**Integrating the Healthcare Enterprise**



**IHE Information Technology Infrastructure (ITI)**

White Paper

Health IT Standards for Health Information Management (HIM) Practices

**Revision <1.0>**

Date: <August XX, 2015>

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**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 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.

For more information regarding IHE in general, see [www.ihe.net](http://www.ihe.net). For more technical information, see the IHE Technical Frameworks General Introduction <insert link here when available>. For on-going development work, see wiki.ihe.net.

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# 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 100,000 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]](#footnote-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]](#footnote-2) This IG Initiative is a key component of AHIMA's overall strategy to develop guidelines, operating rules and standards for healthcare documentation practices.

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.

Table 1. AHIMA-IHE White Paper **Task Force Members**

(in alphabetical order)

|  |  |
| --- | --- |
| **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 Huyuk | Beaumont Health System |
| Satyendra Kaith | Kaplan Higher Education Group |
| Susan Lucci | Just Associates |
| Amber Martinez | Precyse |
| 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 |

# Introduction

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

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 – the three information governance principles selected out of a total of eight principles[[3]](#footnote-3),[[4]](#footnote-4)
3. four 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. 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.

## 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) products – in healthcare and public health organizations. Based on the their experience the following challenges were identified with ICT adoption:[[5]](#footnote-5),[[6]](#footnote-6),[[7]](#footnote-7),[[8]](#footnote-8),[[9]](#footnote-9),[[10]](#footnote-10),[[11]](#footnote-11),[[12]](#footnote-12)

1. *EHR System Design Flaws*
2. *Poor System Usability and Improper System Use*
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 paper-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;

Effort 2: standards are adopted in the HIT products; and

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

**Goals and Objectives**. 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.

**Scope**. 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.

In the future, we anticipate further working with 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. We realized though that developing the use cases and their functional requirements required much more time that we anticipated. Therefore, this White Paper presents

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. four 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.

**OUTCOME**. 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; (c) Use Cases and functional requirements to support HIM practices in HIT products. This methodology describe in details in the correspondent section below. Specific six deliverables listed in Introduction section above are described in details in the White Paper. Intended Audience

The intended audience of the White Paper includes HIM professionals, 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 implementaton of HIT/ICT in healthcare, public health and reaseach organizations.

# Methodology

## 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]](#footnote-13),[[14]](#footnote-14),[[15]](#footnote-15) we specified HIM business requirements under information availability, 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.

## Project Participants

The project was conducted under the IHE ITI Planning Committee. HIM professionals – subject matter experts - were recruited via the Call for Participation[[16]](#footnote-16) among those serving on AHIMA volunteer initiatives as follows:

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.

Table 2. Task Force Members: Organizations and Roles

|  |  |  |
| --- | --- | --- |
| **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 Represenative | 1 |
| Vendor | Associate Identity Manager | 1 |
| Consultant, Chief Privacy Officer | 1 |
| Consultant, Sr. Information System  | 1 |

* One participant did not specify role

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

## Project Tasks, Timeline and Deliverables

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

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

Table 3. Tasks, Timeline and Deliverables

|  |  |  |
| --- | --- | --- |
| **Task** | **Timeframe** | **Deliverable** |
| 1. Develop and defend proposal to the IHE ITI Committee
 | Sept.-Nov.2014 | Proposal for the 2014-15 IHE development cycle  |
| 1. Develop Project Infrastructure
 | Dec. 2014 | Wiki Pages |
| 1. Assemble AHIMA HIM SME Task Force
 | Jan. 2015 | Call for Participation |
| 1. Develop project methodology
 | Jan. 2015 | Methodology |
| 1. Document business requirements and HIM best practices by selected IG principle: availability, protection and integrity
 | Jan.-April2015 | Business RequirementsLiterature ReviewHIM Practice Checklist |
| 1. Define Use Cases for selected HIM best practices
 | Feb.-April 2015 | HIM Use Case List  |
| 1. Conduct gap analysis of HIT standards to assess their relevance to supporting HIM practice
 | Mar.-Apr.2015 | Standards Gap Analysis Table  |
| 1. Develop recommendations and roadmap for addressing identified gaps in HIM practices and HITstandards
 | Mar.-Apr.2015 | Recommendations and Roadmap  |
| 1. Publish draft White Paper for public comments
 | May 2015 | Draft White Paper  |
| 1. Publish final White Paper
 | Aug. 2015 | Final White Paper  |
| 1. Communication, outreach and marketing
 | May-Sept. 2015 | Spotlight in HIMSS Media Article in Journal of AHIMAPresentation at AHIMA Convention |
| 1. Develop proposal for the IHE 2015-16 development cycle
 | Sept. 2015 | Proposal for the 2015-16 IHE development cycle  |

Figure 2 presents summary of the project activities.



Figure 2. Project Activities

# Overview of Health Information Management

## 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]](#footnote-17) Table 4 presents current roles of HIM professionals in healthcare organizations.

Table 4. Roles of HIM Professionals in Healthcare Organizations[[18]](#footnote-18)

|  |
| --- |
| **HIM Roles** |
| **Data Capture, Validation, and Maintenance** |
| 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 |
| 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 |

The emerging roles for HIM professionals in the new interoperable electronic data sharing environment include Standard setters, Educators, Consumer advocates, Brokers of information. [[19]](#footnote-19)

## 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]](#footnote-20) Thus HIM practices include various activities aimed to support basic HIM functions: Capture, Process, Use, Store, and Dispose health information. Table 4 presents HIM activities under these functions.[[21]](#footnote-21)

Table 4. HIM Activities by HIM Function

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Capture** | **Process** | **Use** | **Store** | **Dispose** |
| CreateEnterRecord DictateWriteReceiveInterface | ClassifyValidateAnalyzeQC/QAComplianceInterface Integrate | CodeExamineAnalyticsBusiness IntelligenceReleaseDiscoverHold RetainExportTransmitExchangeShare | StorePreserveArchive | DeleteDeprecateDestroyPermanent StoreDiscoverPermanent ArchiveTransition |

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

Figure 3. HIM Functions to Support Information Lifecycle

## 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 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 the 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.

Each of these functions is associated with capturing/producing/sharing/using specific information in the records. Table 5 shows the examples of episode of care’s functions and correspondent information.

Table 5. Functions of the Episode of Care and Examples in Health Information in the Record

|  |  |
| --- | --- |
| 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 ProcedureTest 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 |

Figure 4 presents the hierarchy of the records such as

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

Level 2 – Episode of Care’s record that is consisted of multiple information components generated during a specific function shown in Table 5

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

Level 4 – Record at data entry level which is associated with the standards-based representation of data in a record, e.g., using Health Level Seven (HL7) Clinical Document Architecture (CDA) standard[[22]](#footnote-22) [ref]; HL7 Fast Health Interchange Resource (FHIR) standard[[23]](#footnote-23) [ref]; and/or other information content standards.

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.

a

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

## Information Governance

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]](#footnote-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:

1. **Accountability**
2. **Transparency**
3. **Protection Record Attributes**
4. **Integrity**
5. **Compliance**
6. **Availability**
7. **Retention Record States**
8. **Disposition**

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

In 2014 AHIMA launched Information Governance Initiative to adopt these IG principles in healthcare - IGPHC[[25]](#footnote-25) – and conducted the first survey of the healthcare stakeholders on the state of information governance.[[26]](#footnote-26) As the result of the survey, AHIMA has developed the IG Maturity Model that is currently piloted in healthcare and health information exchange (HIE) organizations.[[27]](#footnote-27)

Figure 6 presents AHIMA framework for information governance that enables organizational policies and processes to support information lifecycle.[[28]](#footnote-28)

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]](#footnote-29),[[30]](#footnote-30)

These representatives may include:

* patient care providers
	+ 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.)
* other.

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 defining HIM practices and documentation when implementing information governance within organization. This is specifically important because in the interoperable, electronic information sharing environment, lack of sounded organizational policies and practices on HIM may compromise shared data, information and knowledge. Our suggestions regarding standardization of 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.

### 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]](#footnote-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
* Internal and external reviewers for purposes including but not limited to payer audit, financial audit, case management, and quality assurance.

Table 6 presents HIM business requirements under **Principle of Information Availability** to retrieve, use, audit, and manage information.

Table 6. 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 having the right information available at the right time for the right requestor |
| 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 non-availability 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, develop the Use Cases to specify functional requirements for HIT standards, and conduct gap analysis of existing standards supporting these business requirements (please see below Appendices A, B and D, respectively).

### 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]](#footnote-32)

Table 7 presents HIM business requirements under **Principle of Information Integrity**.

Table 7. HIM Business Practices: Information Integrity

|  |
| --- |
| Information Integrity: Business Requirements |
| 1. Maintain information in a manner that ensures confidence in its authenticity, timeliness, accuracy, and completeness.
 |
| 1. Ability to maintain integrity of information to comply with safety, quality of care, and compliance with applicable voluntary, regulatory and legal requirements,
 |
| 1. Ability to maintain integrity of information in adherence to the organization’s policies and procedures.
 |
| 1. Ability to provide appropriate workforce training on information management and governance to support integrity of information.
 |
| 1. 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
 |
| 1. Ability to ensure integrity of information through reliable system controls that support the organization’s ongoing activities across various systems.
 |
| 1. 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.
 |
| 1. Ability to demonstrate oversight by senior management of adherence to approved policies and procedures necessary to maintain reliability of information.
 |
| 1. 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.
 |
| 1. 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.
 |
| 1. Ability to prove reliability and integrity of the information through the employment of audit trails that are acceptable and verifiable.
 |
| 1. Ability to monitor hardware, network infrastructure, software, storage, and other system components for reliability of performance
 |
| 1. Maintain formal change controlprocesses as part of a reliable information environment. That incomplete required testing of functionality, and validation of data and all appropriate metadata.
 |

### 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]](#footnote-33) Thus part 1 of this definition relates to protection of Information Availability when part 2 – to protection of Information Integrity.

Table 8 presents HIM business requirements under **Principle of Information Protection**.

Table 8. HIM Business Practices: Information Protection

## HIM Practice CheckList

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 describes in Tables 6-8. Appendix A presents the HIM Practice Checklist by business requirements under selected information governance principles; availability, integrity and protection.

## HIM Practice Use Cases

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

## Glossary

To assure the use of consistent terms and definitions across Use Cases we develop a Glossary of terms and concepts used in HIM practices (Appendix C). In some cases we use definitions from the AHIMA HIM Glossary;[[34]](#footnote-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.

# Gap Analysis of HIT Standards to Support HIM Practices

Based on the business requirements, we conducted the high level analysis of HIT standards developed by standards development organizations to date 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).

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 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: ftp://ftp.ihe.net/IT\_Infrastructure/iheitiyr13-2015-2016/Planning\_Cmte/WorkItems/HIM\_Practices/Standards\_Table\_0507/).

# Recommendations

Working on the analysis of the HIM business requirements (Tables 6-8), HIM Practices Checklist (Appendix A) and Use Cases (Appendix B), we identified gaps in both HIM as well as standards development practices. Table 9 presents our recommendations for affected stakeholders to better align HIM practices and capabilities of HIT product through standards.

Table 9. Recommendation to HIM Professionald and SDOs

|  |
| --- |
| **HIM Professionals** |
| A. Standardize Policies for Organizations’ Form Management Committee[[35]](#footnote-35) including |
| 1. Standardize/harmonize scope and operations of the Committee according with the information governance principles
2. Harmonize existing policies across healthcare organizations
3. Develop a template organizational policy related to documentaiton development and management
4. Define standardized set of documentation for the Episode of Care
5. Get samples of all possible documents that HIM have to have for the Episode of Care
	1. 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.)
	2. Define policy that outlines how clinicians are notified of open and closed records when
		* 1. Procedures ordered but not performed
			2. Documentation components are missing
			3. Signatures are missing. [[36]](#footnote-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**
	1. Review Patient Friendly/Plain Language ballot[[37]](#footnote-37)
	2. Review CBCC documentation in wiki (URL: <http://wiki.hl7.org/index.php?title=Community-Based_Collaborative_Care>
2. **EHR Workgroup**
3. Normalize definitions for records/document lifecycle.

Specific examples of statements from the HL7 EHR Functional Model standard[[38]](#footnote-38) 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 level2. 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 be analyzed for timeliness and completeness and provide a report of the status.”[[39]](#footnote-39)* 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. [[40]](#footnote-40)*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).[[41]](#footnote-41),[[42]](#footnote-42)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/Plain Language ballot[[43]](#footnote-43) with HIM professionals**2. HL7 FHIR (Fast Healthcare Information Resources) Workgroup**a. Enable review of EHR System Functional Model - Record Lifecycle Events Implementation Guide ballot[[44]](#footnote-44) with HIM professionals“Record Amendment” should be replaced with “Record Retraction” that includes Record Amendment and Record Addendum1. **EHR Workgroup**

a. Enable review of the HL7 EHR Functional Model standard to incorporate recommendation from HIM professionals.  |
| **B. Integrating the Healthcare Enterprise** |
| 1. Enable review of the IHE profiles with HIM professionals. |
| **C. Other SDO (to be determined)** |
|  |

# Roadmap

The ultimate goal of our effort 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 represented 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.

The deliverables presented in this White paper – Business requirements for Information Availability, Integrity and Protection (Tables 6-8), HIM Practice Checklist (Appendix A), Use Cases (Appendix B) and an examples of HIT standard gap analysis by business requirements (Appendix D) – as well as the consensus-based process employed to develop these deliverable outline the overall methodology (how and what) for aligning the HIM practices needs with the capabilities of HIT products to support these needs. Through this effort we build the foundation for the amalgamation of the HIM and HIT universes (Figure 7).

Figure 7. Amalgamation of HIM and HIT Universes

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

1. Continue to elicit business requirements for additional 5 information governance principles using the format of Tables 6-8: 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),
3. Continue to develop Use Cases for the HIM practices under Information Availability, Integrity and Protection (Appendix B) and
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)
5. Based on the experience from Years 1 and 2 defining the timeline for the completion of the development of the HIM practice Use Cases.
6. Define the maintenance process for developed Use Cases.
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*; 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.

# Appendix A: HIM Practice Checklist

|  |  |  |
| --- | --- | --- |
| Business Requirements | HIM Practice Checklist[[45]](#footnote-45) | Use Case |
| **Information Availability (A)** |
| 1. Maintain information in a manner that ensures *timely, accurate, and efficient* 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 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 |
| 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 State and Federal regulations, accreditation organizations (e.g. Joint Commission, Det Norske Veritas Healthcare - ISO 9000), 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 as allowed by Health Insurance Portability and Accountability Act (HIPAA)  | **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 as allowed HIPAA | **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 as allowed HIPAA | **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 as allowed by HIPAA | **A2.1** and **A2.2** (above) |
| 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 as allowed by HIPAA | **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 |
| **Information Integrity[[46]](#footnote-46) (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 |
| 1. 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. |  |
| 1. 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.[[47]](#footnote-47)  |  |
| 1. 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.  |  |
| 1. 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 |
| 1. Ability to ensure integrity of information through reliable system controls that support the organization’s ongoing activities across various systems.
 |  |  |
| 1. 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.  |  |
| 1. 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.[[48]](#footnote-48) |  |
| 1. 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. |  |
| 1. 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 |  |
| 1. Ability to prove reliability and integrity of the information through the employment of audit trails that are acceptable and verifiable.
 |  |  |
| 1. Ability to monitor hardware, network infrastructure, software, storage, and other system components for reliability of performance
 |  |  |
| 1. Maintain formal change controlprocesses as part of a reliable information environment. That incomplete required testing of functionality, and validation of data and all appropriate metadata.
 |  |  |
| **Information Protection**[[49]](#footnote-49) **(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.
 |  |  |
| 1. Ability to consistently applied 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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 open access.  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. Ability to establish a 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.
 |  |  |
| 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.
 |  |  |
| 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.
 |  |  |
| 1. Ability to consistently applied 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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 open access.  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. 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.
 |  |  |
| 1. Ability to establish a 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.
 |  |  |

# Appendix B: HIM Practice Use Cases-TO BE UPDATED

TO BE UPDATED

**Information Governance Principle:** Record Availability

**HIM Practice 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.[[50]](#footnote-50)

See Appendix A: HIM Checklist

### Use Case A1.1. All documents can be accounted for within a specific time period post completion episode of care/encounter

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

The term "accounted for" is defined as the following:

System shall support all types of medical records (paper and electronic) generated during a specified timeframe of an Episode of care/Encounter.

The time period for document completion is dependent on the record type as defined by each specific function/event/step within the episode of care/encounter , i.e., workflow steps and sub-steps. This includes completed, incomplete or documents of the episode of care/encounter (See Use Case A1.2).

 Organizational policy developed by the Form Management Committee defines who is responsible for documenting information in the health records - the **business actors** for the episode of care/encounter. They include:

* patient care providers
	+ clinicians (MDs, PA, RNs, residents, other credentialed providers ) and
	+ staff who supports ancillary services (laboratory, radiology, pharmacy, etc.)
* patient or patient representative for patient-generated data entered via web-portals and mobile/virtual technology (e.g., diabetes monitors).

The custodian of the forms/documents is the health information management (HIM) department (former medical records department).

The list of forms/documents and personnel for defining and maintaining these forms/documents are specified by organizational policies.[[51]](#footnote-51) If other facility are involved in providing services, data sharing agreements between two facilities shall define the policies on how documentation will be accounted for when shared. The list of tools and resource utilized by the Form Management Committee to define and maintain forms/documents accordance with organizational policies functions in the correspondent records/ documents as shown in figure 2.

**The Start and End of the Inpatient Episode of Care/Encounter**

The **start and the end** of each function/event/step within the episode of care/encounter are defined by the creation and completion of the correspondent record/document related to the specific function/event/step.

The **start of the episode of care/encounter** is defined by the **initial interaction** of the patient with the healthcare facility (e.g., present at the facility, e-mail, phone or other). This initial interaction sets into motion the chain of functions/events/steps defined by the clinical pathway of activities for a specific episode of care/encounter. This initial interaction acts as a trigger of a specific clinical pathway (Table 3).

**Table 3. Relationship between Episode of Care/Encounter’s Flow of Events and Documents**

|  |
| --- |
| Episode of Care/Encounter |
| Clinical Pathway for <Function: Registration, Assessment, testing, etc.> |
| Workflow Activities or Flow of Events | Records/Documents |
|  | Initial interaction with healthcare facility (visit, e-mail, phone) |
| Step 1 | Document 1 – output for Step 1 and input /trigger for Step 2 |
| Step 2 | Document 2 – output for Step 2 and input/trigger for Step 3 |
| Step 3 | Document 3 – output for Step 3 |

For patient registration, the start of the registration is triggered by the patient presenting at the facility in person or contacting the facility by phone or e-mail. Registration staff activates the command “Register a New Patient” or “Look up for the Existing Patient” in facility’s health information system (HIS) to initiate the specific record/document for Step 1 (Patient Registration Form).

For assessment that follows the registration, the completed Patient Registration form serves as a trigger of the history & physical form

**States of Interactions**

Patient’s **registration, admission, disposition, discharge/transfer** are the **states of the patient’s interaction** within the healthcare facility. The health information systems (HIS) must capture change in these states via Open and Closed documentation related to each of the states (see Use Case 2). The HIS must also support the document flow across all states within the episode of care (Table 1).

 In the HIS the patient status is typically monitored in the **Capacity/Bed Management** application**.** For example, under disposition when patient is moved to another floor for testing, all previous documents that trigger this new function (input documents) and new documents generated by this new function (output documents) must be captured in the HIS.

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

The **end** of the function as well as an episode of care/encounter, in general, is defined by providing capabilities to electronically sign the output document. This action is called “**Verified by Authentication**” 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 person including digital signature on a specific document. Furthermore, within each document there can be multiple authentications as defined by organizational policy.

Figure 2 represent example of episode of care/encounter and various HIS (applications (APP)) involved in documenting clinical pathway followed in the episode of care. Specific examples of participating information systems (technical actors) include:

1 – EHR System – Record Originator

2 – Ancillary System (Laboratory, Radiology, etc.) – Record Receiver (order) and Record Originator (result report)

3 – Ancillary System (Laboratory, Radiology, etc.) – Record Receiver (prescription) and Record Originator (prescription dispense report)

Figure 8. Example of Episode of Care/Encounter and Various Health Information Systems (Technical Actors) Involved in Documenting Clinical Pathway

In the above Figure 3: Please note that every participating technical actor may also exchange the following documentation:

1 – Notification of Document Availability (Sender to Receiver)

2 – Acknowledgement of Document Receipt (Receiver to Sender

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

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

**Open Record**

**Open** **record** is the document that is created to begin a new function.

An **Open record** has to be completed within defined timeframe for a specific function. The Forms Management Committee defines policies on the processes and timeliness of the record completion, e.g., 30 days for discharge summary for US Joint Commission and Medicare Conditions of Participation.

**Delinquent** records are considered as **Open** records**.**

HIS must support capabilities to notify clinician (1) when the record is open; (2) when the record is outside of the time limits set for a specific function; (3) ready to be signed, i.e., verified by authentication; and (4) when the record is closed.

The record remains Open until all its parts are assembled and the appropriate documents are authenticated according to organizational policies. [[52]](#footnote-52)

**Record completion** is the process defined by the organizational policy. This process specifies activities of the authorized personnel to be able to

1. open (initiate the new record),
2. access existing record to contribute new information
3. access existing record to modify/correct existing information and
4. close (verify by authentication) a specific component of the record and/or the full record.[[53]](#footnote-53)

In the paper based environment, term **Retraction (go back)** was used to access the record for correcting information that was inaccurate, invalid, or made in error. Retraction is aimed to modify the Open record. [[54]](#footnote-54)Audit trail must capture all modifications done to the record.

The term **Retraction** is used in HIM to modify existing information in the record through record **amendment** or **addendum,** i.e., modification of the original record entry.

**Closed Record**

**Closed record** is the record that (1) contains all necessary clinical information to substantiate the care rendered, (2) verified by authentication by the authorized clinician, and (3) meets the requirements of the legally defensible health record as defined by organizational policies, Or (4) administratively closed record.

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

1. generate the Open records list for all patients of a clinician on a daily basis upon opening the HIS
2. generate notifications about the record for which the timeframe is expiring, so clinician could act upon this notification as follows:
	1. close the record supplying appropriate description for the reason of the record closure
	2. sending reminder
		1. to the patient via phone, e-mail, etc.
		2. to the ancillary system(s)
	3. other
3. generate audit reports on records generation, retraction for modification (amendment or addendums) and completion.

**HIM Practice A.2.** Documents within the electronic medical record can be viewed by or released to the external requestor as allowed by Health Insurance Portability and Accountability Act (HIPAA) (1. p.40).

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

This Use Case is focused on the continuous maintenance of the health record necessary to maintain a current and accurate Legal Health Record (LHS) and Designated Records Set by the facility staff under the leadership of the custodian of the health records the health information management department in accordance with organizational policy.

Working with representatives from clinical, business and technology departments, the health information management department is responsible for defining the content of the Legal Health Record (LHS) and Designated Records Set. These representatives (policy makers) include:

* patient care providers
	+ 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)
* medical information services directors/medical informatics (CMIO)
* health information technology department (CIO)
* medical records directors (HIM, CDI, ROI)
* compliance officers (legal and regulatory support) (CLO, Audit)
* purchasing and financial managers (CFO) and
* vendors (scanning, imaging, EHR, laboratory, etc.)
* other.

 Whenever, changes are made to the health information system, they must be reviewed and approved by the health information system committee. Whenever, a new form is added, a current form is revised, documentation tasks are added, deleted, or revised, or other elements of the health information system, the content of the LHS must be updated**.**

The ability to rapidly gather and assemble all records regardless of format (paper, electronic, or hybrid) and make the documents availability for release electronically is a performance criteria key to the effective delivery of the **release of information (ROI)** workflow process and providing full access on demand to the documents maintained in the enterprise-wide health information system (HIS).

**Release of Information (ROI)** is defined as the process of disclosing patient identifiable information from the health record to another party.[[55]](#footnote-55)

The factors that influence the effectiveness of the release of information process are numerous, multi-faceted, and interrelated. The ideal process should be based upon the implementation of an **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.[[56]](#footnote-56)

Successful implementation of an **electronic document management system (EDMS)** is contingent upon a number of factors, including the intricacy of the organization’s systems and culture, the health IT infrastructure present, interoperability capabilities, and meeting legal and regulatory requirements—whether mandatory or voluntary.

It will be it will be necessary to develop a comprehensive and knowledgeable taskforce to oversee the process:

* **Senior leadership:** Provide support and sponsorship of the project.
* **Health information management (HIM) professional:** Provide knowledge of the organization’s data and information, data integrity, privacy and security, and EHR systems.
* **Physicians/clinicians:** Help determine what information will be displayed and when **Privacy and security officer(s):** Ensure organizational policies, processes, and education is in place to prevent inappropriate access and disclosure.
* **Patient advocates:** Speak on behalf of caregivers, patients, and personal representatives in a range of delivery settings to meet the expectations of patient interactions (i.e., appointments, profile updates, billing, and communication).
* **Risk management/legal counsel/compliance:** Ensure overall compliance with all applicable laws and requirements.
* **Information technology:** Program and maintain the software, interfaces, etc. to support the EDMS, including safeguarding protected health information (PHI) as obligated by organizational policies and procedures and federal regulations.
* **Marketing:** Review and promotion of organizational and patient information materials as well as providing support for any organizational branding needs.[[57]](#footnote-57)

The use and disclosure functions can be one of the most obscure and confusing business processes owing to the difficulty and capacious nature of state and federal regulations. At a basic level the release of information function consists of a request or authorization from an entity or individual seeking to access, review, or use health information or receives copies of records for specific purposes.

The terms **“Use and Disclosure”** came into common use with the creation of the Privacy Rule under HIPAA and are foundational building blocks to understanding how to apply the rule.[[58]](#footnote-58) Individual state laws must be reviewed for additional definitions for use and disclosure and any privacy provisions that may differ from the Privacy Rule.

**Use** is defined 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.”[[59]](#footnote-59) The key word hereis **within** because it addresses how entities covered under HIPAA are allowed to use PHI for internal purposeswithout patient authorization.

**Disclosure** is defined by federal regulations disclosure as “the release, transfer, provision of, access to, or divulging in any othermanner of information outside the entity holding the information.”[[60]](#footnote-60) The key word here is **outside**, such asdisclosing a patient’s medical record to an attorney.

**Management of Release of information function can be organized into four steps:**

1. Enter the release of information request into the ROI database. Capturing patient name, date of birth, record number, name, address, and telephone number of the requestor, purpose of the request, and specific health information requested.
2. Validating the authorization. Validate the completed authorization form signed by the patient against the organization’s requirements for a valid authorization. Requirements must compile with federal and state regulations. If authorization is found to be invalid access will be denied.
3. Verify the patient’s identity by validating patient name, date of birth, social security number, address, and phone number in the master patient index. Patient signature on authorization is compared to patient’s signature on file.
4. Process the request for release of information. Record is retrieved, and the information authorized for release is copied and released.[[61]](#footnote-61)

**Use Case for Release of Information process:**

1. An electronic health information document is an amalgamation of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange.
2. Receive request for ROI. Request may be verbal or written.
3. Log receipt of the ROI request into the system. The system must be able to capture date the request was received so that the turnaround time can be monitored to ensure compliance with regulations.
4. Match request to patient admission(s)/ encounter(s) in Master Patient Index (MPI). Record determination.
5. Does the request provide proof of authority to authorize ROI? Record determination.
6. Can requestor verify identity? Record Determination
7. Produce copies of required record components in the format requested by the requestor.
8. Provide copied record(s) to requestor or designated entity in the format requested by the requestor according to organizational policy.
9. System should include a ROI request checklist designed screen ROI request content against policies and procedures and regulatory criteria.
10. Shouldrequest content fail to meet the required policies, procedures and regulatory requirements; log denial of request and return the request to the originator with a return letter.
11. Log completed request in the tracking system.
12. End task[[62]](#footnote-62)

All authorizations for ROI should be visible at the episode-specific level affiliated with a specific encounter number. The business process implemented to review authorizations for release of information for validity and verification against a specific encounter in an electronic health information system can be an extremely time consuming task. Best practice indicates the implementation of 24/7 access via a combination of external patient portal and appropriate staff use. In such environments, consideration must be give to the release of information staffing and logistics concerns for departments located remotely from the main healthcare facility; that might not be fully staffed to support release of information.

Increased risk mitigation is realized when review of all requests for access, use, and release of information is managed from a single central location. Furthermore, a single centralized processing and storage management location allows for enhanced identification and control of disparate records. Additionally, records maintained to support the billing and collections process could be supported via the **electronic document management system,** or modifications could be made to incorporate the process into apt financial systems. Finally, externally maintained records (digitally or paper –based) could be included in the **EDMS.** Increased record access, control, and security of all requests and accounting of disclosures could be realized through the implementation of a combined centralized logging and audit trail process that could be referenced on demand 24/7.

With multiple potential disclosure points in the average healthcare enterprise, it is important for organizations to collaborate on the creation of a single point of oversight and accountability for **personal health information disclosure management**. **Enterprise-wide disclosure management** enables quality control, standardization, and better adherence to policies. It allows for the development of the best possible processes, while also setting the stage for continuous improvement.

Implementing a **centralized PHI disclosure management program** can mitigate opportunities for risk, improve compliance, and better prepare an organization for audits. Below are four key steps to compliance. Ideally, health information management can conduct these steps in a centralized fashion, collaborating with information technology and other departments as appropriate.

**1. Policy and Procedure Review**

The focus of this use case is proper and consistent protected health information disclosure management based on compliance with organizational policies and procedures related to the following:

* Patient Access (very important for OCR desk audits)
* Corrections/Amendments
* Release of Information
* Minimum Necessary (Employee access & Patient transfer, or patient referral)
* Designated Record Set Definition
* Legal Health Record Definition
* HIPAA Complaints
* Mobile Devices
* Encryption of Email

In addition, the review should include policies related to the health information exchange (HIE) environment such as the Data Use and Reciprocal Support Agreement (DURSA) and data sub-sets created through the DURSA, and HIE audits.

**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**

### A3.1 An audit log of all requests for release of information and accounting of disclosures should be maintained for historical purposes.

This Use Case is focused on the maintenance release of information and accounting of disclosure logs for historical and audit purposes. When organizations are considering new health information system technologies, consideration should be given to systems that provide functionality that allow for the capture of release and disclosure logs and the ability to conduct appropriate ad hoc audits. Working with representatives from clinical, business and technology departments, the health information management department is responsible for the design and implementation of the type and format of logs used to record and monitor request-processing activities. Currently, no specific federal laws govern the type and format of logs maintained. The retention of these logs should be in accordance with state laws and hospital policy.

**Elements of the release of information log:**

1. Patient Name
2. Medical Record Number
3. Requestor Name
4. Requestor Address
5. Request Date
6. Time Period of Request
7. Specific Exclusions
8. Date Request Sent
9. Charges
10. Scan of ROI Request

Release of information logs must be retained for 6 years. (HIPAA Privacy Rule)

**The following disclosures must be accounted for:**

1. Government mandated reporting
2. Research
3. Disclosures by business associates that are not for treatment, payment, and healthcare operations[[63]](#footnote-63)

**Though exceptions apply, disclosures typically included in response to an AOD request include:**

* All disclosures of PHI that are not for treatment, payment, or delivery of healthcare operations
* Suspected domestic and child violence and abuse reporting
* Disclosures made for research unless authorized by the patient or legal representative
* Disclosures made to government agencies (excluding intelligence/national security)
* Disclosures to public health authorities
* Disclosures to the Food and Drug Administration
* Disclosures to employers
* Disclosures to health oversight agencies
* Vital statistics reporting
* Disclosures to law enforcement
* Disclosures regarding deceased persons
* Disclosures for research purposes
* Disclosures for specialized government functions
* Disclosures for workers' compensation purposes[[64]](#footnote-64)

Appendix C: Glossary

|  |  |
| --- | --- |
| **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. [[65]](#footnote-65)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.[[66]](#footnote-66)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.[[67]](#footnote-67) |
| **Designated record set** | An individual has a right to access and request under the HIPAA regulation. According to the ROI Toolkit, “The HIPAA Privacy Rule requires that organizations 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”[[68]](#footnote-68)

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 othermanner of information outside the entity holding the information.”[[69]](#footnote-69) |
| **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.[[70]](#footnote-70) |
| **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[[71]](#footnote-71)**Document** is any analog or digital, formatted and preserved “container” of data or information[[72]](#footnote-72)**Screen** prototype is a sketch of the user interface of each screen that is anticipated in a project[[73]](#footnote-73)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)[[74]](#footnote-74)Term **interaction** includes phone calls, e-mail communication, telemedicine sessions, e-visits and other. Specific states of the interaction (**registration, admission, disposition, discharge/transfer)** are the **states** of the patient’s interaction, as an inpatient, are described under **Start and the End of the Episode of Care/Encounter** below.  |
| **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, [[75]](#footnote-75) 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.[[76]](#footnote-76)The **Step** is defined as a sub-action or sub-activity that occurs within a specific event of care. |
| **Legal health record (LHR)** | 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[[77]](#footnote-77) |
| **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.”[[78]](#footnote-78) |
| **Record** | According to HIMSS, **record** is defined as a document stating results achieved or providing evidence of activities preformed.[[79]](#footnote-79) 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: 1. **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.[[80]](#footnote-80)
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 situ**ation. 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.[[81]](#footnote-81)For some functions, this can be o**ne document, e.g., registration form; for ot**her functions, several documents can 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.1. R**ecord at Data Entry Level** is defined asa 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 **Da**ta **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. |
| **Release of Information (ROI)** | the process of disclosing patient identifiable information from the health record to another party.[[82]](#footnote-82) |
| **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.”[[83]](#footnote-83) |

# Appendix D: HIT Standards for HIM Practices

|  |  |
| --- | --- |
| Business Requirements | Standards Development Organizations |
| HL7  | ISO | ASTM |
| Maintain information in a manner that ensures *timely, accurate, and efficient* retrieval. | EHRS FM R2 | ISO/HL710781ISO/IEEE IS 11073-10101 2004ISO/IEEE IS 11073-10103 2014ISO/IEEE IS 11073-10201 2004ISO/IEEE IS 11073-10404 2010ISO/IEEE IS 11073-10407 2010ISO/IEEE IS 11073-10408 2010 | E1633 -08a |
| Enable trust of requestor in information by ability to ensure the timeliness, accuracy (completeness and correctness), and efficiency of information availability. | EHRS FM R2CDA R2 | ISO/HL710781ISO IS 13606-1 2008ISO IS 13606-2ISO IS 13606-3 2009 | E1633 -08aE2369-12 |
| 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 |
| Ability to address multiple demands having the right information available at the right time for the right requestor | EHRS FM R2 | ISO/HL710781ISO IS 13606-1 2008ISO IS 13606-2ISO IS 13606-3 2009ISO/TS TS 14265 2011 | E1744-04E2369-12E2473 |
| 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 |
| 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 |
| 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.  |  |  |  |
| 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 |
| Ability to manage both vendor relationships and employee turnover to maintain the workforce capabilities on the most current methods to access information. |  |  |  |
| 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. |  |  |  |
| Information Integrity |
| Maintain information in a manner that ensures confidence in its authenticity, timeliness, accuracy, and completeness.  | EHRS FM R2 | ISO/HL710781ISO/IEEE IS 11073-10101 2004ISO/IEEE IS 11073-10103 2014ISO/IEEE IS 11073-10201 2004ISO/IEEE IS 11073-10404 2010ISO/IEEE IS 11073-10407 2010ISO/IEEE IS 11073-10408 2010 | E1633 -08a |
| 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 |  |
| Ability to maintain integrity of information in adherence to the organization’s policies and procedures. | EHRS FM R2 | ISO/HL710781ISO IS 22600-1 2014 |  |
| Ability to provide appropriate workforce training on information management and governance to support integrity of information. |  |  |  |
| 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 |  |
| Ability to ensure integrity of information through reliable system controls that support the organization’s ongoing activities across various systems. | EHRS FM R2 | ISO/HL710781ISO IS 22600-1 2014 |  |
| 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/HL710781ISO/IEEE IS 11073-10101 2004ISO/IEEE IS 11073-10103 2014ISO/IEEE IS 11073-10201 2004ISO/IEEE IS 11073-10404 2010ISO/IEEE IS 11073-10407 2010ISO/IEEE IS 11073-10408 2010ISO IS 13606-3 2009 | E1384-07E2369-12E2473 |
| Ability to demonstrate oversight by senior management of adherence to approved policies and procedures necessary to maintain reliability of information. |  |  |  |
| 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/HL710781ISO/IEEE IS 11073-10101 2004ISO/IEEE IS 11073-10103 2014ISO/IEEE IS 11073-10201 2004ISO/IEEE IS 11073-10404 2010ISO/IEEE IS 11073-10407 2010ISO/IEEE IS 11073-10408 2010ISO/TS TS 21547 2010 |  |
| 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. |  |  | E2117- 06 |
| 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 | E2147-01 |
| Information Protection |
| 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/HL710781ISO IS 27799 2008 |  |
| Ability to consistently applied 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/HL710781ISO IS 27799 2008 |  |
| 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/HL710781ISO IS 22600-1 2014ISO IS 27799 2008 |  |
| 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 |  |
| 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/HL710781ISO IS 17090-1 2013ISO IS 17090-2 2008ISO IS 22600-1 2014 ISO IS 27799 2008 |  |
| 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/HL710781ISO IS 17090-1 2013ISO IS 17090-2 2008 |  |
| 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. |  |  |  |
| 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 |  |
| Ability to establish a 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 |

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