Project Planning
EHR as Legal Record
(supported by EHR System Functionality)

Team Update
9 February 2016

Legal Record Project
HL7 Side – Initial Action Plan

What	Who	When
Establish Formal <u>Scope</u> and <u>Justification</u>	All	By mid-Feb
Identify <u>Actions</u>, <u>Key Topics</u> to Address	All	By mid-Feb
Identify, <u>Outreach</u> to Potential Participants	All	Ongoing
Join Biweekly Teleconferences	All	Ongoing
Schedule Functional Model Overview Session	Gary	Soon
Project Scope Statement for Legal Record FP	TBD	TBD
New term instead of "Legal Record"	Reed	
Outline Objectives, Targets	All	By mid-Feb

Scope – Actors and Accountability

- Accountability (of Actors):
  - Individuals
    - Actors in support of individual health and provision of healthcare services
    - Actors as authors, scribes, sources of record entries
  - Organizations
    - Actors as business/clinical record keepers
  - Systems
    - Software functions
    - Record management architecture
    - Vendors, software developers

Scope – Authenticity and Integrity

- Providing evidence of:
  - Identity: individuals, organizations, systems
  - Authentication: of EHR entry content
  - Source of truth, trust anchor
  - Provenance: who, what, when, where, why
  - Traceability: end-to-end, to/from source
  - Ceremonies: create/originate, attest/sign, update/amend, read/access, transformation/translation...
  - Revision history

Scope – Record Protection

- Authorization, permission, consent
- Access (control)
  - User/use authentication
- Indelibility, non-alteration
- Encryption
- Audit

Scope – Record Management

- Record Entry = Unit of Record Management
- Record Lifespan
  - Point of Origination to Point of Use
  - Point of Origination to Point of Deletion
- Record Lifecycle Events and "Ceremonies"
  - Create/originate, attest/sign, update/amend, read/access, transform/translate...
  - Revision history
- Standard Format: EHR Record Rendering for Investigation/Evidence Purposes

Justification

- Lack of basics in EHR system capture, retention and rendering of "evidentiary" record content
  - Who did What When (Where and Why)
- Lack of uniform view/description of provenance requirements
- Lack of uniform, reliable and standard audit events, audit logs across systems/vendors
- Lack of evidence of authorship/accountability for record content

Justification

- ## Lack of uniformity in EHR export content
  - Paper vs. electronic content: screen vs. paper rendering
  - Differing outputs, based on various requests
  - Authentication of content

Key Topics

- [See Scope]
- How to interpret EHR content
  - Paper chart is known entity, is tangible
  - EHR chart is un- or much less known entity
- Cross-walk paper to electronic equivalent?

Outreach

- Legal
  - Plaintive, Defense Attorneys
  - ABA, Sedona
- Providers
- Government: ONC, CMS, VA, DoD
- Vendors

Open Questions/Issues

- How deep in audit log to support provenance (metadata)?
  - What is auditable: audit events/triggers
  - What detail is/should be captured, retained, rendered?
- Do EHRs create additional liability, in terms of evidence?
  - Or reduce exposure/liability?
- Request is often for "any electronic information", beyond EHR record content

Objectives/Targets

- ## Outline mutual objectives
  - Which resonate with ONC?
  - Here's what lawyers need
  - Here are identified problems with current EHRs
  - Include regulatory and legal investigations

- ## Targets
  - Federal HIT Plan?
  - ONC Interoperability Roadmap?
  - Sedona eDiscovery principles?
  - Supplemental Certification (MU or otherwise)?

Legal Record Project
Initial Participants

Participant	Affiliation
Elise Anthony, JD	US Office of National Coordinator
Michael Lipinski, JD	US Office of National Coordinator
Mark Knee, JD	US Office of National Coordinator
Karson Mahler	US Office of National Coordinator
Gary Dickinson	CentriHealth, HL7 EHR WG Co-Chair
Reed Gelzer, MD	Provider Resources, HL7 EHR WG Co-Chair, RM-ES Co-Facilitator
Diana Warner	AHIMA, HL7 EHR WG Co-Chair, RM-ES Co-Facilitator
Chad Brouillard, JD	Foster and Eldridge, LLP
Don Mon	Research Triangle Institute
Michelle Dougherty	Research Triangle Institute
Kim Baldwin-Stried Reich	KBS Consulting, Lake County Physicians Association

Reference Materials

- Healthcare IT News, 4 February 2016:
  - "Amid surge in malpractice lawsuits, EHRs often targeted in litigation, attorney says
  - "Providers often wind up defending their electronic health records, rather than what got them sued in the first place, Mary Re Knack will explain at HIMSS16"
  - http://www.healthcareitnews.com/news/amid-surge-malpractice-lawsuits-ehrs-often-targeted-litigation-attorney-says

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Reference Materials

- Healthcare IT News, 13 April 2015:
  - "EMRs can be costly in malpractice suits
  - "HIMSS15 session shows the perils of poor documentation"
  - http://www.healthcareitnews.com/news/emrs-can-be-costly-malpractice-suits

- Healthcare IT News, 28 September 2010:
  - "At AHIMA, defining 'The Legal EHR'"
  - http://www.healthcareitnews.com/news/ahima-defining-legal-ehr

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Reference Materials

- HIT Policy Committee recommendations and RM-ES advice to John Halamka, then Vice-Chair HIT Standards Committee, 12 August 2013
  - https://www.dropbox.com/s/9k142gmiy2xrxt3/Halamka-Legal%20Record-HL7%20RMES%20Response-20130812.docx?dl=0
- ISO/HL7 10781 EHR System Functional Model Release 2
  - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

Reference Materials

- ONC Interoperability Roadmap v1.0
  - https://www.healthit.gov/policy-researchers-implementers/interoperability

- End-to-End Interoperability of Health Data/Records – Validation Framework to ensure Affirmative Trust Decision
  - http://wiki.hl7.org/images/c/cd/Validation_Framework-End2End_Interoperability-Matrix-Slides-20151113.pdf