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

Team Update
9 February 2016
## Legal Record Project

### HL7 Side – Initial Action Plan

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

9 February 2016 EHR as Legal Record Project Planning
Legal Record Project

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
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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
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Scope – Record Protection

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

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

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

• Healthcare IT News, 28 September 2010:
  – “At AHIMA, defining 'The Legal EHR’”
Legal Record Project

Reference Materials

• HIT Policy Committee recommendations and RM-ES advice to John Halamka, then Vice-Chair HIT Standards Committee, 12 August 2013

• ISO/HL7 10781 EHR System Functional Model Release 2
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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