ability to implement ongoing quality control measures include field- specific data edits built into systems/applications; monitoring and correction of vendor identity errors and patient identity errors; monitoring and correction of documentation completeness and data accuracy; and ongoing data quality controls.	A6 and A7 above.	TBD
11. Ability to prove reliability and integrity of the information through the employment of audit trails that are acceptable and verifiable.	TBD	TBD
12. Ability to monitor hardware, network infrastructure, software, storage, and other system components for reliability of performance.	TBD	TBD
13. Maintain formal change control processes as part of a reliable information environment. That incomplete required testing of functionality, and validation of data and all appropriate metadata.	TBD	TBD

14. 15.	 I4. Appropriate workforce education and training on information management and governance and ongoing technical support has been proven to support improved electronic health record system proficiency resulting in successful adoption and use⁵⁰. I5. Accurate capture of patient data by electronic health record system. Reduction 	
	of medical errors that cause inaccurate recording of patients' allergies and medications, compromising quality of care and patient safety ⁵¹ .	
	Information Protection ⁵² (P)	
1. Ability to ensure appropriate levels of protection from breach, corruption and loss are provided for information that is private, confidential, secret, classified, essential to business continuity, or otherwise requires protection.	P1 . MPI contain the correct number of entries in the right sequence, so that it has episode of care integrity within its account number.	TBD
2. Ability to consistently apply and enforce levels of protection to information, regardless of medium, from the moment the information is created until the moment it reaches or exceeds its retention period and is appropriately disposed.	P3. Full release of information functionality, including tracking receipts for requests, gathering electronic medical records from all facilities, and processing those files, the billing and collections associated with the release, and the actual distribution of the copies for the records.	TBD
3. Ability to manage and balance compliance with the varying degrees of protection, mandated by laws, regulations, and/or organizational policies for information generated and managed by an organization.	P2. Global or universal authorization can be filed at the enterprise (medical record number) vs. individual episode of care.	TBD
4. Ability to provide security, business continuity, and disaster recovery processes that will ensure continued operation and continued protection, during and after periods of failure or disruption.	TBD	TBD

 ⁵⁰ Nguyen, L, Bellucci, E, & Nguyen, LT Electronic health records implementation: An evaluation of information system impact and contingency factors. International Journal of Medical Informatics. 2014. 83(11): 779-796.
 ⁵¹ Bowman, S. Impact of electronic health record systems on information integrity: Quality and safety implications.

Perspectives in Health Information Management, 2013, pp.2, 3. URL: <u>http://perspectives.ahima.org/impact-of-electronic-health-record-systems-on-information-integrity-quality-and-safety-implications/#.VUOOLPm6e00</u>. ⁵² Grzybowski, D. Strategies for Electronic Document and Health Record Management.. AHIMA, Chicago, IL. 2014, p. 159

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

5. Ability to assign and manage appropriate levels of information access and security clearance to all members of the workforce and other authorized parties relevant to their roles or duties	P4. Enforce a need to know (minimum necessary) privacy and security policy for all users of patient-protected information and records as opposed to open access.	TBD
6. Maintain appropriate security safeguards, clearly defined and enforced by organizational policies, designed to protect electronic information from being inappropriately viewed, e-mailed, downloaded, uploaded, or otherwise proliferated— intentionally or inadvertently, even by individuals with legitimate access to the system.	P3. Full release of information functionality, including tracking receipts for requests, gathering electronic medical records from all facilities, and processing those files, the billing and collections associated with the release, and the actual distribution of the copies for the records.	TBD
7. Ability to provide physical security safeguards of computing and access devices or any equipment containing private, secret, or confidential information or intellectual property of the organization.	P5. Limit clinician documentation entry to only those practitioners who are associated with a specific patient within the system.	TBD
8. Adhere to security, privacy and confidentiality requirements (rules, regulations, policies) when determining a method for the final disposition of information, regardless of source or media. Whether that disposition is archival, transfer to another organization, preservation for permanent storage, or destruction.	P3. Full release of information functionality, including tracking receipts for requests, gathering electronic medical records from all facilities, and processing those files, the billing and collections associated with the release, and the actual distribution of the copies for the records.	TBD
9. Ability to establish an audit program that defines a clear process for verifying whether sensitive security information is being handled in accordance with the organization's policies and procedures, and compliant with applicable laws and business practices.	P6. Employ a break-the-glass emergency access methodology to override access control measures designed to protect patient privacy and confidentiality. Utilize audit trails to monitor compliance with organization privacy policy and procedures.	TBD

Appendix B: HIM Practice Use Cases

520

Sections below describe Use Cases developed from the harmonized HIM business requirements
 and HIM practices checklist (Appendix A) under information availability (A) principle as
 follows:

Use Case A1.1: All documents are accounted for within a specific time period post completion of the episode of care

Use Case A1.2: Record is closed as complete within a specific time period post completion of the episode of care

Use Case A2.1: Documents within the record can be viewed by or released to the external requestor

Use Case A3.1: An audit log of the episode of care record

Use Case A3.2: An audit log of requests for release of information and accounting of disclosures

525 The following numbering convention was used to manage the Use Cases:

A1.1: A – availability principle; 1– HIM Practice #1 as listed in the Checklist (Appendix A); 1 – number of the Use Case under HIM Practice #1.

Information Governance Principle: Record Availability

530 **<u>HIM Practice A1</u>**. All documents can be accounted for and the record closed as complete within a specific time period post patient discharge in accordance with State and Federal regulations, accreditation organizations (e.g., Joint Commission[ref], Det Norske Veritas Healthcare - ISO 9000[REF]), or organizational policy.⁵³

535 B.1 Use Case A1.1: All documents are accounted for within a specific time period post completion of the episode of care

This Use Case is focused on <u>inpatient encounter</u>. Other types of encounter (outpatient, long-term care and others) are out of scope and will be addressed in the future.

The statement "<u>All Documents"</u> is referred to <u>open and closed records</u> generated within the episode of care (Figures 55- and 8). Please see Use Case A1.2 for the description of <u>open and</u> <u>closed records states</u>.

The term **<u>record</u>** is used in the context of the episode of care, i.e., level 2 of the record hierarchy depicted in Figure 4 in the Information Governance section above.

⁵³ Grzybowski, D.Strategies for electronic document and health record management. Chicago, IL: AHIMA. 2014. p.40

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

The term "accounted for" means that the EHR system shall support all types of medical documentation, i.e., records (paper and electronic) generated during a specified timeframe of an 545 episode of care.

The list of records and personnel for defining and maintaining these records are specified by organizational policies.⁵⁴ As it was described in the Information Governance section above, the authority on establishing organizational policies and processes as well as specific documentation 550 (records) generated via these policies and processes and/or mandated by regulatory bodies falls on a Committee (Form Management Committee or other name may be used for this Committee as described in the Information Governance section above) comprised of representatives from clinical, business and technology departments within the facility.^{55,56}

If other facilities are involved in providing services, data sharing agreements between two 555 facilities shall define the policies on how documentation will be accounted for when shared.

The custodian of the records within the facility is the health information management (HIM) department (former medical records department).

Figure 8 presents the episode of care record lifecycle that include various functions

(registration/admission, triage, assessment, testing, diagnosis confirmation and care plan, 560 prescription, discharge/transfer) performed in the context of a clinical pathway; records generated within each function; as well as record sharing between EHR and ancillary systems (diagnostic testing, pharmacy) involved in the clinical pathway. Examples of these functions and records generated by function are presented in Table 5 under Information Governance Section above. 565

Figure 8 also presents various HIT applications (APP) involved in documenting clinical pathway with the episode of care. Specific examples of participating information systems (technical actors) include:

- 1. EHR System Record Originator
- 2. Ancillary System 1 (e.g., Laboratory, Radiology, etc.) Record Receiver (order) and 570 Record Originator (result report)
 - 3. Ancillary System 2 (Pharmacy) Record Receiver (prescription) and Record Originator (prescription dispense report)

Please note that every participating technical actor in addition to function-specific records also exchange the following documentation: 575

- 1. Notification of Document Availability (Sender to Receiver)
- 2. Acknowledgement of Document Receipt (Receiver to Sender)

⁵⁴ Forms Management. Hospital Policy. University of Vanderbilt, Nashville TN. June 12, 2000 55 Ibid

⁵⁶ Quinsey CA. Managing forms and legal electronic health records. JAHIMA, July 2007, p.58-59

The <u>time period for documentation/record completion</u> depends on the record type as defined by each specific function/event/step within the episode of care, i.e., function-specific workflow steps and sub-steps (Figure 8).

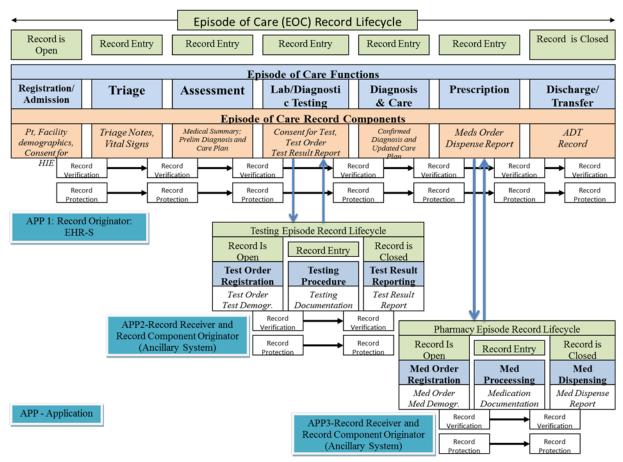


Figure 8: Example of Episode of Care and Various Information Systems (Technical Actors) Involved in Documenting Clinical Pathway

585

The "<u>Start and the End</u> of each function/event/step within the episode of care are defined by the creation and completion of the correspondent record related to the specific function/event/step.

More specifically, the <u>start of the episode of care</u> is defined by the <u>initial interaction</u> of the patient with the healthcare facility (e.g., present at the facility, e-mail, phone or other). This

590 initial interaction sets into motion the chain of functions/events/steps defined by the clinical pathway of activities for a specific episode of care. This initial interaction acts as a trigger of a specific clinical pathway (Table 11).

Episode of Care			
Clinical Pathway for <function: assessment,="" etc.="" registration,="" testing,=""></function:>			
Workflow (Flow of Records Events)			
Initial interaction with healthcare facility (visit, e-mail, phone)			
Step 1	Record 1 – output for Step 1 and input /trigger for Step 2		
Step 2	Record 2 – output for Step 2 and input/trigger for Step 3		
Step 3 Record 3 – output for Step 3			

- For example, for patient registration, the start of the registration process is triggered by the patient presenting at the facility in person or contacting the facility by phone or via e-mail. Registration staff initiates the command "Register a New Patient" or "Look up Existing Patient" in the facility's EHR system to initiate the specific record for Step 1. This record may contain several documents/forms (Patient Registration Form, Medical and Social History Update Form,
 Information Exchanges Consent Form, patient's privacy and confidentiality protection forms
- 600 Information Exchanges Consent Form, patient's privacy and confidentiality protection forms, etc.).

For the functions that follow the registration (Step 1), the completed set of documents/forms for Patient Registration in EHR (Record 1) serves as a trigger to begin the next step, e.g., triage (Step 2) that trigger the Record 2 set of documents/form (e.g., the history & physical form) to be completed.

- Patient's <u>registration</u>, <u>admission</u>, <u>disposition</u>, <u>and discharge/transfer</u> define the <u>status (states) of</u> <u>the patient's interaction</u> within the healthcare facility. EHR system must support the document flow across all patient states within the episode of care (Figure 8 and Table 11). EHR system must also capture change in these states via the Open and Closed record status associated with
- 610 each state. (Please see Use Case A1.2 for Open and Closed records as well as Use Case A3.1 for the Audit log of the records in the episode of care).

In EHR system the patient status (state) is typically monitored in the <u>Capacity/Bed Management</u> application. For example, under disposition when patient is moved to another floor for testing, all previous documents in the record that triggered this new state (input documents) and new documents generated by this new state (output documents) must be captured in EHR.

Please note that <u>Patient Status</u> (data element, field) was traditionally used for billing. Now this field may be used as a trigger to determine the corresponding documentation in the record.

The <u>end</u> of a specific function as well as the episode of care, at large, is defined by providing capabilities to electronically sign the output document. This action is called <u>"Verified by</u>

620 <u>Authentication</u>" and includes the time stamp (date and time) of verification for each output document. The completion of this capability is done by obtaining signature of an authorized

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

605

615

person including digital signature on a specific document. Furthermore, within each document there can be multiple authentications as defined by organizational policy.

B.2 Use Case A1.2: Record is closed as complete within a specific time period post completion of the episode of care

There are two states of the record/document - **Open and Closed** - that represent the state of the record.

<u>Open record</u> is a record (one document) or a set of record components (several documents) that is/are created to begin a new function (level 3 in the record hierarchy (Figure 4)).

630 An open record has to be completed within defined timeframe for a specific function. The Committee (Forms Management Committee) defines policies on the processes and timeliness of the record completion, e.g., 30 days for discharge summary as per the requirements of the Joint Commission and Medicare conditions of participation.

Delinquent records are considered open records.

- 635 EHR system must support capabilities to notify the clinician
 - 1. When the record is open
 - 3. When the record is outside of the time limits set for a specific function
 - 4. Ready to be signed, i.e., verified by authentication, and
 - 5. When the record is closed.

640

The record remains <u>open</u> until all its parts are assembled and the appropriate documents are authenticated according to organizational policies.⁵⁷

<u>Record completion</u> is the process defined by the organizational policy. This process specifies activities of the authorized personnel to be able to

- 645 1. Open (initiate the new record),
 - 2. Access existing record to contribute new information
 - 3. Access existing record to modify/correct existing information
 - 4. Close (verify by authentication) a specific component of the record and/or the full record.⁵⁸
- 650 In the paper-based environment the term <u>**Retraction**</u> (go back) was used to access the record for correcting information that was inaccurate, invalid, or made in error. Retraction is aimed to

⁵⁷ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 32

⁵⁸ Same, p. 126

modify the Open record. ⁵⁹ The term <u>retraction</u> is used in HIM to modify existing information in the record through record <u>amendment</u> or <u>addendum</u>, i.e., modification of the original record entry.

655 Whenever, changes are made to the record (e.g., new document was added; the part of the record was revised, etc.) the changes/revisions must be reviewed and approved by the authorized person.

An audit trail must capture all modifications done to the record. (Please see Use Case 3.1 below about audit trail for retraction).

- 660 **<u>Closed record</u>** is the record that
 - 1. Contains all necessary clinical information to substantiate the care rendered
 - 2. Verified by authentication by the authorized clinician
 - 3. Meets the requirements of the legally defensible health record as defined by organizational policies, and/or
- 4. Administratively closed record, i.e., closed based on the administrative decision with documentation supporting this decision.

EHR system must have capabilities to assure the completion of the records by the authorized personnel, as follows:

- 1. Generate a list of Open records for all patients of a clinician on a daily basis upon opening the EHR
 - 2. Generate notifications about the record for which the timeframe is expiring, so clinician could act upon this notification as follows:
 - a. Close the record supplying appropriate description for the reason of the record closure
- b. Sending reminder to the:
 - i. Patient via phone, e-mail, etc.
 - ii. Ancillary system(s)
 - c. Other
 - 3. Generate audit reports on records generation, retraction for modification (amendment or addendums) and completion. (Please see Use Case 3.1 below about audit trail for retraction).

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

670

675

680

⁵⁹ Same, p. 130

<u>HIM Practice A.2.</u> Documents within the electronic medical record can be viewed by or released to the external requestor.

685

705

B.3 Use Case A2.1: Documents within the record can be viewed by or released to the external requestor

This Use Case is focused on effective delivery of the **release of information** (**ROI**) by a facility according to organizational policies defined by the facility's Committee. ^{60,61,62}

690 <u>Release of information (ROI)</u> is defined as the process of disclosing patient identifiable information from the health record to another party.⁶³

ROI function is based on

- 1. Availability of all documentation that comprises a current and accurate Legal Health Record (LHR) and Designated Records Set (DRS) in EHR system (see Use Case A1.1);
- 695 2. Ability of the record custodian (HIM department) to maintain LHR and SDR in EHR system;
 - 3. Ability to assemble all records in a timely manner in LHR and DRS and
 - 4. Ability to provide LHR and DRS to the authorized external requestor.

Examples of information that may be requested by external requestor include:^{64,65}

- Disclosures of protected health information (PHI) that are not for treatment, payment, or delivery of healthcare operations
 - Disclosures for research purposes
 - Disclosures to government agencies (excluding intelligence/national security)
 - Disclosures to public health authorities (public health reporting including vital statistics reporting)
 - Disclosures to the Food and Drug Administration (FDA) on adverse event reporting
 - Disclosures to employers
 - Disclosures to health oversight agencies

⁶⁵ Downing, K, McLendon, K. Checking in on accounting of disclosures. JAHIMA. 2013, 84(11): 50-52.

 ⁶⁰ Forms Management. Hospital Policy. University of Vanderbilt, Nashville TN. June 12, 2000
 ⁶¹ Ibid

⁶² Quinsey CA. Managing forms and legal electronic health records. JAHIMA, July 2007, p.58-59

⁶³ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 128

⁶⁴ Stuard. S. Developing a plan of action – How to conduct an accounting of disclosures. American Health Information Management Association (AHIMA), In Confidence. 2003, 211(7): 4-5.

- Disclosures to law enforcement, e.g., suspected domestic and child violence and abuse reporting
 - Disclosures regarding deceased persons
 - Disclosures for specialized government functions and
 - Disclosures for workers' compensation purposes.
- ROI function is supported by the electronic document management system (EDMS)
- application, designed to serve as a platform from which release of information is managed.⁶⁶

Basic ROI workflow consists of the following steps:

- 1. Capture the request for information from the requestor
- 2. Verify that the request for information is not in violation of the privacy, confidentiality and security rules, jurisdictional and organizational policies
- 720 3. Verify the requestor's rights to view information requested
 - 4. Assemble information that was requested
 - 5. Verify the assembled information by authorized person
 - 6. Authorize the release of assembled information to the requestor
 - 7. Release information to the requestor and
- 725 8. Record information requests and releases in the audit trail.

Each step in the ROI workflow may have additional sub-steps. Involvement of specific actors (both business actors (facility's personnel) and technical actors (information systems including both internal and external (ancillary) systems) in these steps has to be further defined/modeled.

Each of these steps is associated with specific data content. For example, data for Step 1 – capture the request for information from the requestor - may include

- 1. Patient Name
- 2. Medical Record Number
- 3. Requestor Name
- 4. Requestor Address
- 735 5. Request Date

710

- 6. Request Purpose
- 7. Timeframe for Request, i.e., when requestor anticipates to receive the information

⁶⁶ Kohn, D. How information technology supports virtual HIM departments. JAHIMA. 2009, 80(3): URL: <u>http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043005.hcsp?dDocName=bok1040035</u>

- 8. Date When Information Was Released
- 9. Charge for Information Release

740

Please note that, specification of the data content is out of scope of this White Paper. In the future, we will work with the IHE Content Committees, e.g., Patient Care Coordination (PCC); Quality, Research and Public Health (QRPH) and others, to define data content for specific requests as needed.

745 <u>Risk mitigation</u> procedures for ROI must be supported by EHR system. Examples of these procedures may include (a) recording of all requests for information, (b) accounting of all disclosures, and other. Please see Use Case A3.1 below regarding audit trail that may be applicable to enabling these procedures.

HIM Practice A.3. A log of all requests and accounting of disclosures is kept as an audit trail
 and can be referenced as needed [REF]

B.4 Use Case A3.1: An audit log of the episode of care record

This Use Case is focused on the maintenance of logs for the episode of care records for clinical documentation improvement and audit purposes. The retention of these logs will be done according to the federal and state regulation and organizational policies defined by the facility's Committee. ^{67,68,69}

755

760

The following states of the record should be recorded in the audit log:

- Record Creation Record is Open
- Record Retraction for Corrections, Modification, Amendments and Addendums
- Record Completion Record of Closed
- Record Access by Authorized Users
 - Clinicians involved in patient care,
 - Patient or Caregiver
 - Record Assembled for the Release of Information (See Use Case A2.1 above)

IHE ITI Technical Framework (TF) Supplement Add RESTful Query to ATNA draft standards⁷⁰
 specified various use cases that call for audit trail capabilities in EHR systems. We will work

 ⁶⁷ Forms Management. Hospital Policy. University of Vanderbilt, Nashville TN. June 12, 2000
 ⁶⁸ Ibid

⁶⁹ Quinsey CA. Managing forms and legal electronic health records. JAHIMA, July 2007, p.58-59

⁷⁰ IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA. In Preparation for Public Comments. 2015. URL:

with IHE ITI to align our Use Case A3.1 that specified needs for an audit log for the episode of care record with the use cases defined in the draft IHE ITI standard.

B.5 Use Case A3.2: An audit log of requests for release of information and accounting of disclosures

770 This Use Case is focused on the maintenance ROI and information disclosure logs for risk mitigation and audit purposes. The retention of these logs should be done according with the organizational policies defined by the facility's Committee. ⁷¹,⁷²,⁷³

The IHE ITI TF Supplement Add RESTful Query to ATNA draft standard provide examples of audit log use cases for ROI and disclosures similar to the ones we specified in Use Case A2.1 above. We will work with IHE ITI to align our Use Case A3.2 that specified needs for audit log

above. We will work with IHE ITI to align our Use Case A3.2 that specified needs for audit log for ROI and disclosures with the use cases defined in the draft IHE ITI standard.

⁷¹ Forms Management. Hospital Policy. University of Vanderbilt, Nashville TN. June 12, 2000

⁷² Ibid

⁷³ Quinsey CA. Managing forms and legal electronic health records. JAHIMA, July 2007, p.58-59

Term	Definition
Clinical Pathway	A flow of activities and documentation derived from the clinical guidelines as related to a specific episode of care (Figure 5).
	Clinical pathway is a tool designed to coordinate multidisciplinary care planning for specific diagnoses and treatments. ⁷⁴
	Clinical pathway – also known as a clinical workflow document (specification or checklist) – is developed by physicians (medical informaticians) at the facility. It serves as a practice management protocol. This protocol defined information and data requirements (forms, documents) associated with the episode of care. The information and data requirements (forms, documents content) are also called case definitions, i.e., specific instructions on how to document specific activity within the function based on the clinical guidelines. ⁷⁵
	The oversight of the correct recording of information according to the clinical pathway protocol and case definition is conducted by the facility's Clinical Documentation Improvement (CDI) team of the HIM department. CDI team is also involved in developing templates (standardized formats) for forms and documents used in the clinical pathway to document the episode of care/encounter. ⁷⁶
Designated record set	Organizations may be required to identify their designated record set, which is defined as a group of records maintained by or for a covered entity that is: The record of what you acted upon to treat the patient.
	1. The medical records and billing records about individuals maintained by or for a covered healthcare provider
	2. The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan
	3. Used, in whole or part, by or for the covered entity to make decisions about individuals." ⁷⁷
	With the definition of the designated record set in mind, the organization must identify the content and data sets specific to their facility. Once the necessary information for the designated record set has been determined, it is required that this information and content be defined and documented within organizational policies.
Disclosure	Defined by federal regulations disclosure as "the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information." ⁷⁸

Appendix C: Glossary

⁷⁴ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 28

⁷⁵ Children's Medical Center. Guide to Clinical Documentation Improvement. 2nd Edition. Dallas TX. 2015.

⁷⁶ Solicit from SMEs the samples of such templates and provide the link to the examples of these templates.

 ⁷⁷ American Health Information Management Association (AHIMA). Release of Information Toolkit. May 2013.
 <u>http://library.ahima.org/xpedio/groups/secure/documents/ahima/bok1_050184.pdf</u>.
 ⁷⁸ United States Department of Health and Human Services (HHS), National Institutes of Health (NIH). How Can

⁷⁸ United States Department of Health and Human Services (HHS), National Institutes of Health (NIH). How Can Covered Entities Use and Disclose Protected Health Information for Research and Comply with the Privacy Rule? URL: <u>http://privacyruleandresearch.nih.gov/pr 08.asp</u>

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

Term	Definition
Electronic document management system (EDMS)	A multi-component health information technology system designed to serve as a single central platform from which release of information is managed. ⁷⁹
Form/Document/Screen	The terms "Form", "Document" and "Screen" are used interchangeably in this White Paper. Form/document/screen is the representation of knowledge assembled from data collected during the Episode of care/Encounter or Function/Record Entry. Formal definitions of these terms are the following:
	Forms are pages that allow users to fill in and submit information ⁸⁰
	Document is any analog or digital, formatted and preserved "container" of data or information. ⁸¹
	Screen prototype is a sketch of the user interface of each screen that is anticipated in a project. ⁸²
	Information in the Form/Document/Screen can be delivered as scanned document, .pdf, structured text (based on HL7 CDA or FHIR standards) or message (string of data).
	The content for specific forms/documents generated under the episode of care/encounter's functions such as patients demographic, assessment notes, test orders and results, care plans, medication prescriptions and other (Table 1) is out of scope for this White Paper. It may be developed under the IHE Content Profiles in the future.
Episode of Care/Encounter	In this White paper, the episode of care/encounter is referred to a visit or multiple visits or interaction(s) between patient and provider and/or ancillary services within the facility. The type of episode of care/encounter is defined by the service type (e.g., inpatient, outpatient, emergency department (ED), long-term care and others). Additional discussions are needed to align the terms for episode of care/encounter/ and visit with terminology used by other countries.
	The term "episode of care" is also the unit of payment under the home health prospective payment system (HHPPS) ⁸³
	Term interaction includes phone calls, e-mail communication, telemedicine sessions, e-visits and other. Specific states of the interaction (registration , admission , disposition , discharge or transfer) are the states of the patient's interaction, as described under Start and the End of the Episode of Care/Encounter below.

⁷⁹ Kohn, D. How information technology supports virtual HIM departments. JAHIMA. 2009, 80(3): URL: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043005.hcsp?dDocName=bok1040035 ⁸⁰ McGraw Hill Dictionary of Scientific and Technical Terms. 2003

⁸¹ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 49

⁸² Ibid, p. 133

⁸³ Ibid, p. 55

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

Term	Definition
Function, Event, Step	The episode of care/encounter is comprised of functions/events/steps . The Function of the episode of care/encounter is defined as entity or the activity that involve a single healthcare department, service area or discipline, ⁸⁴ e.g., visit registration/admission; triage; nurse's and physician's assessment; laboratory and diagnostic testing; diagnosis and care plan; prescription; discharge/transfer/disposition and other (Figure 5). The Event is defined as an action or activity that occurs within a system and/or network, inclusive of its boundaries. ⁸⁵
Legal health record (LHR)	The Step is defined as a sub-action or sub-activity that occurs within a specific event of care. The subset of all patient specific data created or accumulated by a healthcare provider that constitutes the organization's official business record, and is typically used when responding to formal requests for information for legal and legally permissible purposes ⁸⁶
Provenance	This is a very broad topic that has many meanings in different contexts. The W3C Provenance Incubator Group developed a working definition of provenance on the Web: "Provenance of a resource is a record that describes entities and processes involved in producing and delivering or otherwise influencing that resource. Provenance provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility. Provenance assertions are a form of contextual metadata and can themselves become important records with their own provenance." ⁸⁷

⁸⁴ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 62

⁸⁵ Health Information Management and Systems Society (HIMSS). Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations. 2010. p. 49

⁸⁶ Servais, CE. The Legal Health Record. 2008. Chicago: AHIMA

⁸⁷ World Wide Web Consortium (W3C). Provenance XG Final Report, 2010. URL

http://www.w3.org/2005/Incubator/prov/XGR-prov-20101214/

HL7®, HEALTH LEVEL SEVEN®, CCD®, CDA®, and FHIR® are trademarks owned by Health Level Seven International and are registered with the United States Patent and Trademark Office.

Term	Definition
Record	According to HIMSS, record is defined as a document stating results achieved or providing evidence of activities preformed. ⁸⁸
	Our record definition analysis showed the need to define further the relationship between records generated throughout healthcare delivery in the context of record lifecycle for the lifetime record, episode of care record, function record and record entry. We proposed the following record hierarchy and definitions:
	 Lifetime Record (-9mos, birth-death) is defined as longitudinal health record, i.e., a permanent, coordinated patient record of information that was acted upon to treat the patient, listed in chronological order and maintained across time from birth to death.
	2. Record of Episode of Care (admission-discharge) is defined as full medical documentation generated during the episode of care, i.e., in a period of continuous medical care performed by healthcare professionals in relation to a particular clinical problem or situation. This period may include one or more heal thcare services given by a provider. (For our purposes we are limiting the definition to inpatient status.)
	3. Record at the Function Level or Record Entry is defined as full medical documentation generated during the activities performed under a function. It is defined as the notation made in a patient's health record, whether paper or electronic, by the responsible healthcare practitioner to document an event or observation associated with healthcare services provided to the patient. ⁹⁰ For some functions, this can be one document, e.g., registration form; for other functions, in which several documents may comprise the record entry, e.g., testing: consent for procedure, test order, test result report.
	Please note that in the standards development organizations (HL7, ISO), the term Record Entry is used for a single document only.
	4. Record at Data Entry Leve l is defined as a collection of parts that are related to, or associated with, a record for a specific activity.
	Using the terminology of the HL7 Clinical Document Architecture (CDA) standards, these parts follow the following hierarchy: record's Sections, Templates and Data Fields .
	Using terminology of HL7 Fast Healthcare Information Resource (FHIR) standard, these parts can be represented as record's " resources ." These parts of the record can be completed by various business actors.

⁸⁸ Health Information Management and Systems Society (HIMSS). Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations. 2010. p. 101

⁸⁹ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 88

⁹⁰ American Health Information Management Association (AHIMA). Pocket Glossary of Health Information Management and Technology. 2014. p. 70

Term	Definition
Release of Information (ROI)	The process of disclosing patient identifiable information from the health record to another party. ⁹¹
Use	Under federal regulations; use of PHI is "the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information." ⁹²

780

 ⁹¹ Ibid, p. 128
 ⁹² United States Department of Health and Human Services (HHS). Administrative Data Standards and Related Requirements: Definitions.

Appendix D: HIT Standards for HIM Practices

	Standards Development Organizations					
Business Requirements	HL7	ISO	ASTM			
	Information Availability					
1. Maintain information in a manner that ensures <i>timely, accurate, and efficient</i> retrieval.	EHRS FM R2	ISO/HL710781 ISO/IEEE IS 11073-10101 2004 ISO/IEEE IS 11073-10103 2014 ISO/IEEE IS 11073-10201 2004 ISO/IEEE IS 11073-10404 2010 ISO/IEEE IS 11073-10407 2010 ISO/IEEE IS 11073-10408 2010	E1633 -08a			
2. Enable trust of requestor in information by ability to ensure the timeliness, accuracy (completeness and correctness), and efficiency of information availability.	EHRS FM R2 CDA R2	ISO/HL710781 ISO IS 13606-1 2008 ISO IS 13606-2 ISO IS 13606-3 2009	E1633 -08a E2369-12			
3. Ability to identify, locate, and retrieve the information required to support organization's ongoing activities via queries and access to data across various systems.			E1384-07			
4. Ability to address multiple demands having the right information available at the right time for the right requestor.	EHRS FM R2	ISO/HL710781 ISO IS 13606-1 2008 ISO IS 13606-2 ISO IS 13606-3 2009 ISO/TS TS 14265 2011	E1744-04 E2369-12 E2473			
5. Ability to search for information in continually expanding volumes of information and multiple systems including multiple electronic and manual systems.		ISO/TS TS 14265 2011	E2369-12			
6. Ability to assemble information from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.	CDA R2		E2369-12			

7. Ability to access information created with legacy hardware and software systems. In case of impending system obsolescence, information with organizational value should be migrated to currently supported hardware and/or converted into a machine-readable format.			
8. Ability to maintain metadata services across all participating systems assigning structural and descriptive characteristics to information including data provenance information, e.g., authors and dates of creation, modification, sending, receipt, access, etc.	EHRS FM R2	ISO/TS TS 17948 2014	E1384-07
9. Ability to manage both vendor relationships and employee turnover to maintain the workforce capabilities on the most current methods to access information.			
10. To ensure levels of redundancy, failover, contingencies and other risk management practices to minimize risks of non-availability of information due to a disaster, system malfunction, or data corruption.			
	Informatio	on Integrity	
1. Maintain information in a manner that ensures confidence in its authenticity, timeliness, accuracy, and completeness.	EHRS FM R2	ISO/HL710781 ISO/IEEE IS 11073-10101 2004 ISO/IEEE IS 11073-10103 2014 ISO/IEEE IS 11073-10201 2004 ISO/IEEE IS 11073-10404 2010 ISO/IEEE IS 11073-10407 2010 ISO/IEEE IS 11073-10408 2010	E1633 -08a
2. Ability to maintain integrity of information to comply with safety, quality of care, and compliance with applicable voluntary, regulatory and legal requirements.	EHRS FM R2	ISO/HL710781	
3. Ability to maintain integrity of information in adherence to the organization's policies and procedures.	EHRS FM R2	ISO/HL710781 ISO IS 22600-1 2014	

	1	r	1
4. Ability to provide appropriate workforce training on information management and governance to support integrity of information.			
5. Enable trust of requestor in the integrity of information by ability to ensure the authenticity, timeliness, accuracy, and completeness, admissibility of records for litigation purposes.	EHRS FM R2	ISO/HL710781	
6. Ability to ensure integrity of information through reliable system controls that support the organization's ongoing activities across various systems.	EHRS FM R2	ISO/HL710781 ISO IS 22600-1 2014	
7. Ability to classifying and manage information received from disparate electronic systems, both internal and external to the actual or virtual location(s) of the organization.	EHRS FM R2	ISO/HL710781 ISO/IEEE IS 11073-10101 2004 ISO/IEEE IS 11073-10103 2014 ISO/IEEE IS 11073-10201 2004 ISO/IEEE IS 11073-10404 2010 ISO/IEEE IS 11073-10407 2010 ISO/IEEE IS 11073-10408 2010 ISO IS 13606-3 2009	E1384-07 E2369-12 E2473
8. Ability to demonstrate oversight by senior management of adherence to approved policies and procedures necessary to maintain reliability of information.			
9. Ability to ensure reliability of data and information based on the nature and type of healthcare organization processes and systems for creation and capture, processing, and other applicable stages of the information's lifecycle.	EHRS FM R2	ISO/HL710781 ISO/IEEE IS 11073-10101 2004 ISO/IEEE IS 11073-10103 2014 ISO/IEEE IS 11073-10201 2004 ISO/IEEE IS 11073-10404 2010 ISO/IEEE IS 11073-10407 2010 ISO/IEEE IS 11073-10408 2010 ISO/TS TS 21547 2010	

 10. Ability to implement ongoing quality control measures include field-specific data edits built into systems/applications; monitoring and correction of vendor identity errors and patient identity errors; monitoring and correction of documentation completeness and data accuracy; and ongoing data quality controls. 11. Ability to prove reliability and integrity of the information through the employment of audit trails that are acceptable and verifiable. 	EHRS FM R2	ISO/HL710781 ISO IS 22600-1 2014	E2117-06 E2147-01		
Information Protection					
1. Ability to ensure appropriate levels of protection from breach, corruption and loss are provided for information that is private, confidential, secret, classified, essential to business continuity, or otherwise requires protection.	EHRS FM R2	ISO/HL710781 ISO IS 27799 2008			
2. Ability to consistently apply and enforce levels of protection to information, regardless of medium, from the moment the information is created until the moment it reaches or exceeds its retention period and is appropriately disposed.	EHRS FM R2	ISO/HL710781 ISO IS 27799 2008			
3. Ability to manage and balance compliance with the varying degrees of protection, mandated by laws, regulations, and/or organizational policies for information generated and managed by an organization.	EHRS FM R2	ISO/HL710781 ISO IS 22600-1 2014 ISO IS 27799 2008			
4. Ability to provide security, business continuity, and disaster recovery processes that will ensure continued operation and continued protection, during and after periods of failure or disruption.	EHRS FM R2	ISO/HL710781			
5. Ability to assign and manage appropriate levels of information access and security clearance to all members of the workforce and other authorized parties relevant to their roles or duties	EHRS FM R2	ISO/HL710781 ISO IS 17090-1 2013 ISO IS 17090-2 2008 ISO IS 22600- 1 2014 ISO IS 27799 2008			

6. Maintain appropriate security safeguards, clearly defined and enforced by organizational policies, designed to protect electronic information from being inappropriately viewed, e-mailed, downloaded, uploaded, or otherwise proliferated—intentionally or inadvertently, even by individuals with legitimate access to the system.	EHRS FM R2	ISO/HL710781 ISO IS 17090-1 2013 ISO IS 17090-2 2008	
7. Ability to provide physical security safeguards of computing and access devices or any equipment containing private, secret, or confidential information or intellectual property of the organization.			
8. Adhere to security, privacy and confidentiality requirements (rules, regulations, policies) when determining a method for the final disposition of information, regardless of source or media. Whether that disposition is archival, transfer to another organization, preservation for permanent storage, or destruction.	EHRS FM R2	ISO/HL710781	
9. Ability to establish an audit program that defines a clear process for verifying whether sensitive security information is being handled in accordance with the organization's policies and procedures, and compliant with applicable laws and business practices.	EHRS FM R2	ISO/HL710781	E2147-01