

Trust Infrastructure: Evidence Initiative

The Electronic Health Record (EHR) as “Legal Record”

Health Level Seven (HL7) EHR Work Group – Project Proposal

In Consultation with US Office of National Coordinator (ONC)

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Introduction: The HL7 EHR Workgroup invites ONC to consider near-term next steps toward advancing “legal record” issues in the EHR marketplace, referencing the international normative standard (ISO/HL7 10781 EHR System Functional Model Release 2), supportive resources, and subject matter experts. This invitation follows on related presentations to the US Health Information Technology (HIT) Policy Committee’s Clinical Documentation Hearing on February 13, 2013. Testimony was offered by Chad Brouillard JD, Michelle Dougherty, and Don Mon with subsequent support from Dr. John Halamka (past Vice Chair of the HIT Standards Committee (HITSC)) and Dr. Karen DeSalvo. Following the hearing, the HIT Policy Committee identified seven recommendations including standards development activities targeted to certified EHR systems maintaining a full legal record.¹

Problem Statement: Various EHR-related challenges pertaining to US legal domains are gaining visibility and generating drag for healthcare improvement and healthcare finance reform. Those arising from how EHR systems are designed, implemented, trained and used appear potentially amenable to mitigation through ONC and standards development activities. Three problem areas appear to distinguish themselves among subject matter experts and published reports as among the “most impactful”. As outlined in Mr. Brouillard’s “Statement from the Defense” summary (previously forwarded), these are:

1. Audit Trail Usability
2. Export Distortion
3. E-Discovery

Among many factors and objectives driving ONC initiatives, some may be enhanced by more heavily weighting mitigation of these challenges.

Opportunities Overview:

1. Audit Trail: The EHR System Functional Model (EHR-S FM) has conformance criteria addressing fundamentals of Record Entry Origination including defining key events, minimum content (including provenance), and their associated audit log entries. The EHR-S FM also specifies audit events for updates to records that already exist in a system. Lastly, the FM stipulates reporting functions, including Audit Log reporting. A distillation or combination of these could establish an initial “minimum metadata set” to populate something akin to a “Common Model Audit Trail Report” that would act as a guide to normalize audit trail content and usability.
2. Export Distortion: The EHR-S FM includes a number of reporting functions that, taken together, provide a logical framework for constructing a “Basic Export” for, for example, an attorney’s Release of Information request. One foundational requirement is the ability to “tell the patient’s healthcare story”, requiring at least, chronological representations of what happened during the course of care. Since some EHR systems do not provide this minimal basic functionality, even if the information exists in the system, its renderings, whether digital or printed, make it difficult to impossible to tell the actual story of patient health and healthcare. Without this story, there is no organizing framework to even ask clinicians about their specific activities, including input to and output from the EHR system during the course of patient care. Since the EHR-S FM is an internationally-recognized Normative Standard, it can provide the basis and an authoritative resource for constructing the basic necessity of, and logical framework for, an undistorted export of the full patient care story. Once that story is

¹ Recommendation: “Propose that **HITSC** review what **standards** are needed to ensure that **CEHRT maintains legal medical record** content for disclosure purposes (e.g. **what was accessed** during the encounter and what gets printed out as the legal medical record?).” ONC HIT Policy Committee Meeting, April 3, 2013. “Clinical Documentation Hearing Recommendations Meaningful Use and Certification and Adoption Workgroups” https://www.healthit.gov/archive/archive_files/HIT%20Policy%20Committee/2013/2013-04-03/hitpc_mu_ca_clin_03_apr_13.pdf

able to be constructed in a recognizable way, all parties then can turn their attention from whether the story is actually evident, to the meaning of story details. A “framework” of this sort, offered as a resource, could initially signal priority of “Export Distortion mitigation” and later provide the basis for more detailed treatment.

3. e-Discovery: As a very complex set of tasks and requirements, eDiscovery includes many elements, including some that may be deemed “basic” or “critical”, on which other elements can then depend. EHR systems often introduce legal risk variables in such basic and critical requirements as ESI preservation (see Section H, Reference 1). The EHR-S FM includes requirements supporting foundational elements, for example the ability to render key clinical summaries (ex: Problem List, Allergies List, Medication List) both in current state and their states at previous points in time. The latter may not be a widely recognized requirement which, as foundational attribute for other eDiscovery elements, may merit special and more immediate attention. Other key elements for discovery, such as reproducing the state of a system’s configuration as of a previous date/time, may be implicit in requirements supporting Disaster Recovery support, which similarly require the ability to reconstruct the past state of an EHR system in the event of unavoidable system failure. Further alignments between key and foundational eDiscovery requirements may be found within the EHR-S FM, as well as substantial gaps that can be addressed by a number of means, including a formal Functional Profile.

Conclusion: We appreciate ONC interest in the subject matter and in exploring options for next steps. The legal community will undoubtedly appreciate increased attention to the challenges they experience. We look forward to hearing more about ONC priorities and views, planning for “what next”. For your possible further interest, below you will find an extensive reference list (Section H) as well as further background, justification, and resource ideas.

Next Steps:

1. At HIMSS: Informal conversation between ONC and HL7 EHR WG representatives (as schedules permit)
2. Later in March: Teleconference to review this proposal, identify areas of interest and establish corresponding priorities
3. Early April: Draft specific proposal and work plan

Background

A. Key Fundamentals Underpinning the EHR System Functional Model, Release 2

The most basic of EHR System functions is to manage the EHR Record itself: as a persistent chronicle (evidence) of Actions taken in support of individual health and provision of healthcare. These Actions are typically documented as EHR record entries, readily indexed and forming a chronology of:

Who did What When, Where and Why

	Who	(did) What	When	Where	Why
1	Action taken...				
	Actor(s)	Took Action	At Action date/time (with duration)	At Action Location	To fulfill Action Reason or Purpose
2	Then, Action documented in EHR record entry...				
	Actor(s) as Author, Enterer	Recorded Action Details, including Facts, Findings, Observations	At Recording date/time	At Recording Location	To create EHR record entry documenting Action taken

Actors are accountable for Actions taken. Actors are accountable to document (provide evidence of) those Actions by capturing authentic facts, findings and observations in EHR record entries.

Actions include: register patient, schedule appointment, begin/end encounter, perform history and physical, perform assessment, plan care protocol, place order, do diagnostic test, interpret results, report test results, provide basic patient care, provide treatment, plan discharge, create discharge summary, etc.

Accountable Actors – responsible for EHR record content and management – include:

- Individuals
- Organizations, including Providers and Vendors
- Software, including Systems and Devices

Actor	Role/Participation	Target	Frequency
Individuals	As subject of... As performer of... As observer/witness of...	Action taken	Per occurrence
	As subject of... As author/originator of... As scribe/enterer of... As verifier of... As attester of...	EHR record entry content	
Software – systems, devices	As source of...		
Organizations	As performer of...	Action taken	Continuously, uninterrupted
	As steward of...	Persistent EHR-based clinical/business record	
→ Audit/Legal	As inquirers, reviewers of...		Periodically
→ Providers	As implementer of...	EHR system software	At setup
	As configurator of...	EHR system parameters	Periodically
→ Vendors	As developer/proprietor of...	EHR system software	Ongoing

B. Evidentiary Scope of EHR System

What are the key characteristics of EHR records that ensure evidence (of who did what when, where and why) is captured, retained and available to be consistently rendered? See table following. Note close relationship of accountability/authenticity characteristics for both evidentiary and primary use (clinical care, interventions and decision making).

	Use		
	Primary	Evidentiary	Secondary
Evidentiary Scope of EHR System and Applicability of Key Characteristics – Based on Purpose of Use (of EHR record content)			
<i>Showing accountability of Actors for Actions...</i>			
Actors taking Conscious Actions: individuals, organizations	X	X	
Actors taking Programmed Actions: software and devices	X	X	
<i>Ensuring evidence of...</i>			
Identity: individuals (patients and professionals), organizations, software and devices	X	X	
Authentication: of EHR record entry content	X	X	
Source of truth – trust anchor – at point of record entry creation/origination	X	X	
Provenance: of EHR record entry content creation/update	X	X	
Traceability: end-to-end			
a) Forward: source to use, across zero or more points of exchange	X	X	
b) Backward: use to source, across zero or more points of exchange	X	X	
Audit			
a) Audit triggers	X	X	
b) Audit log (trail)	X	X	
<i>Ensuring protection of EHR records and record content...</i>			
Authorization, permission, consent	X	X	
Access (control)			
a) Actor (user)/use authentication	X	X	
Indelibility, non-alteration of record content	X	X	
Encryption			
a) Data at rest	X	X	
b) Data in motion	X	X	
<i>Continuously managing EHR records and record content...</i>			
Unit of record management = record entry	X	X	
Record lifespan			
a) Point of origination to point of use (within/across systems)	X	X	
b) Point of origination to point of deletion (within systems)	X	X	
Record lifecycle events (occurring during record lifespan)			
a) Creation/origination/retention	X	X	
b) Verification	X	X	
c) Attestation/signature	X	X	
d) Update/amendment	X	X	
e) Read/access/view	X	X	
f) Transformation/translation	X	X	
g) Outbound exchange: extraction, output, disclosure, transmittal	X	X	
h) Inbound exchange: receipt/retention	X	X	
i) De-identification, pseudonymization	X	X	
k) Deprecation	X	X	
l) Archival	X	X	
m) Deletion, destruction	X	X	
n) Encryption, decryption	X	X	
o) Place/remove legal hold		X	
User ceremonies (whilst acting as source/author in EHR record lifecycle events a-e)	X	X	
Revision history	X	X	

C. Justification

Following are some of the current challenges in relying on the EHR record for evidentiary and legal purposes:

1. Authenticity risks due to EHR variances from long-accepted records management principles, practices, and Standards. These include:
 - a. Capturing all authors contributing to patient care and to the care record;
 - b. Associating each author with their contributions to care and the care record;
 - c. Indication that a record has been altered (amended) after origination or authentication;
 - d. Accurate rendering of record entry dates, times in outputs, whether electronic or hard copy;
 - e. Systematic capture of sufficient supportive data (metadata) to demonstrate the reliability of the system for authentic records and for meeting end-users' data quality requirements

Since a number of these were included in earlier Certification regimes (CCHIT and MU 1/2/3), testing protocols may already exist, as well as a substantial base of already-conformant EHRs.

2. Insufficient due-diligence reference tools for EHR users to employ in evaluating and minimizing their evidentiary risks, including foundational requirements for means, methods and tools for capture (aka, origination), retention, update and rendering of EHR record content. These would be similar to the standard framework of guidelines for business records, financial and accounting practices, known as the "Generally Accepted Accounting Principles" (GAAP), and also known as *accounting standards* or *standard accounting practices*.
3. Lack of uptake or assurances of indelibility of authorship founded on non-repudiable accountability for EHR record content and including persistence and renewal when record content is originated, updated, rendered, abstracted or exchanged.

These variances introduce unknowable risks to the trustworthiness (and verifiability) of EHR systems and records as sources for data key to national healthcare improvement objectives, such as eQMs.

D. Key Areas in Development at this Time

1. Provenance: To address the anchor point (source of truth) and "chain of custody" beyond creation of Record Entries in EHR Systems. Although provenance may exclude coverage of the first steps in a "chain of trust", provenance support is a necessarily integrity component for a complete end-to-end "chain of trust".
2. Origination: To address the "chain of trust" back to the first capture of Acts or Events into the EHR system, including assuring transparency of key record authenticity and data quality attributes for the source system itself.
3. Audit: To address requirements for normalizing the 24/7/365 capture, persistence, and production of audit events, triggers and logs, to ensure support for digital records trust assurance requirements, necessarily including metadata, throughout EHR Record Entry lifecycle management. (This requirement overlaps substantially with gaps in support for HIPAA Access Audit reporting capabilities.)

E. Key Area Not Known to be in Development at this Time

EHR Systems ability to render outputs that align with longstanding requirements for Release of Information reporting for normal business processes for regulatory compliance and for other legal processes, including risk assessment, risk management/mitigation, and litigation support.

F. Possible Focus Areas, Action Items

1. Objective options
 - a. "Trust Infrastructure: Evidence Profile": a consensus developed and approved (balloted) HL7 EHR Legal (Evidentiary) Record Functional Profile, based on ISO/HL7 10781 – Health Informatics – Electronic Health Record (EHR) System Functional Model, Release 2
 - b. Supplemental Certification – MU or otherwise, starting with voluntary participation
 - c. "Guidance" information: Due-diligence support
 - d. "Public service information": Raising awareness of "Trust Infrastructure: Evidence" topics
2. Environmental scan and outreach
 - a. Further literature search
 - b. Stakeholder interest
 - i. Legal Community: Defense, Plaintiff, Judicial
 - ii. Providers
 - iii. Vendors
 - iv. Government
 - v. Records Management

G. Other Resources and Potentials for Alignment

1. ISO 21089 – Health Informatics – Trusted End-to-End Information Flows
2. Federal Health IT Strategic Plan
3. Office of National Coordinator – Interoperability Roadmap
4. Sedona eDiscovery principles
5. ISO/IEC 27050 – Information technology – Security techniques – Electronic discovery
6. HIPAA Security Rule: Access Audit Report

H. References

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