



Defining, Maintaining and Using the Legal Electronic Health Record


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Agenda

- Introduction
- The Legal EHR Foundation / Regulations
- EHR Management & Defining the Legal EHR
- Functionality for Maintaining the Legal EHR
- Resources and Tools
- Questions / Answers



**Regardless of its format –
paper, hybrid, or fully
electronic –
the health record must meet
the requirements of the
legal and business record
for the organization.**



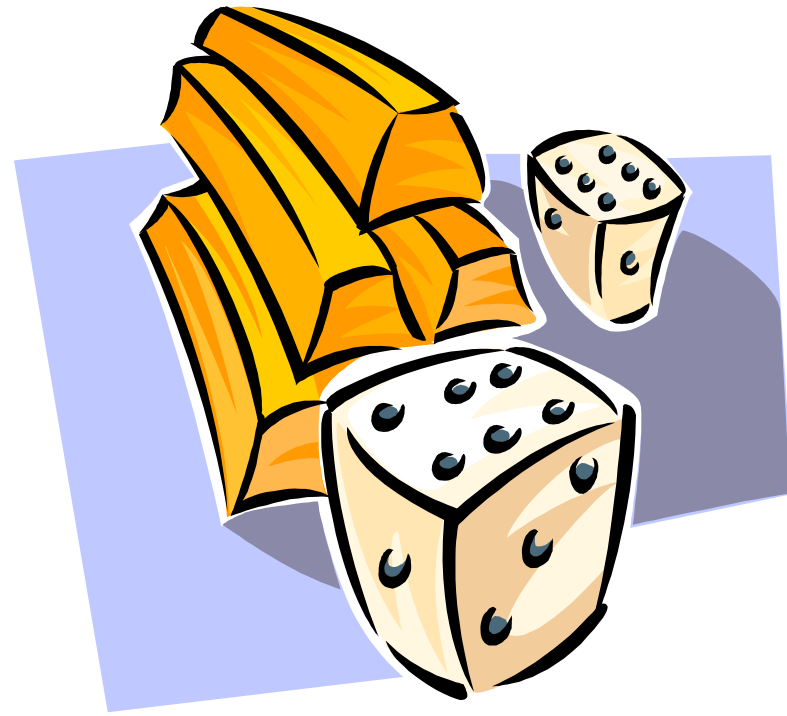
Why does the EHR have to be a Legal Record?

1. Because the organization, by law, must have a medical record
2. The “medical record” by definition, must meet the all statutory, regulatory, and professional requirements to be a valid medical record for clinical purposes as well as for business purposes.
3. If the record does not qualify as a medical record, it becomes hearsay, not a bona fide record and its integrity for any and all uses becomes suspect.

The legal record must conform to federal regulations, state laws and voluntary accreditation standards.

So, Why Does It Matter

- Consider the risks of not addressing legal needs
 - Challenges to documentation that supports billing
 - Potential increase in litigation costs
 - Potentially higher settlements



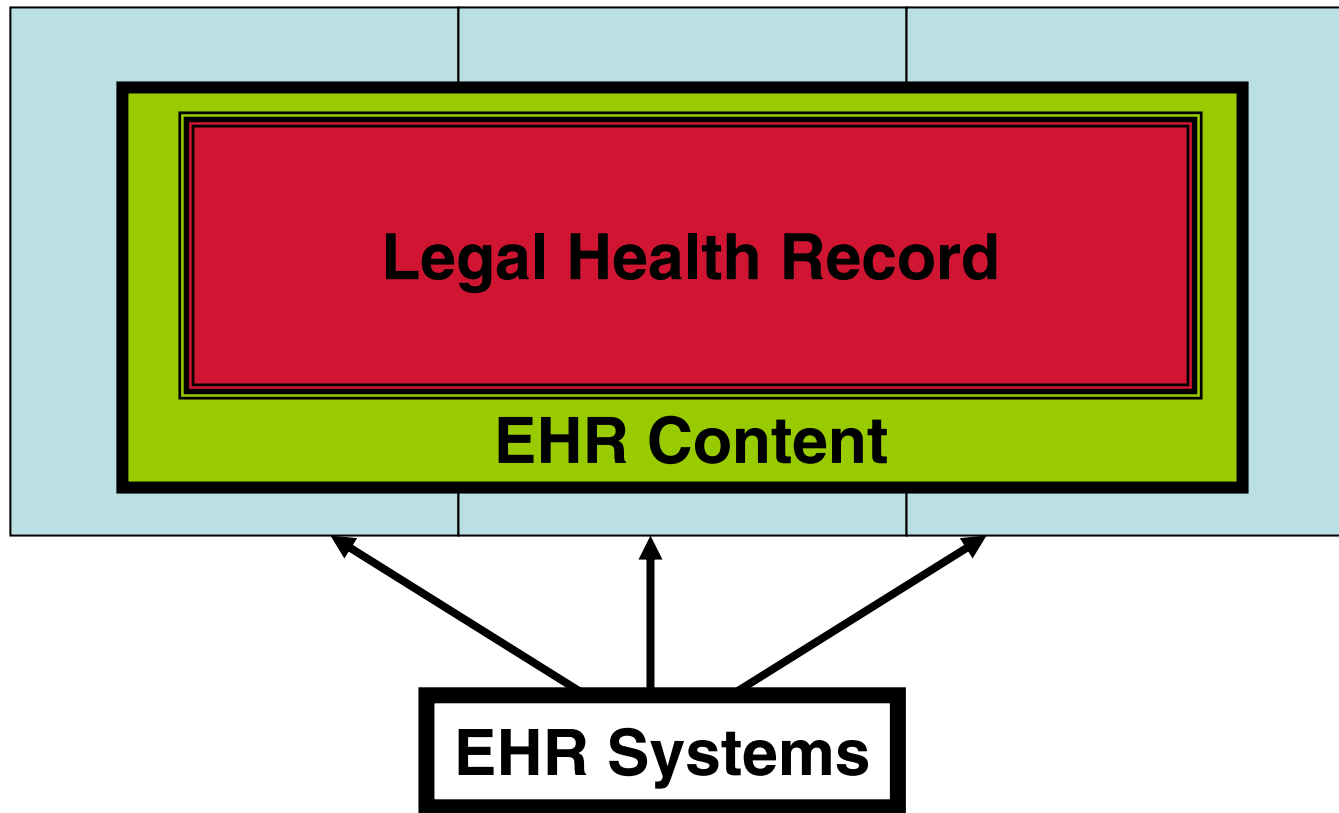


CMS Conditions of Participation:

These requirements apply to **both manual and electronic** medical record systems.

- **Maintain a medical record** for each patient.
- **Properly filed and retained to ensure prompt retrieval.**
- The medical record must be **accessible**.
- The medical record system must ensure that medical record entries are **not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner**.
- Locations where medical records are stored or maintained must ensure the **integrity, security and protection** of the records.
- All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author.

The Legal EHR is a Subset of EHR Systems





Foundation for a Legal Record

**Rules of Evidence
(State and Federal)**

**Regulations
(Content of Record)**

**Regulations
(Electronic Records
And Signatures)**



Rules of Evidence - Health Records

- The record was documented in the normal course of business (following normal routines)
- The record was kept in the regular course of business
- The record was made at or near the time of the matter recorded
- The record was made by a person within the business with knowledge of the acts, events, conditions, opinions, or diagnoses appearing in it



EHR – Additional Factors

- The type of computer used and its acceptance as standard and efficient equipment
- The record's method of operation
- The method and circumstances of preparation of the record, including:
 - the sources of information on which it is based
 - the procedures for entering information into and retrieving information from the computer
 - the controls and checks used as well as the tests made to ensure the accuracy and reliability of the record
- The information has not been altered



Regulations – Health Record Content

- What is required to be in your organization's medical record?
 - Federal regulations by practice setting
 - State regulations by practice setting
 - Requirements of accrediting bodies (e.g., JCAHO, AOA, CARF)
 - Payer requirements
 - Other laws



§482.24(c) Standard: Content of Record

- The medical record contains written documentation, computerized information, radiology film/scans, lab reports...
- It must contain documentation & assessments to justify continued stay
 - To support the diagnosis,
 - To describe the patient's progress, and
 - To describe the patient's response
 - to medications
 - interventions
 - services
- The medical record documents planning for a patient's care and the decisions made on the provision of care.



Regulations – Health Record Storage Media

- Do regulations require records to be maintained in paper?
- Do regulations address electronic records and electronic signatures?
 - Federal regulations
 - State statutes
 - Other (Medicare and Payers)

The Legal Process and the EHR

- Define the Legal EHR
- Custodian of the Record
- Discoverability vs. Disclosure
- Responding to Requests for Electronic Records
 - What format?
 - What is releasable?
 - Disclosing metadata and audit trails



Anti-Fraud Report Recommendations

- Adopt a national definition for the legal health record
- Define a minimal content standard
- Laws, regulations and standards need to be consistent
- EHR software must conform to a minimum standard



Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities

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Electronic Health Records Management and Defining the Legal EHR



Electronic Health Records

- Encompass health information recorded on **any digital medium** as read-only or rewritable formats
 - Magnetic tape
 - Optical disk
 - CD / DVD
- Are evidence of transactions or events that
 - have **legal or business value** (i.e., the records reflect the business objectives of the organization, such as receiving reimbursement for services provided)
 - indicate an **intention to be memorialized**



Electronic Health Records Management (EHRM)

“the processes by which electronic (i.e., digital) health records are created or received and preserved for evidentiary discovery (i.e., **legal / business**) purposes.”*

The requirements for **EHRM** remain the same as HRM (indeed, with some new wrinkles); only the processes change.

*AHIMA's 2004 e-HIM™ Workgroup

EHRM: Requirements

- **Creating and maintaining** EHR retention and disposition schedules based on administrative, legal, fiscal, and historical needs
- **Establishing documented procedures** for the scheduled destruction of obsolete EHRs and retaining proof of such destruction
- **Developing, implementing, and maintaining** efficient EHR filing systems
- Quickly **locating and organizing** EHRs
- **Training** personnel in the use and function of EHR management processes
- **Ensuring** the confidentiality, security, and integrity of the information contained in the EHRs
- **Monitoring / auditing** the completeness and accuracy of the EHR content



EHRM: Processes

- The **EHRM processes** require astute decision making throughout the electronic health record life cycle.
 - ✓ Creating / Receiving
 - ✓ Indexing
 - ✓ Searching
 - ✓ Retrieving
 - ✓ Processing
 - ✓ Routing / Distributing
 - ✓ Storing
 - ✓ Maintaining
 - ✓ Securing
 - ✓ Purging / Archiving / Destroying



EHRM – Strategic Importance

*From a strategic standpoint, it is important to go beyond the record creation phase and develop a plan that results in an EHR and EHR system that maintain a **high level of integrity for business and legal purposes**. The management of the EHR and the EHR system is and will continue to be a mission-critical function in the provision of care across the healthcare continuum.*

*However, given today's urgency to begin deploying EHRs, healthcare entities, vendors, and others sometimes neglect to build in the processes and system capabilities needed to enable optimal EHRM functions and ensure the electronic rather than the paper version can stand as the **legal business record**.*



The Legal Health Record

The legal health record is generated at or for a healthcare organization as its **BUSINESS RECORD** and is the record that will be disclosed upon request.



Re-Defining the Legal Health Record

- Within the health record life cycle, the key health information management EHRM task is to assure the uninterrupted validity of all components of the legal health record.
- The characteristics are standard but each organization's designated legal records can vary over time and therefore **require a periodic, updated definition.**



Re-Defining the Legal Health Record

What Are Your Organization's EHRM Policies?

- What are your organization's record / document:
 - creation and completion policies?
 - storage / maintenance policies?
 - purge / archive / destruction policies?
- Who can document using what tools with what constraints?
- Who decides?

Sample Legal Source Legend

Report/Document Types	LHR Media Type (P)aper/ (E)lectronic	Source System Application (nonpaper)	Electronic Storage Start Date	Stop Printing Start Date
Admission History & Physical	P/E	System 1	1/1/2002	1/1/2003
Attending Admission Notes	P			
Physician Orders	E			
Inpatient Progress Notes	P			
Discharge Summary	E	System 1	1/1/2002	4/1/2002
Inpatient Transfer Note	E	System 1	1/1/2002	



Defining the Legal EHR

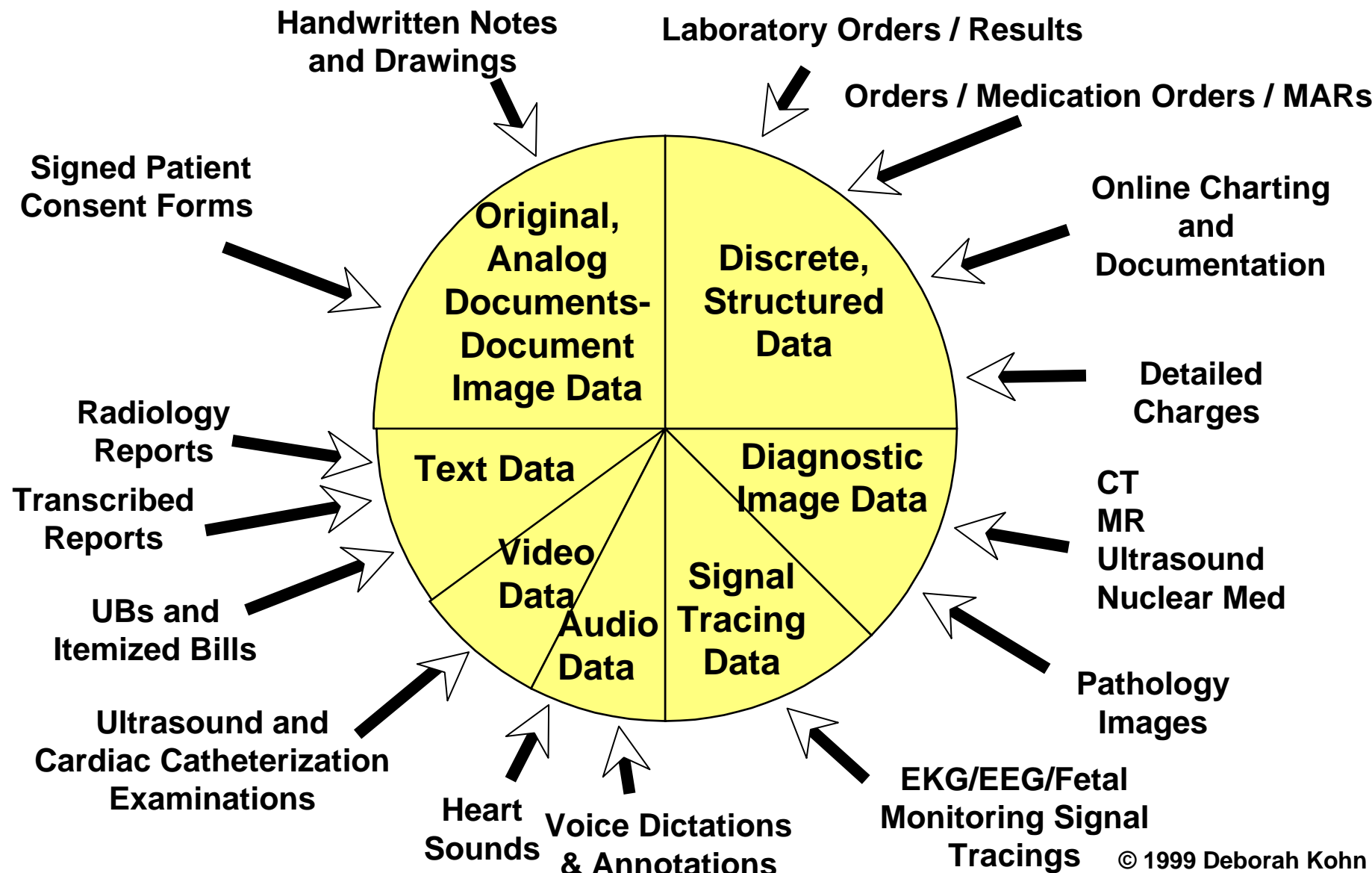
No
“one-size-fits-all”
definition



Defining the Legal EHR – What's In?

- **Typically, any data / documents that can be disclosed upon request**
 - Advanced Directives
 - Anesthesia Records
 - Care Plans
 - Discharge Summaries
 - Progress Notes
 - Wave Forms
 - Required by Medicare, statutes, 3rd party payors
 - 48 items...

Defining the Legal EHR – Data / Document Types





Defining the Legal EHR –What's Out?

- **ADMINISTRATIVE DATA / DOCUMENTS**
 - Abbreviation lists
 - Audit trails, metadata, business rules
 - Financial and insurance forms
 - Indices
 - Logs
 - Worksheets/ Worklists
- **DERIVED DATA / DOCUMENTS**
 - Accreditation reports
 - Best-practice guidelines
 - Statistical reports
- **28 items...**



Defining the Legal EHR – What About...?

- Alerts, reminders and pop-ups (i.e., decision support)
- Continuity of care records (CCRs)
- Personal health records (PHRs)
- Future issues – interoperability



Defining the Legal EHR

- Form an interdisciplinary team to **define the health record content for disclosure purposes** that best fits your organization's EHR system capabilities, hybrid environment, if applicable, and legal environment
 - Legal counsel
 - Clinical / Medical staff
 - HIM
 - IT
 - C suite
- Employ EHR systems that support your organization's EHRM policies and procedures



Functionality for Maintaining the Legal EHR



Functionality for Maintaining the Legal EHR

The Basics

- The EHR is not a valid medical record until it is a valid Medical Record in all its attributes.
- An electronic version of a Medical Record is not valid until the evidentiary criteria for electronic records are met.
- The core functions required for maintaining the Legal EHR are those that reflect and demonstrate conscientious adherence to the well-established rules of medical records.



The Basics in Practice: Consumers and Users

The burden is on the purchaser and the user for these new tools, to assure that in actual use their EHR system qualifies as a legal record.

In these new environments as with the old, proactive due diligence and compliance in the selection, use, and protection of your organization's medical records, in all media, will be required.



The Basics in Practice: Vendors

- High degree of variance among products' abilities to support the Legal EHR.
- The Legal EHR is a critical market-distinguishing feature in a crowded EHR market.
- The ONC Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities highlights the Legal EHR as a critical element to national HIT goals for fraud reduction.

HIM Functions: Testable

In the absence of translations of standards into specific, detailed simple “do’s” and “don’ts”, you can either:

- **Accept** on faith that your system will stand up under use (and under scrutiny)

-or-

- **Test and affirm**
 - As a matter of due diligence
 - As a matter of your organization’s policies and procedures for operation
 - As a matter of quality assurance for HIM principles’ applications



HIM Functions: Test and Affirm

Your Guides:

The principles:

- The Practice Briefs: Defining..., Maintaining..., and the Process...
- The AHIMA On-Line Library

The Methodologies:

- CCHIT draft guidelines and draft testing protocols
- HL7 draft guidelines

Maintaining the Legal EHR: Verification Legend

Report/Documentation Type	Audit	Authenti- cation	Authorship	Documentation Principles			
				Copy/Paste	Amend	Correct	Clarify
Encounter History	X	X	X	X	O		
Encounter Physical	X						
Medical History							
Family History							
Social History							
Medications List							
Problem List							



HIM Functions: Test and Affirm

Your Tools:

- Your organization's policies and procedures, adapted to the EHR environment
- Your organization's means for orienting, training, and enforcing medical records principles

Your Skills:

- Observing and Evaluating EHR Functions
- Creating and Applying Testing Protocols and Vignettes



Observing and Evaluating: EHR Business Rules

Business Rules: Embedded Use Policies and Procedures That Derive From HIM Principles

Examples from “The Paper World”

Don't Use Pencil
Don't Leave Blank Spaces
Don't Remove Pages
Don't Obliterate Entries

EHR Business Rule Variation 4

User marks “Normal”
for “All systems
reviewed”

Database records
“Normal” for all
systems with pre-set
structured data
elements

Database may or may
not record “Normal”
for “All systems
reviewed”

Review of Systems:

Normal

- ✓ All systems negative
- Constitutional negative for fever, chills, sweats, unexpected weight loss or weight gain, activity tolerance changes, or dizziness
- Eyes negative for visual disturbances, floaters, flashes, blurred or double vision.
- Ears, Nose, Mouth, Throat negative for hearing changes, tinnitus, vertigo. No mouth lesions, dental caries, tongue masses or irregularities. No sore throats, hoarseness, or nasal drainage.
- Cardiovascular negative for palpitations, angina, peripheral swelling etc.
- Respiratory negative for productive or non-productive cough, dyspnea on exertion, pain with cough, snoring, or shortness of breath
- Gastrointestinal negative for W, X, Y, and Z
- Genitourinary negative for W, X, Y, and Z
- Musculoskeletal negative for W, X, Y, and Z
- Integumentary negative for W, X, Y, and Z
- Neurological negative for W, X, Y, and Z
- Psychiatric negative for W, X, Y, and Z
- Endocrine negative for W, X, Y, and Z
- Hematologic/Lymphatic negative for X, Y, Z
- Allergic/Immunologic negative for W, X, Y, and Z



Testing: The Structured Protocol, Script, or Vignette

- Evaluation and testing is best done if it is methodical and reproducible, based on HIM principles.
- This may be accomplished by developing a script or protocol that can be applied to different types of EHRs.
- As an illustration, see the sample vignette.



Functionality for Maintaining the Legal EHR

- Authentication for Legal Admissibility
- Who May Document in the Record
- Authentication of Entries
- **Documentation Principles**
- Linking Each Patient to an Entry
- Timeliness and Chronology of Entries
- Legibility and Display
- Corrections, Errors, and Amendments
- Chart Content
- Formats
- **Output/Printing**
- Permanency, Retention, Purging and Storage
- **Data Integrity: Access, Audit Trails, and Security**
- Disaster Recovery and Business Continuity



Functionality for Maintaining the Legal EHR

Commonly Observed Gaps:

Limited or inaccessible metadata tools (Audit/Event Logs)

- Event logs may not be available at reasonable cost
- Event logs may not capture some events
- Event logs may not be available at all.

Undefined metadata functions

- Missing data elements
- Obscured data elements

Documentation overwriting

- Author info accurate but incomplete
- Author info inaccurate



Functionality for Maintaining the Legal EHR

Mitigation Strategies:

Drivers:

- Does the function exist at all?
- Does the function exist partially?
- Does the function have multiple, variable iterations?
 - Are some iterations acceptable?
 - Are no iterations acceptable?

Options:

- Stipulate specific use requirements
- Enable, constrain, or disable specific use options
- Augment automated processes with manual processes



The EHR Team

- **Clinical**-First and foremost, those who use the tools.
- **IT**-The information technology experts who create, maintain, and improve the tools
- **HIM**-Those who assure that the technology “fits” the environment formed within the medical-legal, regulatory, and information management standards domains

Working together to ensure that the technical tools fit the tasks and the environment for all uses of health care information.

The EHR Team

HIM Professionals

- Ideally suited to provide domain expertise and leadership
- Conscientious advocates, ensuring that the EHR system is optimally planned, chosen, implemented, and managed
- The traditional and continuing custodian of the medical record and medical record system, regardless of media
- Trained to ensure the quality, privacy, and integrity of the EHR.

Today, the HIM Professional is an integral part of the team that maintains vigilance over the health information technology realm, so that health information management standards are consistently applied across all systems in order to maintain the level of integrity necessary for the clinically and medical-legally sound operations of the healthcare organization.

Resources:

- HL7 Workgroup Legal EHR www.hl7.org/ehr
 - Defining functionality related to legal issues in HL7's EHR Functional Standard
- Certification Commission for Health Information Technology (CCHIT) www.cchit.org
 - Establishing basic functional requirements for EHR “certification” (However, not yet certifying the Legal EHR)
- eHIM Workgroups
 - Defining the Legal EHR (Sept. 2005)
 - The EHR and the Legal Process (Oct. 2005)
 - Maintaining the Legal EHR (Nov/Dec 2005)
 - Legal EHR Model Power Point Presentation
- Available
 - in AHIMA Body of Knowledge
 - at www.ahima.org/infocenter/ehim/

Other Resources for Legal EHR

- e-HIM Practice Briefs
 - Electronic Health Records Management:
 - The Strategic Importance
 - Issues in Electronic Health Records Management
 - Checklist for Transition to the EHR
 - Hybrid Records: Part I, II, and III
 - Electronic Signatures
 - Electronic Document Management Systems
 - E-mail as a Provider/Patient Communication Medium
- Plus More...
- Coming Soon
 - Patient Identification in RHIOs
 - Data Content and the EHR

www.ahima.org/infocenter/ehim/



Thank You!

Questions?



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