**Appendix 1. Health Information Management (HIM) Practice Use Cases by Information Governance Principle**

1. **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.[[1]](#footnote-1)

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 as well as the type of the record is defined by the type and duration of each specific function/event/step of care within the episode of care/encounter, i.e., workflow steps and sub-steps. This includes completed, incomplete or cancelled documents of the episode of care/encounter (See Use Case A1.2).

The episode of care/encounter may consist of the various functions with the correspondent records/ documents as shown in Table 1.

Table 1. Functions of the Episode of Care and Corresponding Documentation

|  |  |
| --- | --- |
| Episode of Care/Encounter’s Functions | Examples of Records/Documents |
| Visit Registration/Admission  | Patient and Facility Demographics, Billing, Consent for Information Exchange |
| Triage | Triage Notes and Vital Signs |
| Assessment | Medical Summary, Preliminary Diagnosis and Care Plan |
| Laboratory and Diagnostic Testing  | Consent for ProcedureTest Orders and Test Result Reports |
| Diagnosis and Care Plan | Confirmed Diagnosis and Updated Care Plan |
| Prescription  | Medication Order and Dispense Report |
| Discharge/Transfer/Disposition (ADT) | ADT Record |

Please note that relevant paper-based documents provided by patient, caregiver and/or clinicians in the episode of care can be scanned and amended to 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

b

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 that will be accounted for is made by the facility's Form Management Committee[[2]](#footnote-2),[[3]](#footnote-3) comprised of representatives from clinical, business and technology departments. 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.

Organizational policy developed by the Form Management Committee defines who is responsible for documenting information in the medical 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 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.[[4]](#footnote-4) If other facility is involved in providing services, data sharing agreements between two facilities shall define the policies on how documentation will be accounted for when shared.

**The Start and End of the 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 1).

Table 1. 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. The registrars’ person 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 Medical Summary Form

**States of Interactions**

Patient’s **registration, admission, disposition, discharge/transfer** are the **states of the patient’s interaction** with healthcare facility. HIS must capture change in these states via Open and Closed documentation related to each of the states (see Use Case 2). HIS also must 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 **Patient Status** application**. – NEED TO GET BETTER DESCRIPTION OF THIS 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.

In this year, we will focus on inpatient facilities only, so the **end of the episode of care/encounter** is defined as **patient discharge** from this episode of care/encounter.

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)

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

**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.

In the paper-based environment, **Open record** can be a synonym to the **incomplete record**. In some cases, **incomplete record** term was used for a **lost record,** i.e., the record that could not be found or record that had not been completed when physician left an organization. In the electronic environment these records can be traced as **Open** records.

An **Open record** has to be completed within defined timeframe for a specific function. The Form 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. [[5]](#footnote-5)

**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.[[6]](#footnote-6)

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. [[7]](#footnote-7)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.

In some cases, the function can be initiated but not completed. For example, the test was ordered but the procedure was never performed because patient did not show up.In this case, in the Open record (test order for this procedure) information about the reason why the procedure was not performed must be captured, so the record can be closed.

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

1. generate the list Open records 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. to follow-up
		2. to the ancillary system to follow-up
	3. providing other explanation why the record cannot be closed at this time and
	4. other
3. generate audit reports on records generation, retraction for modification (amendment or addendums) and completion.

**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 Single documents within the electronic medical record can be viewed by or released to the requestor (1. p.40)**

To keep a Legal Health Record (LHS) current and accurate requires continuous maintenance by the facility staff under the leadership of the custodian of the health records the health information management department. Whenever, the all changes to the health information system must be reviewed and approved by the forms management 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.[[8]](#footnote-8)

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

The use and disclosure functions has the potential to 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 specific records.

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.[[10]](#footnote-10) 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** as 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.”[[11]](#footnote-11) 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.”[[12]](#footnote-12) 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.[[13]](#footnote-13)

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

1. Requestor submits a request for ROI. Request may be verbal or written.
2. Receipt of the ROI request is logged into the system. System may be manual or electronic. If manual, the ROI must be date stamped with date received so that the turnaround time can be monitored to ensure compliance with regulations.
3. ROI request content is reviewed against policies and procedures and regulatory criteria.
4. **Decision Point:** Does the request content meet the required policies, procedures and regulatory requirements?

4a. No: Return the request to the originator with a return letter.

1. Yes: **Decision Point:** Does the request provide proof of authority to authorize ROI?
2. Yes: **Decision Point:** Can requestor verify identity?
3. Yes: **Decision Point:** Is requested patient’s admission(s)/ encounter(s) in Master Patient Index (MPI).
4. Pull/retrieve/electronically access record(s) of concern.
5. Produce copies of required record components in the format requested by the requestor.
6. Provide copied record(s) to requestor or designated entity in the format requested by the requestor according to organizational policy.
7. Log completed request in the tracking system
8. End task[[14]](#footnote-14)

**Releasing information to law enforcement:**

Most often requests from law enforcement are related to the active investigation of an open police case Requests that may not require a patient’s authorization because the disclosure is permitted by regulation:

* Police requests emergency room records for a victim of a violent crime
* Release is mandatory to report injuries such as a gunshot or stab wounds
* Response to judicial officer by subpoena, court order, warrant, summons, or investigative demand
* For locating a suspect, fugitive, witness, or missing person if the victim cannot consent due to an emergency and when it would affect the investigation
* If a person has died due to a criminal act
* If the PHI is evidence of criminal conduct
* If the release helps avert a serious threat to the health and safety of the public
* Response to judicial officer by subpoena, court order, warrant, summons, or investigative demand
* To provide medical care to those in custody at a correctional facility or to protect the health and safety of employees and others[[15]](#footnote-15)

**Requests for disclosure permitted by regulation that may not require a patient’s authorization:**

**Continuity of Care:** Requests to disclose information for the continuity of care of the patient.

Examples:

• Nursing home requesting information from a patient’s previous hospitalization

• Physician clinic requesting lab report from visit

**Legal:** Requests from attorneys or judges. Examples:

• An attorney request for litigation

• An attorney office requests all records for a deceased patient from hospital to pursue closing an estate

• An attorney sends a court order requesting records related to a guardianship

**Government Agency:** Requests that may not require a patient’s authorization because the disclosure is permitted by regulation. Examples:

* State Disability Determination Program—requests received to determine the patient’s physical and mental condition to assess whether patient should receive benefits under the disability program plan
* Workers’ Compensation—requests received by the agency that determines whether an injury occurred as a result of the patient’s work and to assess whether the patient should receive benefits under the workers’ compensation plan

**Insurance:** Requests for patient information for purposes of determining the appropriateness of healthcare insurance payment. Examples:

• Commercial insurers

• Governmental insurers

**Patient:** Requests from patient or their legal/personal representative to see or obtain a copy of their health information for services provided. Example:

• Patient asks for a copy of a radiology report and film of a recently conducted test

**Third Party Reviewers (such as QIO/RAC/MIC/MAC/other reviewers for commercial insurers):**

Requests to provide copies of records for review by an entity that determines the appropriateness of care provided, determines whether the care met quality expectations, or determines whether the care provided is accurately reflected on the claim that will be or has been paid by the organization that the review entity represents. Example:

• Request to send copy of record to the Recovery Audit Contractor to review for suspected inappropriate billing practices

**Release of Information for External Database Reporting: (such as state cancer registries, core measure reporting, state trauma registries, center of excellence reporting):**

These requests are usually mandated by state or federal regulations; however, a covered entity may volunteer to participate in a reporting initiative for benchmarking and quality improvement purposes. These requests may or may not identify the patient and may include aggregate patient information or single patient occurrence (i.e. Center for Disease Control) for surveillance or outcomes purposes. Because of their nature, often this information may be released for external database reporting purposes without prior consent. Example:

• Reporting of all cases that presented to the hospital with an initial diagnosis of cancer

Research: Requests to provide copies of information for review by an external researcher. These are typically accompanied by a patient authorization when the request is received from an organization not associated with the covered entity. However, for research projects approved by an institutional review board (IRB) an authorization is not required. Example:

The American Cancer Research Organization requests records of a patient for cancer research. A valid authorization is submitted with the request.[[16]](#footnote-16)

**A2.2 Multiple groups of documents within the electronic medical record can be viewed by or released to the requestor (1. p.40)**

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 staff internal viewing application. 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 over 40 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**

A key component of OCR audit preparation—and ensuring proper PHI disclosure management on an ongoing basis—is a comprehensive review of policies and procedures. HIM’s longstanding responsibility as the owner of PHI policies and procedures puts the department in an ideal position to offer this same expertise across the organization.

The review should include 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

In addition, the review should include policies related to the HIE environment such as the Data Use and Reciprocal Support Agreement (DURSA) and the sub-data set available through the DURSA, and audits of the HIE environment.

**2. Internal Audits**

Conducting internal audits in a variety of ways (planned, unplanned, or even “mystery” audits, when the staff doesn’t know it’s being audited) can promote better compliance. By going on the offensive, organizations also ensure more thorough preparation for possible OCR audits or state health department reviews. Internal audits at some facilities have revealed dangerous practices—for instance, nursing stations leaving patient information visible on a monitor, and emergency department (ED) clinicians burning CD copies of patient records for unauthorized family members. That said, consider developing an audit program that addresses various privacy and security issues. Develop a checklist and visit various areas of the hospital to review the following:

* Are printers and fax machines secured from public view?
* Are waste bins free of PHI?
* Are computer monitors equipped with privacy screens or kept away from public view?
* Can staff discussing PHI be overheard?
* Are print capabilities limited to only the necessary departments?
* If patient names are used in waiting rooms, do clinicians and staff use only the minimum necessary? (i.e., Ms. Smith)
* If sign-in sheets are used, is the minimal amount of PHI requested?
* Are doors locked and access limited to departments housing PHI?
* Is the Notice of Privacy Practices posted?

Also, conduct various tests to determine if staff is protecting PHI:

* Walk through the nursing station to see if it’s possible to remove a chart or access documents.
* Ask IT to call a staff member to see if he or she will give out password information.
* Call release of information staff to ask how to obtain a medical record.
* Call the facility and attempt to find out verbal information about a patient.
* Call the HIM department to ask for a correction to your patient record.
* Verify the organization has revoked computer rights and badge access for recently terminated employees.

**3. Tools and Technology**

While departmental and enterprise-wide IT systems have advanced, their capability to support proper PHI disclosure may not be keeping up with increasingly stringent requirements. Working with IT and other appropriate departments, HIM can help ensure software is supporting the organization’s enterprise-wide PHI disclosure management goals. Software enhancements such as flagging for minors’ records, computing turnaround times for fulfilling requests, and adding access trails within the platform can facilitate compliance.

It’s also helpful to review departmental processes and see where technology can be improved to support compliance, or where it currently creates risk by being misused. For instance, in the previous example where ED staff burned patients’ records onto CDs for family members, the use of the CD burner led to improper distribution of patient records. In this case, the organization’s replacement workstation didn’t have a CD burner.

**4. Adequate Training**

A sharp increase in PHI disclosure points and a more networked and complex digitized environment are two factors that increase the importance of comprehensive, organization-wide privacy and security training. Clinicians and staff have numerous opportunities each day to disclose PHI, and if they haven’t received full, up-to-date training, they can unknowingly create risk. The HIPAA privacy and security rules require healthcare organizations to formally educate the workforce to ensure ongoing accountability for the handling of PHI, as well as documentation verifying that it was provided.

While there are no set guidelines for how to conduct training, AHIMA’s best practices include the following:

* Provide annual training for all staff
* Include education, training, and ongoing awareness and cover PHI in all its forms (verbal, written, electronic)
* Develop a repository of current policies and procedures
* Test staff on information to ensure that they have completed training before they are able to access PHI

Role-based training is especially important, as it enables trainees to focus on their daily responsibilities and specifically where they will encounter potential compliance risk. In addition to comprehensive employee training, it is important to work closely with BAs to ensure both thorough training and documentation is conducted.”[[17]](#footnote-17)

**Definitions**

**Record**

According to HIMSS, **record** is defined as a document stating results achieved or providing evidence of activities preformed.[[18]](#footnote-18)

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.[[19]](#footnote-19)
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.[[20]](#footnote-20)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

**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. [[21]](#footnote-21)

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.[[22]](#footnote-22)

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

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

**Document** is any analog or digital, formatted and preserved “container” of data or information[[25]](#footnote-25)

**Screen** prototype is a sketch of the user interface of each screen that is anticipated in a project[[26]](#footnote-26)

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

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, [[28]](#footnote-28) 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.[[29]](#footnote-29)

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[[30]](#footnote-30)

**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”[[31]](#footnote-31)

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.

**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.”[[32]](#footnote-32)

**Out of Scope 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.

**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. [[33]](#footnote-33)
	* 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.[[34]](#footnote-34)*

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. *[[35]](#footnote-35)*

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/>

**Vendors**

**Policy Makers**

**International Community**

International Federation of Health Information Management Associations (IFHIMA)

Harmonize the terms Episode of Care/Encounter/Visit

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