**Integrating the Healthcare Enterprise**



**IHE Information Technology Infrastructure (ITI)**

White Paper

**Revision <1.0>**

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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](ftp://ftp.ihe.net/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/8HNMF0PH/wiki.ihe.net).

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*<Editors notes:*

*Editors notes are denoted by brackets <> and italicized. All editors notes should be deleted prior to publication..*

*All White Papers must be published by the IHE Document Publication specialist, not by individual domains. White papers must be scheduled in advance for publication as part of the regular publication process by the domain co-chair.*

*Unlike the Supplement Template where the format must not be changed, white paper content is not particularly regulated. Any sections of this document may be deleted, removed, or changed.*

*Use of capitalization: Please follow standard English grammar rules (e.g., only proper nouns and names are upper case). For example, “Modality Actor” is upper case, but “an actor which fulfills the role of a modality” is lower case. Do not use upper case to emphasize a word/topic.>*

# Introduction

This document, the IHE Information Technology Infrastructure (ITI) “ Health IT Standards for Health Information Management (HIM) Practices” White Paper, describes the need for and value of aligning HIM business practices and capabilities of standards-based HIT products. The White Paper will demonstrate the alignment between HIM practices (workflow checklist, actions) and capabilities of HIT products to support these actions.

## Purpose of the Health IT Standards for Health Information Management (HIM) Practices White Paper

This white paper is intended to address is the current misalignment of health information management (HIM) practices in healthcare organizations with the capabilities of health information systems (HIS) (Electronic Health Record Systems (EHRS), Laboratory Information Management Systems (LIMS) and others) to support these systems in an electronic environment. HIM professionals, standards developers and health information technology (HIT) vendors do not usually collaborate, so the latter two – standards developers and vendors ⎯are largely unfamiliar with HIM practices and the extent to which these practices can be better supported by HIT standards and standards-based HIT products.

As a result, the availability, protection, and integrity, of health information are at the least, ineffective and at the worst, at risk when health information management practices are not supported by HIT products. It is difficult enough to meet today's goals of improved quality and outcomes, reduced risk, and increased collaboration at healthcare organizations when the data is not adequately managed nor sufficiently leveraged. Our proposal seeks to lead the industry in a better direction through the introduction of health information management practices that offer guidance to address these gaps and omissions.

Again and again, health information system stakeholders are seeing signs and symptoms signaling the need to strengthen health information management and governance. To be of assistance in the effort to improve information management and governance in health information systems, AHIMA convened a health information management Innovation Community to draft guiding principles for enterprise information management and governance and has begun sharing these promising practices. In early 2014, AHIMA launched the first survey of the state of information governance in healthcare. The survey included provider and non-provider organizations. Ultimately the survey findings were published in a white paper authored by AHIMA and Cohasset Associates. The resulting white paper entitled “Information Governance Principles of Healthcare (IGPHC) ™ is intended to be comprehensive and written broadly.

Despite the diversity of stakeholders in healthcare ecosystem, information across the various types of organizations can be governed using eight principles: accountability, transparency, integrity, protection, compliance, availability, retention, and disposition. (Table 1)

Table 1 provides a high level overview of the HIM Principles

|  |
| --- |
| **HIM Principles** |
| 1. Accountability 2. Retention 3. Disposition 4. Transparency 5. Protection 6. Compliance 7. Availability 8. Integrity |

We propose to develop a White Paper on the need for and value of aligning HIM business practices and capabilities of standards-based HIT products. This activity has AHIMA leadership support as a key component of AHIMA's overall institutional strategy approved by the AHIMA Board to develop guidelines, operating rules and standards for healthcare documentation practices. Based on the outcomes of the new globally-focused AHIMA initiative to translate Information Governance (IG) principles[[1]](#footnote-1) into HIM principles,[[2]](#footnote-2) we will develop a framework and a roadmap for developing standards for HIT products[[3]](#footnote-3) aimed to support HIM practices.

The goal of the White Paper is to:

1. Demonstrate the alignment between HIM practices (workflow checklist, actions) and capabilities of HIT products to support these actions;
2. Inform the development of national and international HIT interoperability standards for HIT products for identified HIT product capabilities ;
3. Create the roadmap for the development of these standards.
4. Inform IHE development process by defining Profile Specifier checklist aligned with the HIM practices checklist

Constrained by the limitations of the design, scope, intended use of white paper; the scope and design of the research study and methodology will focus on only three of the HIM principles. The three HIM principles; Availability, Protection and Integrity stand out from the eight HIM principles, the record state of Availability and the two attributes of Protection and Integrity. The analysis of the remaining five HIM principles will be recommended for future research following publication of this white paper. The principles of availability, protection, and integrity in the HIT products and interoperability standards are considered to be paramount to success health information exchanges between products.

Beginning with these three seminal HIM Principles of availability, protection, and integrity; this study seeks to build a roadmap of HIT standards to support information governance and HIM practices that will serve as guide to the development of HIT interoperability standards for HIM practices.

Building upon the prior work of the AHIMA HIM Principles Taskforce and their efforts to align information governance and HIM principles, this proposed research study shall focus on HIM Principles of availability, protection, and integrity developing HIM practice requirements and use cases for HIM workflow steps (actions) identifying key characteristics that are associated with these three principles. In order to conduct a further analysis of the gaps and overlays that exist between HIT standards and HIM practice attributes. HIM practices and use cases will be crafted for each of these three health information record states focusing on the merits and worth of the overall framework for the alignment of the Information Governance principles, HIM principles and practices as well as HIT standards that are needed in health information technology products to support the achievement of HIM practices.

We believe that this project will help to streamline further development of IHE profiles based on better alignment between HIM needs (business practice standards) and HIT product capabilities.

### Recommendation for Future Research

It is our intent to propose that based on the findings of this study, that future research be conducted on the value of the remaining five HIM principles of, accountability, transparency, compliance, retention, and disposition to development of HIT interoperability standards for HIM practices.

**Information Governance Principles\*:**

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

**\* AHIMA Information Governance Principles for Healthcare (IGPHC)™ – July 2014**

## Intended Audience

The intended audience of the IHE Information Technology Infrastructure (ITI) “ Health IT Standards for Health Information Management (HIM) Practices” Includes. Health information management professionals, standards developers, health information technology (HIT) vendors, and other stakeholders involved in current or planned electronic health information systems of any size and scope, that are seeking consistent quality and interoperability record content guidance that support health information exchange models.

The goal of this white paper is to provide guidance tostandards developers as they seek to understand the data needs for health information manager in such domains as:

* Electronic data capture, validation, and maintenance
* Data / information analysis and decision support
* Health information resource management and innovation
* Information governance and stewardship

Contributing to the development of HIT standards and HIM principles and practice standards for the electronic sharing of health information.This paper does not cover the technical details as they are found in the IHE Profiles, White Papers, and Webinar material for systems in an electronic environment.

This White Paper will be applicable to various health information systems such as electronic health record systems (EHRS), laboratory information management systems (LIMS), pharmacy, public health, research and other information systems involved in the management of health information.

The following standards will be relevant to this effort:

HIM Business Standards

1. AHIMA Information Governance Principles for Healthcare, 2014
2. AHIMA First Information Governance Benchmarking White Paper, May 2014
3. ASTM E-31 Standards on HIM practices (URL: <http://www.astm.org/BOOKSTORE/BOS/TOCS_2014/14.01.html> )

HIT Standards

1. HL7 Electronic Health Record Lifecycle Model R1, January 2008 [with additional information from the forthcoming2014/2015 Release2 ]
2. ISO 21089, Health Informatics –Trusted End-to-End Information Flows, 2004 [with additional information from the current new update underway in ISO/TC215]
3. IHE ITI Technical Framework including
4. Cross-Document Workflow (XDW) Integration Profile
5. Integration Profiles related to Information Security
6. Other
7. ISO/TC 215 Standards on Privacy and Security
8. ISO/TC 215 Standards on Medical Records

## Open and Closed Issues

1. Outpatient and other types of episodes of care/encounter are out of scope for this White Paper.

The episode of care/encounter for other visits than in-patient may not be completed within the same visit. It may involve multiple visits.

The terms “**Day Hospital**”, “**Day Patient**” or “**Partial Hospital**” are referred as a partial care administered in the mental health institution, rehabilitation facility, surgery and other outpatient settings defined as an episode of care provided during the day of the visit. This is also out of scope for this for this White Paper.

1. 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.

# Problem

## Problem Description

The use of IT in the clinical setting is no longer in question – it is happening – and as a result, there is an imperative to improve its use and subsequent outcomes. Stakeholders are already seeing unintended problems with information management in the electronic environment associated with failure to ensure accurate data capture, failure to identify the record of care (legal health record); issues associated with e-discovery and e-forensics; and the implications for appearances of fraud and abuse when copy and paste functionality is used inappropriately. Currently, it is unclear how information management (HIM) practices in healthcare organizations are supported by capabilities of health information systems (HIS) to carry out these practices. It is also unclear if current IHE profiles support necessary HIS capabilities for HIM practices. Recommendations for improving electronic documentation creation include defining HIT content standards, developing guidelines for vendors and users of HIT systems for the appropriate use of documentation techniques (information governance) to ensure complete, accurate, and quality documentation.[[4]](#footnote-4)

## Definitions and abbreviations

### Definition of Health Information Management Principles

|  |  |
| --- | --- |
| **HIM Principle** | **Definition** |
| Record Availability | 1. The accessibility for continuous use of data. 2. The property that data or information is timely, accessible and usable upon demand by an authorized person. |
| Record Protection | 1. Guarding against inappropriate acquisition, access, disclosure or use of protected health information. 2. Guarding against loss, tampering, and corruption of health information. |
| Record Integrity | 1. The state of being whole or unimpaired. 2. The ability of data to maintain its structure and attributes, including protection against modification or corruption |

### Abbreviations from HIM Checklist research tool

|  |  |
| --- | --- |
| **Abbreviation** | **Term** |
| ADT | Admission Discharge and Transfer |
| AHIMA | American Health Information Management Association |
| CDI | Clinical Document Improvement |
| CIO | Chief Information Officer |
| CLO | Chief Legal Officer |
| CMIO | Chief Medical Information Officer |
| DNV GL | Det Norske Veritas and Germanischer Lloyd |
| HHS | Department of Health and Human Services |
| HIM | Health information management |
| HIMSS | Healthcare Information and Management Systems |
| HIPAA | Health Insurance Portability and Accountability Act |
| HR | Human Resources |
| HIT | Health information technology |
| ID# | Identification number |
| IHE | Integrating the Healthcare Enterprise |
| ISO | International Organization for Standardization |
| JC | Joint Commission |
| LHR | Legal health record |
| MD | Medical Doctor |
| MPI | Master Patient Index |
| ONC | Office of the National Coordinator |
| OR | Operating room |
| PA | Physician Assistant |
| PI | Performance improvement |
| RN | Registered Nurse |
| ROI | Release of Information |

# Methodology

### Background on research methodologies for the identification of HIM Practices and Use Cases

This section provides background on health information management principles and record states. To improve understanding and applicability definitions of health information states and principles are provided. In addition, health information management practices are identified by record state, and supported by appropriate use cases.

**Objectives:**

1. Explain/model the relationship between HIM practices (clinical-HIM workflow, HIM activities checklist) and capabilities of HIS products to support these practices
2. Conduct a gap analysis between HIM practices and existing IHE and other HIT standards for HIS aimed to support HIM practices
3. Create the roadmap for the development of new IHE profiles to support HIM practices
4. Inform IHE development process by defining Profile Specifier checklist aligned with the HIM practices checklist

### Methodology Table

|  |  |
| --- | --- |
| **TASK** | **DELIVERABLE** |
| 1. Document HIM best practices in electronic environment by selecting information governance principle: 1. Availability; 2. Protection; 3. Integrity. | Literature Review  HIM Practice Checklist |
| 1. Define Use Cases for selected HIM best practices by principle | HIM Use Case List |
| 1. Conduct gap analysis of IHE interoperability standards (integration profiles) to assess their capabilities to support HIM practice by harmonization of the HIM and IHE use cases | Gap Analysis Table |
| 1. Develop recommendations and a roadmap for addressing identified gaps in IHE interoperability standards | Recommendations and Roadmap |
| 1. Publish draft White Paper for public comments | Draft White Paper |
| 1. Publish final White paper based on the reconciliation of public comments | Final White paper |
| 1. Develop proposal for the IHE 2015-16 development cycle | Proposal for the 2015-16 IHE development cycle |
| 1. Communication, Outreach and Marketing | JAHIMA Article  Webinar  2015 Convention |

### Call for Participation

On January 21, 2015 an open call for participation was send to all current volunteers serving on American Health Information Management Association (AHIMA) volunteer initiatives. The target population was recruited and selected utilizing existing volunteer rosters of subject matter experts prepared and maintained by the American Health Information Management Association. The individuals on these volunteer lists include a wide array of industry HIT and HIM experts.

These volunteer work groups and committees include:

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. Standards Task Force (STF)
9. AHIMA IG Advisory Group

### HIM Practices

1. Define HIM practices that can be supported by HIT products.
2. Selected the record state of availability and the two attributes of protection and integrity based on priorities.
3. Develop HIM action checklist for record availability, protection, and integrity.
4. There are 4 components of the HIM Checklist
5. HIM Practices: Established method of conducting professional action supported by literature review.
6. HIM Use Cases: Constructs of processes that support HIM Practices.
7. HIT Use Cases: Constructs of processes that support HIT Standards.
8. HIT standards: Accepted or approved level of health information technology excellence or quality.

The AHIMA Task Force Subject Matter Expert (SME) volunteers were asked to develop a list of HIM best practices under availability, protection, and integrity of the healthcare record/document using publications and experience with HIM in their organizations. Because the focus of the this study is on electronic document sharing it is important that we approach these HIM Practices and Use Cases from the perspective of what a “machine” can do versus an organizational or human perspective

# Use Cases

1. Use Cases: Based on the AHIMA HIM Principles Taskforce Report (Figure 1) with the alignment between IG and HIM principles, we will focus on the Availability state of the record and will develop the checklist of HIM workflow steps (actions) associated with this state. We will further conduct the analysis of HIT standards that are applicable to support actions under these states in the HIT products and interoperability standards applicable to the information exchanges between products under these states.
2. As the result of this analysis we will identify possible gaps and overlaps in existing HIM and HIT standards, including interoperability standards that are needed to support HIT product capabilities for this state of the record.
3. Based on the outcomes of the gap/overlap analysis from both Use Cases we will create a roadmap for the development and adoption of standards in HIT products to support HIM practices by specifying additional Use Cases related to standardization of HIT products for HIM practices and defining the timeline for the development of standards for these Use Cases.
4. Specify HIM Practice Use Cases for standards-based HIT products.
5. The AHIMA Task Force Subject Matter Expert (SME) volunteers were asked to extract HIM Practice Use Cases for the HIT standards from the vetted and validated HIM practices to guide the development of standards for interoperable HIT products.

## Health Information Management(HIM)Practice Use Cases by Information Governance Priniciples

Utilizing an iterative vetting, validation, and ranking process, the AHIMA Task Force Subject Matter Expert (SME) volunteers developed and concurred on a corresponding list of HIM Use Cases selected to support HIM Best Practices by HIM Principle.

**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.[[5]](#footnote-5)

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).

The episode of care/encounter may consist of the various functions within the records/ documents as shown in Table 2.

Table 2. Functions of the Episode of Care and Documentation

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

\* Relative to the type of encounter, institution, specific State requirements.

Please note that relevant paper-based documents provided by patient, caregiver and/or clinicians in the episode of care can be scanned and become part of the Episode of Care/Encounter Record.

Figure 1 presents the examples of the episode of care/encounter’s functions and record components, i.e., individual documents/forms generated at a specific function in the process of care.

a

Figure 1. 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

The decision on the list of the documents mandated by regulatory bodies and will be accounted for by the facility's Forms Management Committee[[6]](#footnote-6),[[7]](#footnote-7) comprised of representatives from clinical, business and technology departments. These representatives (policy makers) 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.

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.[[8]](#footnote-8) 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.



Figure 2. Forms Management Committee Tools and Resources.

**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 3. 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

Figure 4. Example of Episode of Care (EOC) Information Lifecycle, based on Capture, Process, Use, Store, and Dispose (CPUSD) basic functions and Information Governance Principles involved in Documenting Clinical Pathway. Graphic demonstrating non-linear sharing of health information.



Table 4: Defining the Capture, Process, Use, Store, and Dispose (CPUSD) basic information management functions



### 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. [[9]](#footnote-9)

**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.[[10]](#footnote-10)

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. [[11]](#footnote-11)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.[[12]](#footnote-12)

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.[[13]](#footnote-13)

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.[[14]](#footnote-14)

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.[[15]](#footnote-15) 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.”[[16]](#footnote-16) 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.”[[17]](#footnote-17) 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.[[18]](#footnote-18)

**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[[19]](#footnote-19)

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[[20]](#footnote-20)

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

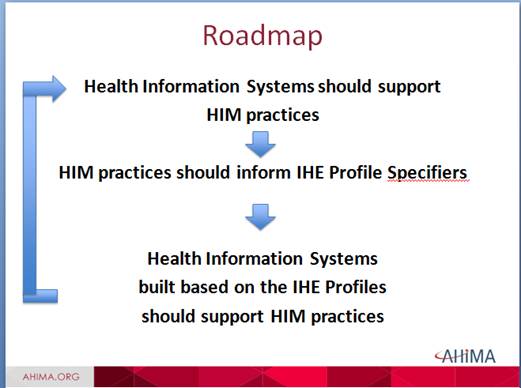
* All disclosures of PHI that are not for treatment, payment, or delivery of healthcare operations
* Suspected domestic and child violence and abuse reporting
* Disclosures made for research unless authorized by the patient or legal representative
* Disclosures made to government agencies (excluding 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[[21]](#footnote-21)

# Roadmap

Based on the outcomes of the gap/overlap analysis from both Use Cases we will create a roadmap for the development and adoption of standards in HIT products to support HIM practices by specifying additional Use Cases related to standardization of HIT products for HIM practices and defining the timeline for the development of standards for these Use Cases. There is a need to conduct a gap analysis of these standards in order to assure their coverage and readiness to support HIM practices in electronic data exchanges.

The identified and aligned HIM Practices and HIT Standards shall become the roadmap. These HIM Practices and HIT Standards shall be bundled together to support record availability, protection, and integrity through electronic document sharing.

The ultimate goal is to have the HIM Principles and Practices included in the portfolio of standards (technical frameworks) that could work together to support data exchanges. We hope to demonstrate that the HIM Principles and Practices represent 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.



Glossary

**Clinical pathway** is defined as a flow of activities and documentation derived from the clinical guidelines as related to a specific episode of care (Figure 1).

Clinical pathway is a tool designed to coordinate multidisciplinary care planning for specific diagnoses and treatments. [[22]](#footnote-22)

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.[[23]](#footnote-23)

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.[[24]](#footnote-24)

**Designated record set** is what 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”[[25]](#footnote-25)

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** 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.”[[26]](#footnote-26)

**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.[[27]](#footnote-27)

**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[[28]](#footnote-28)

**Document** is any analog or digital, formatted and preserved “container” of data or information[[29]](#footnote-29)

**Screen** prototype is a sketch of the user interface of each screen that is anticipated in a project[[30]](#footnote-30)

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)[[31]](#footnote-31)

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, [[32]](#footnote-32) 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 1).

The **Event** is defined as an action or activity that occurs within a system and/or network, inclusive of its boundaries.[[33]](#footnote-33)

The **Step** is defined as a sub-action or sub-activity that occurs within a specific event of care.

**Legal health record (LHR)** is defined as 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[[34]](#footnote-34)

**Provenance** 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.”[[35]](#footnote-35)

**Record**

According to HIMSS, **record** is defined as a document stating results achieved or providing evidence of activities preformed.[[36]](#footnote-36)

Our record definition analysis showed the need to further define 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.[[37]](#footnote-37)
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.[[38]](#footnote-38)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.

Figure 2 presents the record hierarchy.

Figure 2. Record Hierarchy

**Release of Information (ROI)** is defined as the process of disclosing patient identifiable information from the health record to another party.[[39]](#footnote-39)

**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.”[[40]](#footnote-40)

# Appendix A: HIM Checklist

|  |  |  |
| --- | --- | --- |
| **Electronic Health Information Management (HIM) Best Practice Checklist by Selected Information Governance Principle** | | |
|
| **HIM Practice** | **HIM Use Case** | |
| **Record Availability** | | |
| **Definition:** 1. the accessibility for continuous use of data.  2. the property that data or information is timely, accessible and usable upon demand by an authorized person. (AHIMA) | | |
| 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. [1, p.40] | 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 | |
| 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) (1. p.40). | A2.1 Documents within the electronic medical record can be viewed by or released to the external requestor | |
| A3. A log of all requests and accounting of disclosures is kept as an audit trail and can be referenced as needed (1, p. 40) | A3.1 An audit log of all requests for release of information and accounting of disclosures should be maintained for historical purposes. | |
| 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. [1, Page 47] | A.4.1 Release of Information software must identify the physical location and source of the release of information. (1, p. 47). **EG Use Case Feedback:** The ROI function must be a mirror of what was done on paper. The location of the where the information was released from should be part of the IT build. If direct secure faxing is done from the ROI module fax numbers should be hard coded into the system. If manual faxing is done, there should be a way to review that the fax was sent and received. | |
|  | A.4.2 Release of Information software must identify completeness of the documents being released. (1, p. 47).  **EG Use Case Feedback:**  The ROI function must be a mirror of what was done on paper. The location of the where the information was released from should be part of the IT build. If direct secure faxing is done from the ROI module fax numbers should be hard coded into the system. If manual faxing is done, there should be a way to review that the fax was sent and received. | |
|  | A.4.3 Release of Information software must identify the destination for the release or review. (1, p. 47). **EG Use Case Feedback:**  The ROI function must be a mirror of what was done on paper. The location of the where the information was released from should be part of the IT build. If direct secure faxing is done from the ROI module fax numbers should be hard coded into the system. If manual faxing is done, there should be a way to review that the fax was sent and received. | |
| A5. Maintenance of an inventory of discontinued (retired), archived, disposed, revised, current forms according to State and Federal regulations. Maintaining an inventory that is complete, accurate and continually updated based on the organizational policy. Legal health record definition, and records retention policy. [1, p. 159] | A5.1 Software must create inventory of forms (according to the state and federal regulations) including current, revised, discontinued (retired), archived, and disposed forms. **EG Use Case Feedback:** Who owns the form inventory? All paper forms that are still present must be reviewed to ensure that they scan correctly and are bar codes for ease in scanning. The same would be necessary for downtime forms. Systems go down. The Forms Committee in conjunction with HIS should have a firm process for new form creations and revisions. Forms also need to be made available in other languages if they are reproduced for patients or if patients are asked to sign them electronically. | |
|  | A5.2 Software must maintain the inventory of forms (the organizational policy, legal health record definition, and records retention policy) including current, revised, discontinued (retired), archived, and disposed forms. **EG Use Case Feedback:** Who owns the form inventory? All paper forms that are still present must be reviewed to ensure that they scan correctly and are bar codes for ease in scanning. The same would be necessary for downtime forms. Systems go down. The Forms Committee in conjunction with HIS should have a firm process for new form creations and revisions. Forms also need to be made available in other languages if they are reproduced for patients or if patients are asked to sign them electronically. | |
|  | A5.3 A checklist for forms application may be used for maintaining the inventory of forms. **EG Use Case Feedback:** Who owns the form inventory? All paper forms that are still present must be reviewed to ensure that they scan correctly and are bar codes for ease in scanning. The same would be necessary for downtime forms. Systems go down. The Forms Committee in conjunction with HIS should have a firm process for new form creations and revisions. Forms also need to be made available in other languages if they are reproduced for patients or if patients are asked to sign them electronically. | |
|  | A5.4 Templates should be used for individual forms. This specific form characteristics will include: 1. The format of forms in both online and printed states, 2. Consistent placement of identifiers and bar codes (if used), and 3. Standard margin size and font type **EG Use Case Feedback:** Who owns the form inventory? All paper forms that are still present must be reviewed to ensure that they scan correctly and are bar codes for ease in scanning. The same would be necessary for downtime forms. Systems go down. The Forms Committee in conjunction with HIS should have a firm process for new form creations and revisions. Forms also need to be made available in other languages if they are reproduced for patients or if patients are asked to sign them electronically. | |
| 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 (2. p. 2) | A6.1 To validate data accuracy and prevent the capture of erroneous health information, a quality check should be run a each point of health information capture. (5. page 54-55) | |
| 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. (2. p. 3) | A7.2. Health information systems should maintain current controlled medical vocabularies as a quality assurance metric to ensure accurate interchange of data. (6. p. 56-64) | |
| A8. Current trends toward system interoperability and integration require that information quality and service quality be added as **a new health information dimension?** . Key considerations become accuracy and completeness of data, excellent information access , continued availability of data, supported overall by privacy and security safeguards. (3, p. 789) **New health information dimension refers to records in a ready state, more about access and availability, denotes a state of quality and integrity.** | A8.1. Data management software should organize, coordinate facility-wide quality management. (7. p. 49-49) **Define Quality Management software.** **Also add a data quality review. A golden standard for quality, and that a person or machine reviews for the existence of this golden standard. A data scrubber (data editor) could be employed to perform logical edits on the data. These data scrubber edits need to be validated by a person. (i.e. Data normalization, Data Conversion, Data Standardization.)** | |
|  | A8.2 .Data management software should as part of a facility-wide performance improvement program, analyze clinical data to identify trends and present data for healthcare decision making. (7. p. 49-49) | |
|  | | |
| **References:** | |  |
| 1. Grzybowski, D. (2014). Strategies for electronic document and health record management. Chicago, IL : AHIMA . pages. 31, 40, 47, 159    2. Bowman, S. (2013). Impact of electronic health record systems on information integrity: Quality and safety implications. Perspectives in Health Information Management, , 1-1c. Retrieved from http://search.proquest.com.library.capella.edu/docview/1507286703?accountid=27965. pages. 2, 3, 7    3. Nguyen, L., Bellucci, E., & Nguyen, L. T. (2014). Electronic health records i  4. EHR Implementation: An evaluation of information system impact and contingency factors. International journal of medical informatics, 83(11), 779-796. Retrieved from: http://www.sciencedirect.com.library.capella.edu/science/article/pii/S1386505614001233, pages 779, 784, 786, 788, 789    5. AHIMA Maturity Model (Unpublished Draft Version), 2014, p. 3, 4, 6 | | |

# Appendix B: Alignment With Health Information Technology Standards

| ASTM | Record Availability |  |
| --- | --- | --- |
| E1384-07: Standard Practice for Content and Structure of the EHR: (1) Identify the content and logical data structure and organization of an EHR, (2) Explain the relationship of data coming from diverse sources (3)Provide a common vocabulary for those developing, purchasing, and implementing EHR systems (4)Provide sufficient content from which data extracts can be compiled to create unique setting “views.” | A1, A.6 |  |
| E1633 -08a: Standard Specification for Coded Values Used in the EHR this is a Campaign to 1384 Appendix X1: Unify the representations for: (1) primary record of care data elements, (2) the data elements identified in other standard statistical data sets, (3) data elements used in other healthcare data message exchange format standards, or (4) in data gathering forms for this purpose, and (5) in data derived from these elements in order that data recorded in the course of patient care be exchangeable and be the source of accurate statistical and resource management data. | A1, A7.2 |  |
| E1744-04: Standard Practice for View of Emergency Medical Care in the EHR - This practice is a view of the data elements to document the types of emergency medical information that should be included in the electronic health record. (1)The patient’s summary record and derived data sets will be described separately from this practice. (2) As a view of the electronic health record, the information presented will conform to the structure defined in other ASTM standards for the electronic health record. | A1, A2.1, A2.2, A6.1, A7.2 |  |
| E2117- 06: Standard Guide for Identification and Establishment of a Quality Assurance Program for Medical Transcription (this is more human oriented than machine, but can go to some of the principles) | A6.1,A8.1 |  |
| E2147-01: Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems - (1) this specification is to define the nature, role, and function of system access audit logs and their use in health information systems as a technical and procedural tool to help provide security oversight. (2) this specification is to identify principles for establishing a permanent record of disclosure of health information to external users and the data to be recorded in maintaining it. | A3.1, A4.1, A4.2, A4.3 |  |
| E2171-02: Standard Practice for Rating-Scale Measures Relevant to the Electronic Health Record - This standard addresses the identification of data elements from the EHR definitions in Practice E1384 that have ordinal scale value sets and which can be further defined to have scale-free measurement properties. | A8.1 |  |
| E2369-12: Standard Specification for Continuity of Care Record (CCR) - The Continuity of Care Record (CCR) is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient’s healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care | A1.1, A1.2, A2.1, A2.2, A8.2 |  |
| E2436-05: Standard Specification for the Representation of Human Characteristics Data in Healthcare Information Systems - This document presents a standardized representation for the content and structure of human characteristics data for use in healthcare information systems | A7.2 |  |
| E2473: 05 Standard Practice for the Occupational/Environmental Health View of the EHR - This Practice is intended to assemble a logical occupational/environmental health view of the already defined general structure and vocabulary for the EHR and to suggest the ways in which this view can be used to support employee health assessments and other healthcare delivered at the work site. This view is consistent with the ANSI/ADA Clinical Concept Data Model 2005, which identified the major data entities that will need to be involved. This view would complement other views addressed in other settings of care for the employee and could logically either request other EHR data or deliver to other practitioner requester’s record systems portions of occupational/environmental health data that have been recorded at the work site. | A2.1, A2.2 |  |
| HL7 | Record Availability |  |
| EHRS\_FM\_R2 (Only identified the FM as profiles are subsets of the FM). | A1.1, A1.2, A2.1, A2.2, A3.1, A4.1, A4.3 |  |
| CDA R2 | A2.1, A2.2 |  |
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| **ISO** | **Availability** |
| ISO/HL7 10781 2009 Electronic Health Record-System Functional Model, Release 1.1 describes the content and means of functioning of the electronic health record system of the HL7 EHR Work Group. | x |
| ISO/IEEE IS 11073-10101 2004 Health informatics -- Point-of-care medical device communication -- Part 10101: Nomenclature covers nomenclature architecture for point-of-care (POC) medical device communication (MDC). It defines the overall architecture of the organization and relationships among nomenclature components and provides specifications of semantics and syntaxes. | X |
| ISO/IEEE IS 11073-10102 2014 Health informatics -- Point-of-care medical device communication -- Part 10102: Nomenclature -- Annotated ECG extends the IEEE 11073-10101 Nomenclature by providing support for ECG annotation terminology. It may be used either in conjunction with other IEEE 11073 standards (e.g. ISO/IEEE 11073-10201:2001) or independently with other standards. The major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. Additional "global" and "per-lead" numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers also are defined. | X |
| ISO/IEEE IS 11073-10103 2014 Health informatics -- Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac extends the base nomenclature provided in IEEE 11073 to support terminology for implantable cardiac devices. Devices within the scope of this nomenclature are implantable devices such as pacemakers, defibrillators, devices for cardiac resynchronization therapy, and implantable cardiac monitors. The discrete terms necessary to convey a clinically relevant summary of the information obtained during a device interrogation are defined in this nomenclature. | X |
| ISO/IEEE IS 11073-10201 2004 Health informatics -- Point-of-care medical device communication -- Part 10201: Domain information model addresses the definition and structuring of information that is communicated or referred to in communication between application entities. It provides a common representation of all application entities present in the application processes within the various devices independent of the syntax. | X |
| ISO/IEEE IS 11073-10404 2010 Health informatics -- Personal health device communication -- Part 10404: Device specialization -- Pulse oximeter establishes a normative definition of communication between personal telehealth pulse oximeter devices and computer engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play (PnP) interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards and transport standards. It specifies the use of specific term codes, formats and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. | X |
| ISO/IEEE IS 11073-10407 2010 Health informatics -- Personal health device communication -- Part 10407: Device specialization -- Blood pressure monitor establishes a normative definition of communication between personal telehealth blood pressure monitor devices and computer engines (e.g., cell phones and personal health appliances) in a manner that enables plug-and-play interoperability computers, addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and computer engines. This International Standard defines a common core of communication functionality for personal telehealth blood pressure monitors. | X |
| ISO/IEEE IS 11073-10408 2010 Health informatics -- Personal health device communication -- Part 10408: Device specialization -- Thermometer establishes a normative definition of communication between personal telehealth thermometer devices and computer engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and computer engines. | X |
| ISO/IEEE IS 11073-10415 2010 Health informatics -- Personal health device communication -- Part 10415: Device specialization -- Weighing scale addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and computer engines. It establishes a normative definition of communication between personal telehealth weighing scale devices and computer engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. | X |
| ISO/IEEE IS 11073-10417 2014 Health informatics -- Personal health device communication -- Part 10417: Device specialization -- Glucose meter within the context of the ISO/IEEE 11073 family of standards for device communication, ISO/IEEE 11073-10417:2014 establishes a normative definition of communication between personal telehealth glucose meter devices and computer engines (e.g. cell phones, personal computers, personal health appliances and set top boxes) in a manner that enables plug-and-play interoperability. | X |
| ISO/IEEE IS 11073-10418 2014 Health informatics -- Personal health device communication -- Part 10418: Device specialization -- International Normalized Ratio (INR) monitor establishes a normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances and set top boxes) in a manner that enables plug-and-play interoperability. Work done in other ISO/IEEE 11073 standards is leveraged, including existing terminology, information profiles, application profile standards and transport standards. The use of specific term codes, formats and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. | X |
| ISO/IEEE IS 11073-10420 2012 Health informatics -- Personal health device communication -- Part 10420: Device specialization -- Body composition analyze It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. ISO/IEEE 11073-10420:2012 defines a common core of communication functionality for personal telehealth body composition analyzer devices. | X |
| ISO/IEEE IS 11073-10421 2012 Health informatics -- Personal health device communication -- Part 10421: Device specialization -- Peak expiratory flow monitor (peak flow) Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication is established in ISO/IEEE 11073-10421:2012 between personal telehealth peak expiratory flow monitor devices and compute engines (e.g. cell phones and personal health appliances) in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors is specified in telehealth environments restricting optionality in base frameworks in favor of interoperability. | X |
| ISO/IEEE IS 11073-10441 2015 Health informatics -- Personal health device communication -- Part 10441: Device specialization -- Cardiovascular fitness and activity monitor No abstract but it's about personal health communication device therefore, it has to be transparent and available when needed. | X |
| ISO/IEEE IS 11073-10442 2015 Health informatics -- Personal health device communication -- Part 10442: Device specialization -- Strength fitness equipment No abstract but it's about personal health communication device therefore, it has to be transparent and available when needed. | X |
| ISO/IEEE IS 11073-10471 2010 Health informatics -- Personal health device communication -- Part 10471: Device specialization - Independent living activity hub establishes a normative definition of the communication between independent living activity hubs and managers (e.g., cell phones, personal computers, personal health appliances and set top boxes) in a manner that enables plug-and-play (PnP) interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. | X |
| ISO/IEEE IS 11073-10472 2012 Health Informatics -- Personal health device communication -- Part 10472: Device specialization -- Medication monitor establishes a normative definition of communication between personal telehealth medication monitor devices and compute engines (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. | X |
| ISO/IEEE IS 11073-20101 2004 Health informatics -- Point-of-care medical device communication -- Part 20101: Application profiles -- Base standard provides the upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC). | X |
| ISO/IEEE IS 11073-20601 2010 Health informatics -- Personal health device communication -- Part 20601: Application profile -- Optimized exchange protocol addresses a need for an openly defined, independent standard for converting the information profile into an interoperable transmission format so the information can be exchanged to and from personal telehealth devices and computer engines (e.g., cell phones, personal computers, personal health appliances and set top boxes). | X |
| ISO/IEEE IS 11073-30200 2004 Health informatics -- Point-of-care medical device communication -- Part 30200: Transport profile -- Cable connected describes an IrDA-based, cable-connected local area network (LAN) for the interconnection of computers and medical devices and is suitable for new device designs, but is particularly targeted to modifications of legacy devices. |  |
| ISO/IEEE IS 11073-30300 2004 Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless defines an IrDA-based transport profile for medical device communication that uses short-range infrared, as a companion standard to ISO/IEEE 11073-30200, which specifies a cable-connected physical layer. It also supports use cases consistent with industry practice for handheld personal digital assistants (PDAs) and network APs that support IrDA-infrared communication. | X |
| ISO/IEEE IS 11073-30400 2012 Health informatics -- Point-of-care medical device communication -- Part 30400: Interface profile -- Cabled Ethernet The application of the Ethernet family (IEEE Std 802.3-2008) of protocols for use in medical device communication is addressed in ISO/IEEE 11073-30400:2012. The scope is limited to referencing the appropriate Ethernet family specifications and calling out any specific special needs or requirements of the ISO/IEEE 11073 environment, with a particular focus on easing interoperability and controlling costs. | X |
| ISO IS 11073-90101 2008 Health informatics -- Point-of-care medical device communication -- Part 90101: Analytical instruments -- Point-of-care test establishes a set of specifications to allow seamless multivendor interoperability and communication between point-of-care devices, data concentrators, and clinical information systems. CLSI document POCT1 provides the framework for engineers to design devices, workstations and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectional with access points, data concentrators and laboratory information systems from a variety of vendors. | X |
| ISO/TS TS 11073-92001 2007 Health informatics -- Medical waveform format -- Part 92001: Encoding rules specifies how medical waveforms, such as electrocardiogram, electroencephalogram, spirometry waveform etc., are described for interoperability among healthcare information systems. It may be used with other relevant protocols such as HL7, DICOM, ISO/IEEE 11073, and database management systems for each purpose. | X |
| ISO IS 11616 2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information  is intended to provide specific levels of information relevant to the identification of a medicinal product or group of medicinal products. It defines the data elements, structures and relationships between data elements that are required for the exchange of regulated information, in order to uniquely identify pharmaceutical products. This identification is to be applied throughout the product lifecycle to support Pharmaco-vigilance, regulatory and other activities worldwide. In addition, ISO 11616:2012 is essential to ensuring that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders. This ensures interoperability and compatibility for both the sender and the recipient. | X |
| ISO IS 12052 2006 Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management addresses the exchange of digital images, and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information. | X |
| ISO IS 12967-2 2009 Health informatics -- Service architecture -- Part 2: Information viewpoint specifies the fundamental characteristics of the information model to be implemented by a specific architectural layer (i.e. the middleware) of the information system to provide a comprehensive and integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1. | X |
| ISO IS 13120 2013 Health informatics -- Syntax to represent the content of healthcare classification systems -- Classification Markup Language (ClaML) The scope of healthcare classifications systems covered in ISO 13120:2013 encompasses terminologies, and is constrained to traditional paper-based systems (like ICD-10) and systems built according to categorical structures and a cross thesaurus (like ICNP). ISO 13120:2013 is intended for representation of healthcare classification systems in which classes have textual definitions, hierarchical ordering, named hierarchical levels (such as "chapter", "section"), inclusion- and exclusion criteria, and codes. | X |
| ISO IS 13606-1 2008 Health informatics -- Electronic health record communication -- Part 1: Reference model specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository. will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. | X |
| ISO IS 13606-2 2008 Health informatics -- Electronic health record communication -- Part 2: Archetype interchange specification specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. ISO 13606-2:2008 is not intended to specify the internal architecture or database design of such systems. The subject of the record or record extract to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care. | X |
| ISO IS 13606-3 2009 Health informatics -- Electronic health record communication -- Part 3: Reference archetypes and term lists defines term lists that each specify the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take. It also defines informative Reference Archetypes that correspond to ENTRY-level compound data structures within the Reference Models of openEHR and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using ISO 13606-3:2009. | X |
| ISO IS 13606-5 2010 Health informatics -- Electronic health record communication -- Part 5: Interface specification defines the set of interactions for requesting each of these artifacts, and for providing the data to the requesting party or declining the request. An interface to query an EHR or populations of EHRs, for example for clinical audit or research, is beyond its scope, although provision is made for certain selection criteria to be specified when requesting an EHR\_EXTRACT which might also serve for population queries. | X |
| ISO/TS TS 14265 2011 Health Informatics - Classification of purposes for processing personal health information defines a set of high-level categories of purposes for which personal health information can be processed. This is in order to provide a framework for classifying the various specific purposes that can be defined and used by individual policy domains (e.g. healthcare organizations, regional health authorities, jurisdictions, countries) as an aid to the consistent management of information in the delivery of health care services and for the communication of electronic health records across organizational and jurisdictional boundaries. | X |
| ISO/TR TR 16056-1 2004 Health informatics -- Interoperability of telehealth systems and networks -- Part 1: Introduction and definitions gives a brief introduction to interoperability of telehealth systems and networks, along with definitions of telehealth and related terms. An informative annex describing the Telehealth Technical Reference Architecture has also been included to describe more clearly the various components of a telehealth system and the elements that need to be addressed in formulating a set of requirements for these various components. | X |
| ISO/TR TR 16056-2 2004 Health informatics -- Interoperability of telehealth systems and networks -- Part 2: Real-time systems builds on the introduction to telehealth described in Part 1: Introduction and definitions, and focuses on the technical standards related to real-time applications (including video, audio, and data conferencing) and interoperability aspects of telehealth systems and networks. Specifically, this document addresses four main areas: 1. Standards for real-time telehealth systems 2. Interoperability issues in telehealth applications 3. Requirements for interoperable telehealth systems and networks 4. Framework for interoperable architectures | X |
| ISO IS 17090-1 2013 Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services defines the basic concepts underlying the use of digital certificates in healthcare and provides a scheme of interoperability requirements to establish a digital certificate-enabled secure communication of health information. It also identifies the major stakeholders who are communicating health-related information, as well as the main security services required for health communication where digital certificates may be required. |  |
| ISO IS 17090-2 2008 Health informatics -- Public key infrastructure -- Part 2: Certificate profile specifies the certificate profiles required to interchange healthcare information within a single organization, between different organizations and across jurisdictional boundaries. It details the use made of digital certificates in the health industry and focuses, in particular, on specific healthcare issues relating to certificate profiles. | X |
| ISO/TS TS 17948 2014 Health informatics -- Traditional Chinese medicine literature metadata defines the core set of TCM literature metadata, describes the principles and methods of TCM metadata, and specifies the formal description of TCM metadata. It applies to the storage, processing, recording, maintenance and exchange of TCM literature. It covers areas of identification, content, distribution, constraint, quality, maintenance, and relationship of traditional Chinese medicine literature. | X |
| ISO IS 18812 2003 Health informatics -- Clinical analyzer interfaces to laboratory information systems -- Use profiles specifies general messages for electronic information exchange between analytical instruments (AIs) and laboratory information systems (LISs) within a clinical laboratory. It is applicable to the specialties of clinical chemistry/biochemistry, hematology, toxicology, microbiology, virology and immunology. It is not applicable to the blood transfusion and blood bank specialty | X |
| ISO/TS TS 21547 2010 Health informatics -- Security requirements for archiving of electronic health records -- Principles The purpose of ISO/TS 21547:2010 is to define the basic principles needed to securely preserve health records in any format for the long term. It concentrates on previously documented healthcare specific archiving problems. It also gives a brief introduction to the general archiving principles. Unlike the traditional approach to standardization work, where the perspective is that of modeling, code sets and messages, this Technical Specification looks at archiving from the angle of document management and related privacy protection. | X |
| ISO IS 21549-7 2007 Health informatics -- Patient healthcard data -- Part 7: Medication data The purpose of ISO 21549-7:2007 is for cards to provide information to other health professionals and to the patient or its non-professional care giver. It describes and defines the medication data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1). I t specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data-sets for storage on devices. | X |
| ISO IS 21549-8 2010 Health informatics -- Patient healthcard data -- Part 8: Links defines a way to facilitate access to distributed patient records and/or administrative information using health cards. It defines the structure and elements of “links” typically stored in health cards and representing references to individual patients' records as well as to subcomponents of them. Access control mechanisms, data protection mechanisms, access methods and other security services are outside the scope of ISO 21549‑8:2010. | X |
| ISO/TR TR 22221 2006 Health informatics - Good principles and practices for a clinical data warehouse The goal is to define principles and practices in the creation, use, maintenance and protection of a clinical data warehouse (CDW), including meeting ethical and data protection requirements and recommendations for policies for information governance and security. A distinction is made between a CDW and an operational data repository part of a health information system: the latter may have some functionalities for secondary use of data, including furnishing statistics for regular reporting, but without the overall analytical capacity of a CDW. | X |
| ISO IS 22600-1 2014 Health informatics -- Privilege management and access control -- Part 1: Overview and policy management ISO 22600 defines principles and specifies services needed for managing privileges and access control to data and/or functions. It focuses on communication and use of health information distributed across policy domain boundaries. This includes healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members, and trading partners by both individuals and application systems ranging from a local situation to a regional or even national situation. However, ISO 22600-1:2014 proposes a template for the policy agreement. It enables the comparable documentation from all parties involved in the information exchange. | X |
| ISO IS 22857 2013 Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health data It provides guidance on data protection requirements to facilitate the transfer of personal health data across national or jurisdictional borders. It is normative only in respect of international or trans-jurisdictional exchange of personal health data. However it can be informative with respect to the protection of health information within national/jurisdictional boundaries and provide assistance to national or jurisdictional bodies involved in the development and implementation of data protection principles. |  |
| ISO IS 25720 2009 Health informatics -- Genomic Sequence Variation Markup Language (GSVML) It is applicable to the data exchange format that is designed to facilitate the exchange of the genomic sequence variation data around the world, without forcing change of any database schema. From an informatics perspective, GSVML defines the data exchange format based on XML. The scope of ISO 25720:2009 is the data exchange format, but the database schema itself is outside the scope of this International Standard. | X |
| ISO IS 27799 2008 Health informatics -- Information security management in health using ISO/IEC 27002 It specifies a set of detailed controls for managing health information security and provides health information security best practice guidelines. By implementing this International Standard, healthcare organizations and other custodians of health information will be able to ensure a minimum requisite level of security that is appropriate to their organization's circumstances and that will maintain the confidentiality, integrity and availability of personal health information. | X |
| ISO/HL7 IS 27931 2009 Data Exchange Standards -- Health Level Seven Version 2.5 -- An application protocol for electronic data exchange in healthcare environments It establishes an application protocol for the electronic exchange of data in healthcare environments. | X |
| ISO/HL7 IS 27932 2009 Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2 It covers the standardization of clinical documents for exchange. | X |
| ISO/HL7 IS 27951 2009 Health informatics -- Common terminology services, release 1 It seeks to establish an international framework for the development of an application programming interface (API) that can be used by messaging software when accessing terminological content. It is not intended to be a complete terminology service in and of itself. |  |
| ISO/HL7 IS 27953-1 2011 Health informatics -- Individual case safety reports (ICSRs) in pharmaco-vigilance -- Part 1: Framework for adverse event reporting It seeks to establish an international framework for data exchange and information sharing by providing a common messaging format for transmission of ICSRs for adverse drug reactions (ADR), adverse events (AE), product problems and consumer complaints that can occur upon the administration or use of one or more products. | X |
| ISO/HL7 IS 27953-2 2011 Health informatics -- Individual case safety reports (ICSRs) in pharmaco-vigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR It seeks to create a standardized framework for international regulatory reporting and information sharing by providing a common set of data elements and a messaging format for transmission of ICSRs for adverse drug reactions (ADR), adverse events (AE), infections, and incidents that can occur upon the administration of one or more human pharmaceutical products to a patient, regardless of source and destination. | X |
| ISO/TR TR 28380-1 2014 Health informatics -- IHE global standards adoption -- Part 1: Process It describes how the Integrating the Healthcare Enterprise (IHE) process specifies and facilitates profiles of selected standards to support carefully defined healthcare tasks that depend on electronic information exchange. It accelerates the worldwide adoption of standards targeted at achieving interoperability between software applications within healthcare enterprises and across healthcare settings. The Integration and Content Profiles are specified in ISO 28380-2. | X |
| ISO/TR TR 28380-2 2014 Health informatics -- IHE global standards adoption -- Part 2: Integration and content profiles It describes the most recent Integrating the Healthcare Enterprise (IHE) Profiles developed by IHE. These profiles of selected standards support carefully defined healthcare-related tasks that depend on information exchange. It accelerates the worldwide adoption of standards targeted to achieving the interoperability of health information between software applications within enterprises and across various care settings. Each available Integration or Content Profile is described with reference to the specification provided. | X |
| ISO/TR TR 28380-3 2014 Health informatics -- IHE global standards adoption -- Part 3: Deployment It describes the general methodology to analyze interoperability requirements in support of a use case to produce the selection and combination of the relevant Profiles specified in TR 28380-2. It is illustrated by applying this methodology to a small number of examples. It also identifies and proposes a high-level quantification of the benefits gained by the use of a profile based specification of interoperability. Finally this technical report will discuss the approach to effectively test interoperability from the specific of the standards and profiles, up to the level of business use cases. | X |
| ISO/TS TS 29585 2010 Health informatics -- Deployment of a clinical data warehouse It has three sections, 1) general considerations of design and deployment, 2) data aggregation and data modeling and 3) architecture and technology, and is intended to provide an overall set of guidelines for clinical data warehouse deployment supported by useful descriptions concerning different data aggregation and modeling approaches as well as particular aspects of information architecture that contribute to successful deployment. | X |

# Recommendations

**HIM Professionals**

1. Standardize Policies for Form Management Committees including
2. Harmonize existing policies across healthcare organizations
3. Develop a template organizational policy related to form development and management
4. Define standardized set of forms for the Episode of Care
   * Get samples of all possible forms that HIM have to have for the Episode of Care
5. 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.)
   * Define policy that outlines how clinicians are notified of open and closed records when
     + Procedures ordered but not performed
     + Documentation components are missing
     + Signatures are missing. [[41]](#footnote-41)
   * Define a minimum set of content to be analyzed for timeliness and completeness in the legal record

**Standards Development Organizations (SDOs)**

**Health Level Seven (HL7)**

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

1. Review Patient Friendly/Plain Language ballot (URL: here)
2. Review CBCC documentation in wiki (URL: <http://wiki.hl7.org/index.php?title=Community-Based_Collaborative_Care>)

HL7 FHIR (Fast Healthcare Information Resources) Workgroup

1. Review EHRS Functional Model - Record Lifecycle Events Implementation Guide Ballot by May 7. (URL: <http://hl7-fhir.github.io/ehrs-rle.html>

Please note that Record Amendment should be replaced with Record Retraction that includes Record Amendment and Record Addendum

EHR Functional Model Workgroup

1. Normalize definitions for records/document lifecycle as follows:

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

***Statement:*** *Manage Record Completeness.*

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

Define: element, report level, record level

*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~~ to capture a minimum set of content to be analyzed for timeliness and completeness and provide a report of the status.[[42]](#footnote-42)*

EHR system will not define a minimum set of content prior to ROI. The Form Committee will.

1.Change define to capture.

2.Define a report of status?

**Care Provision Support (CPS) (SPELL OUT) 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. *[[43]](#footnote-43)*

Harmonize terms for Incomplete with Open and Closed records

**W3C**

**W3C:** Review W3C documents addressing Provenance on the W3C wiki.

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.

<http://www.w3.org/standards/techs/provenance>

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

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AHIMA. Information Governance Principles for Healthcare (IGHCP). URL:[AHIMA’s Information Governance (IG) resource portal](http://research.zarca.com/survey.aspx?k=SsURPPsUQRsPsPsP&lang=0&data=)

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

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