Health Level Seven
Records Management & Evidentiary Support (RM-ES)

Supporting Clinical Documentation for Legal and Billing Purposes

HIT Policy Committee
Meaningful Use WG/Certification & Adoption WG
Public Hearing

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Donald T. Mon, PhD
RTI International
Health Level Seven

Donald T. Mon, PhD

- RTI International (Research Triangle Institute)
  - Senior Director, Center for the Advancement of Health IT (CAHIT)
  - Director, Standards & Interoperability
- Health Level Seven (HL7)
  - Chair, Board of Directors
  - Co-chair, EHR Work Group – in which Records Management & Evidentiary Support (RM-ES) standards development occurred
  - Here representing HL7

Background

- Clinical documentation presumes a legally sound record for all clinical and business purposes, the objective of HL7's standard for RM-ES
- There are long-standing and universal (U.S.) rules, best practices, research, and standards related to RM-ES
  - Federal Rules of Evidence, Civil Procedure
  - AHIMA: Best practice guidance
  - RTI: Enhancing data quality research
  - HL7: RM&ES FP
- However, there is no specific RM-ES *policy* for HIT (e.g., EHR, administrative, & clinical systems; HIE) to assure source trust

Key Point of This Testimony

- An initial RM-ES policy for HIT is achievable; it can focus on:
  - Data quality, data integrity
  - User authentication
  - Information attestation and authorship
  - Amendment, correction, alteration process
  - Record lifecycle management
  - Minimum metadata set and retention (provenance)
  - Health record outputs, including records for exchange

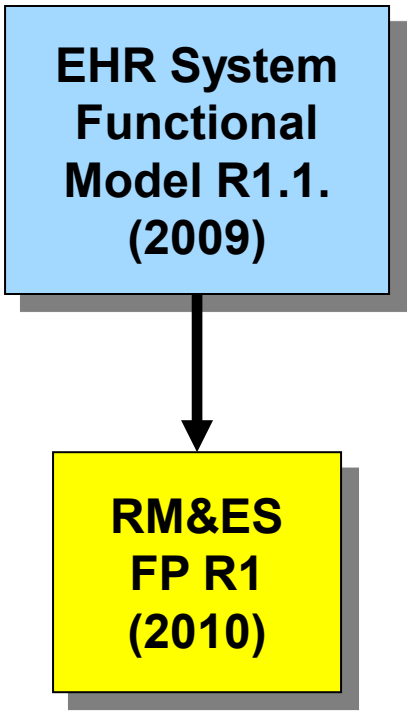
These are areas in which HL7 RM-ES standards specifications exist

Key Point of This Testimony (cont.)

- The Record Infrastructure section of the EHR System Functional Model Release 2 (EHR-S FM R2, 2013) represents HL7's best, current consensus work on EHR-S functions and criteria for trusted record management and evidence of actions taken
- The EHR-S FM R2 can support, and be referenced in, a RM-ES policy for HIT

Records Management & Evidentiary Support Functional Profile (RM-ES FP)

How It All Got Started



- Originally developed as a functional profile (a subset) of the Joint HL7/ISO EHR System Functional Model (EHR-S FM) 10781 R1.1 standard
- Based on published rules, best practices, research, and standards, including:
  - Federal Rules of Evidence, Civil Procedure
  - AHIMA: Best practice guidance
  - RTI: Enhancing data quality research
  - Paul, G.L.: Foundations of Digital Evidence

The Need for RM-ES and the RM-ES FP

- **Without data quality, data integrity, and RM-ES, inaccurate health information could be exchanged or submitted to a quality reporting agency, making the meaningful use of that health information less effective**
- **Inadequate records management/evidentiary support practices could reduce trust in the health record, the authenticity of the authors, as well as the data**
- **An EHR-S must be able to:**
  - **Create, receive, maintain, use and manage the disposition of records for evidentiary purposes**
  - **Capture, manage, and render metadata as evidence for the reliability of the record**
  - **Document "who did what when"**
  - **Preserve evidence throughout care delivery and HIE processes**

Primary and Secondary Uses of EHR-S Data Presume RM-ES Capabilities

- An EHR-S conforming to an RM-ES standard can help an organization maintain a sound health record for clinical, legal, business, and disclosure purposes
- There are open issues about the use of electronic records for evidentiary purposes (e.g., admissibility of medical records); an RM-ES standard can help address those issues
- EHR-S have had to satisfy multiple purposes beyond documenting care (e.g., preventing fraud and detecting/deterring abuse); an RM-ES standard can support these multiple purposes
- There is high variability in basic EHR-S documentation (e.g., reliable authorship of records, treatment of amendments and corrections, and record management auditing capabilities); an RM-ES standard can significantly reduce this variability

Example of How the RM-ES FP Is Based on Principles First: Minimum Metadata Set

Description:

- Metadata provides electronic evidence that describes record characteristics such as the origin, usage and modification. EHR-S information must maintain a minimum set of metadata on medical record information for the legally prescribed timeframe in accordance with organizational policy to retain legal validity of the record.

Legal Rationale:

- Metadata helps to validate the authenticity, reliability, usability and integrity of electronic information over time and enable the management and understanding of electronic information (physical, analogue or digital).
- The capture and retention of select pieces of metadata provides support for the validity of the record and is necessary to establish the trust by a receiving party in data that is being exchanged.

How the RM-ES FP Captures the Principles, Specifies Functional Requirements and Conformance Criteria

IN.2.2.1.1	F	EF [2010]	Point of Record Minimum Metadata Set and Retention	Statement: Metadata provides electronic evidence that describes record characteristics such as the origin, usage and modification. EHR-S information must maintain a minimum set of metadata on medical record information for the legally prescribed timeframe in accordance with organizational policy to retain legal validity of the record. **Description/Legal Rationale:** EHR-S information and records that are part of the organization's formal medical record must include a minimum set of metadata (audit record data) retained over the lifespan of the record/information. This concept is similar to the properties linked to an electronic document in which a minimum set of metadata is retained for the life of the document and provide context on who created a document, when, modifications and access.. Metadata helps to validate the authenticity, reliability, usability and integrity of electronic information over time and enable the management and understanding of electronic information (physical, analogue or digital). Metadata supports the interoperability strategies by enabling the authoritative capture of records created in diverse technical and business environments and is sustained	IN.2.2	1. The system SHALL capture and retain the author(s) of record/information that is part of the organization's medical record. 2. The system SHALL capture and retain the time stamp for an object or data creation, modification, view, deletion as required by IN.2.2 cc 3, 4, 7, 8 for a record that is part of the organization's medical record. 3. The system SHALL capture and retain the viewer of a record as required by IN.2.2 cc 10 for a record that is part of the organization's electronic medical record. 4. The system SHALL capture and retain the author(s) of a change in a record as required by IN.2.2 cc 9 for a record that is part of the organization's medical record. 5. The system SHALL capture and retain the change history of a record as required by IN.2.2 cc 15 for a record that is part of the organization's medical record 6. The system MAY produce metadata that identifies the source of non-originated data (e.g. pre-positioned, templated, copied, duplicated, boilerplate, etc.).

Excerpt from HL7 EHR-S RM-ES Functional Profile Standard R1

HL7's Best, Current Work on RM-ES: EHR-S FM R2 Record Infrastructure Section

- Incorporates key provisions of:
  - ISO 21089 - Trusted End-to-End Information Flows (2004)
  - HL7 EHR Interoperability Model (2007)
  - HL7 EHR Lifecycle Model (2008)
  - HL7 Records Management & Evidentiary Support Functional Profile (2010)

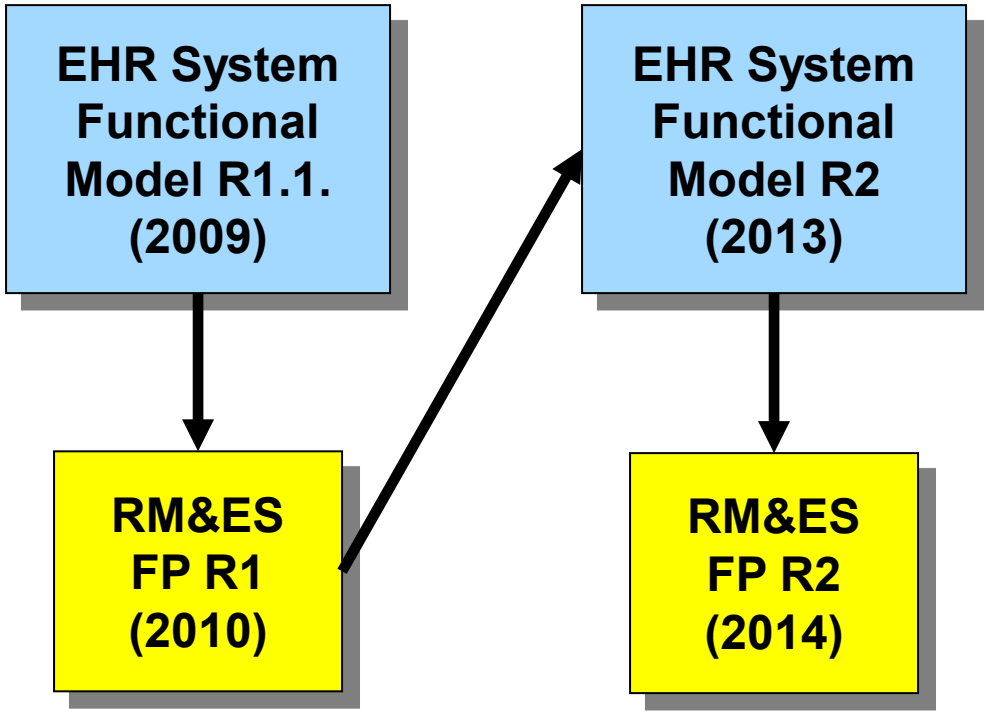
Record Infrastructure	RI.1	Record Lifecycle and Lifespan
	RI.2	Record Synchronization
	RI.3	Record Archive and Restore

RI.1.1	**Record Lifecycle**
RI.1.1.1	Originate and Retain Record Entry
RI.1.1.2	Amend Record Entry Content
RI.1.1.3	Translate Record Entry Content
RI.1.1.4	Attest Record Entry Content
RI.1.1.5	View/Access Record Entry Content
RI.1.1.6	Transmit and/or Disclose Record Entries
RI.1.1.7	Receive and Retain Record Entries
RI.1.1.8	De-identify Record Entries
RI.1.1.9	Pseudomynize Record Entries
RI.1.1.10	Re-identify Record Entries
RI.1.1.11	Extract Record Entry Content

HL7's Best, Current Work on RM-ES: EHR-S FM R2 Record Infrastructure Section

- Describes 24 record lifecycle events
- Each record lifecycle event has specified an extensive set of metadata (PCAST-like), including provenance events (originate, amend)
- Four lifecycle events relate to exchange (output/report, disclose, transmit, receive) and specify consents and authorizations related to the exchange content, when applicable
- The S&I Framework (Cross-Initiative) Simplification Work Group has taken 13 of the EHR-S FM R2 Records Infrastructure lifecycle events and mapped them to 13 S&I Initiative Use Cases (and their 33 Scenarios and Event Steps), inclusion of additional events is anticipated

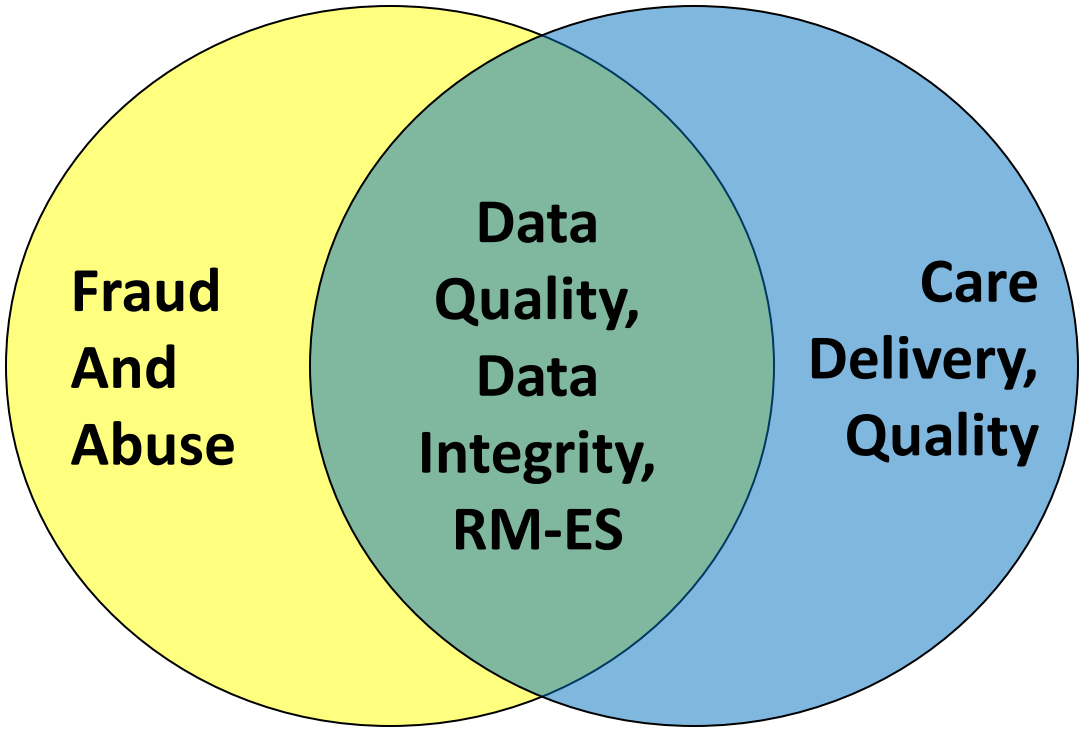
Broad Interest and Support for RM-ES, Next Steps



Six International SDOs:
HL7, ISO, CEN, IHTSDO, GS1, CDISC

- EHR-S FM R2 currently in joint ballot with 6 international SDOs
- ISO TC215 18-0-13 vote in the 1st round R2 ballot indicates broad international interest and support
- RM-ES FP R2 (based on EHRS FM R2) in development; likely balloted in 2014

The Same RM-ES Functionality in EHR-S Can Support Multiple Purposes of EHR Systems



Reference: RTI. (2007). Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems

Selected References

- Federal Rules of Evidence (http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/2010%20Rules/Evidence.pdf)
- Federal Rules of Civil Procedure (http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/2010%20Rules/Civil%20Procedure.pdf)
- Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems (http://www.rti.org/pubs/enhancing_data_quality_in_ehrs.pdf)
- AHIMA: www.ahima.org; click on Body of Knowledge, search for RM-ES, legal EHR

Thank You for This Opportunity

Donald T. Mon, PhD

Chair, HL7

Co-chair, HL7 EHR WG

Senior Director,

Center for the Advancement of Health IT

Director, Standards & Interoperability

RTI International

(708) 250-4374

donmon@rti.org