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Electronic Health Records Systems' Vulnerabilities

EHR Risk Management and Litigation – Mock Deposition and Analysis

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Analysis

- Attribution: the ascribing of a work to an author
- Authenticity: “It is what it purports to be…”
- When is a signature a signature?
- Summary: Oversight as improvement

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Attribution: Definition

1 : the act of attributing; *especially* : the ascribing of a work (as of literature or art) to a particular author or artist

"Attribution." *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 26 Nov. 2016.

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Attribution: EHR Variability

Attributing one author's documentation to another
- Same date and time
- Different date and time
- Same patient date and time
- Different patient date and time

Attributing one author's services to another
- Same date and time
- Different date and time
- Same patient date and time
- Different patient date and time

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Attribution

Templates, Copy Forward, and Cloning

- Attributing an institution's or an individual's templated input as if it was spontaneous and unique to an individual author
- Attributing a device's input as a human's input
- Attributing a human's input as a device input
- Attributing prior information and work from a different date, time, patient, or provider to another

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Authenticity

"Federal Rule of Evidence 901 requires that evidence be "authenticated" with other evidence "sufficient to support a finding that the item is what the proponent claims it is.""

Under Rule 901(a), FRE, "To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is."

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Authenticity

"From an EHR perspective, authenticity has three logical components:

- For what purpose is the document or record offered?
- Is the document or record what it purports to be at the time relevance is asserted? <Clinical v. Legal "Relevance">
- What evidence can be used to authenticate the document or record?"*

*From "Diagnosing and Treating Legal Ailments of the Electronic Health Record: Towards an Efficient and Trustworthy Process for Discovery and Release of Information, pp. 24-25

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Signature/Professionalism

What is a “signature”?

What does it mean?

- I executed this event record (but take no responsibility for its accuracy)
- “Dictated but not read”

What does it do? (Testing)

- “Closes” a record
- “Closes” a record and any edits are amendments (and marked as such)
- Binds the signature to content; if tampering, detected

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Authenticity and Governance

Assuring sound science, sound business practices, and Compliance.

Ex: Templating records requires development, review, approval, and periodic re-assessments

Ex: System-sourced, previously captured information is clearly identified so end-users can triage

Ex: If an Evaluation and Management Service for CMS beneficiary, then adherence to CMS Documentation Guidelines (authoring)

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Signature/Professionalism

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Summary from the Oversight POV: **Determining what works , what doesn't**

a) "Emulating paper charting/routing"

b) "Customization"

c) Attribution

d) Authenticity

e) Signature (who's accountable)

f) Oversight

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Oversight:
Determining what works , what doesn't

(Program) Integrity: Effectiveness, Efficiency

- Accurate records of care
  - Workload
  - Value
  - Outcomes
  - Costs
- Accurate knowledge of care
- Accurate payment for care

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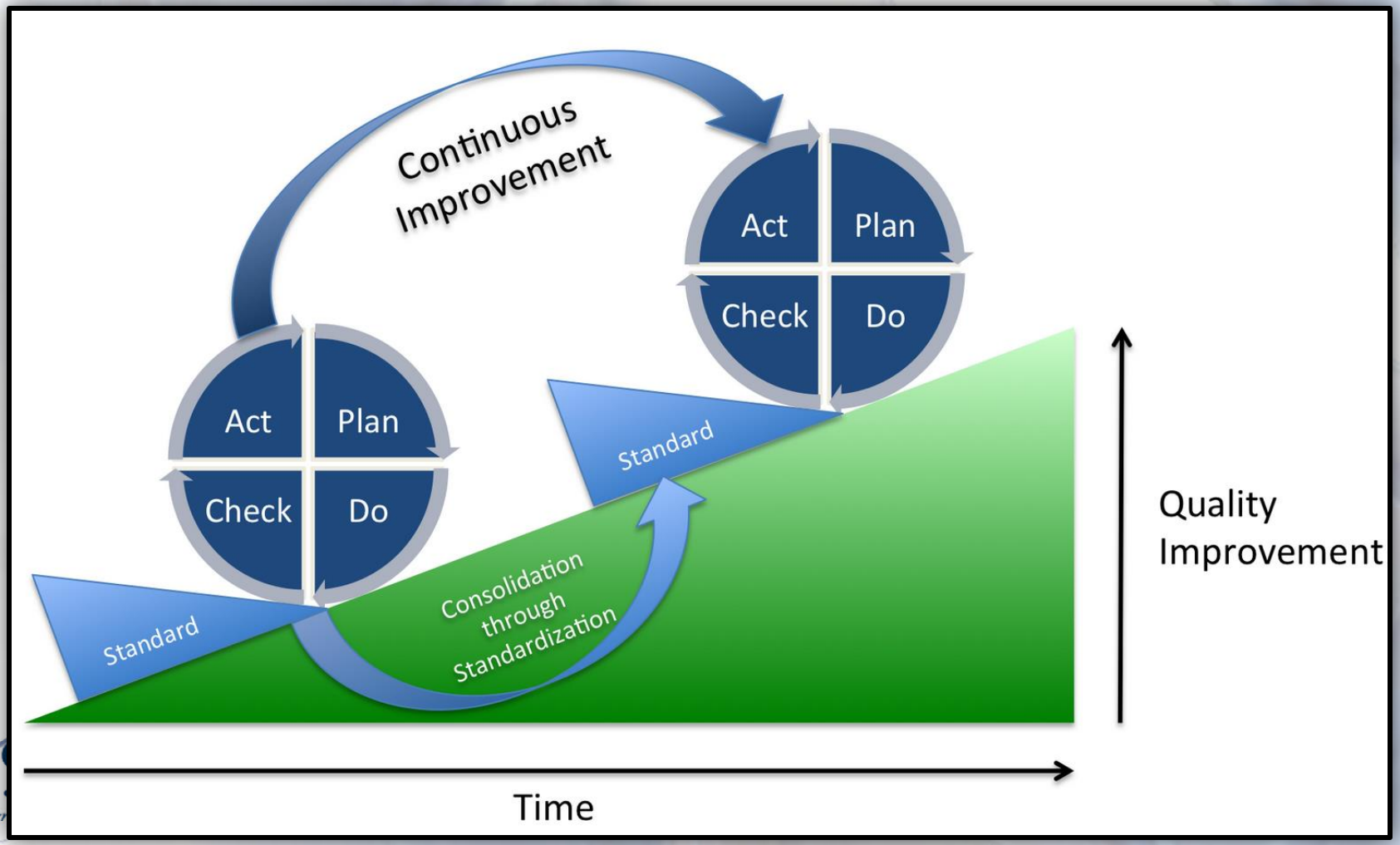
Oversight:
Determining what works, what doesn't

1. Identify a measurable problem
2. Improve it 3. Prove it, 4. Repeat



David Brailer, MD HIMSS 2005

"Healthcare is a remarkable and unique industry. It is the only industry that gives days to our lives."

"Last year, President Bush highlighted health IT as an important priority for the Administration. In the 2004 State of the Union Address, he said: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care.""

http://www.providersedge.com/ehdocs/ehr_articles/DavidBrailerRemarksHIMSS2005.pdf Pages 2 and 3

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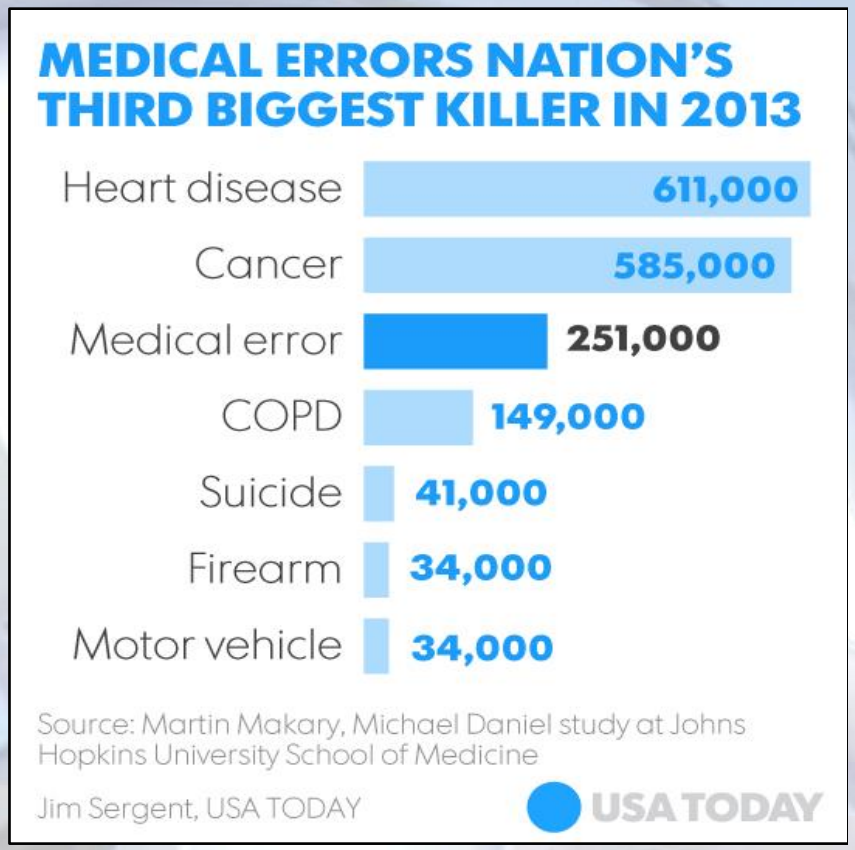
US Healthcare System

- US spends the most, but performs relatively poorly compared to other nations
- More than 250,000 Americans die annually from preventable hospital errors
  - Does not include outpatient, secondary care
  - Does not include non-fatal injuries and near misses
- Total cost of preventable adverse events (lost income, lost household production, disability, health care costs) estimated $17 to $29 billion



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Needed: A Common Operational Picture

- 80% of serious medical errors involve miscommunication *during the hand-off* between medical providers
  - The typical primary care physician (PCP) coordinates care with 229 physicians across 117 practices
- 18% of medical errors leading to adverse drug events are due to missing data
- An emergency department was given access to additional patient data through a Health Information Exchange (HIE):
  - 92% consulted outside information because local information did not answer critical questions
  - 38% found unanticipated info that proved useful in care
  - Decision-making was affected in 32% of cases

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Our 300+ Year Rule of Law

Recognizes the unique shift from physical artifact to digital

Supportive, overlapping objectives with Medicine as Science and as business for a “common operational picture”

Improvement requires accurate information from reliable EHRs

The Sedona Conference

“Moving the law forward in a reasoned and just way”

See the Draft for Comment article, “Diagnosing and Treating Legal Ailments of the Electronic Health Record: Towards an Efficient and Trustworthy Process for Discovery and Release of Information” at https://s3.amazonaws.com/IGG/publications/WG1/EHR_Public+Comment_Draft_11-22-16.pdf

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BREAK

Following slides for the 2:15 section

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Innovation and Problem-Solving: Standards, Technical & Developer Perspectives

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Success Path:
To Verify

"To *evaluate the compliance of data objects* with regulations, requirements, specifications, or other internally imposed conditions based on organizational policy. Contrast with validate."

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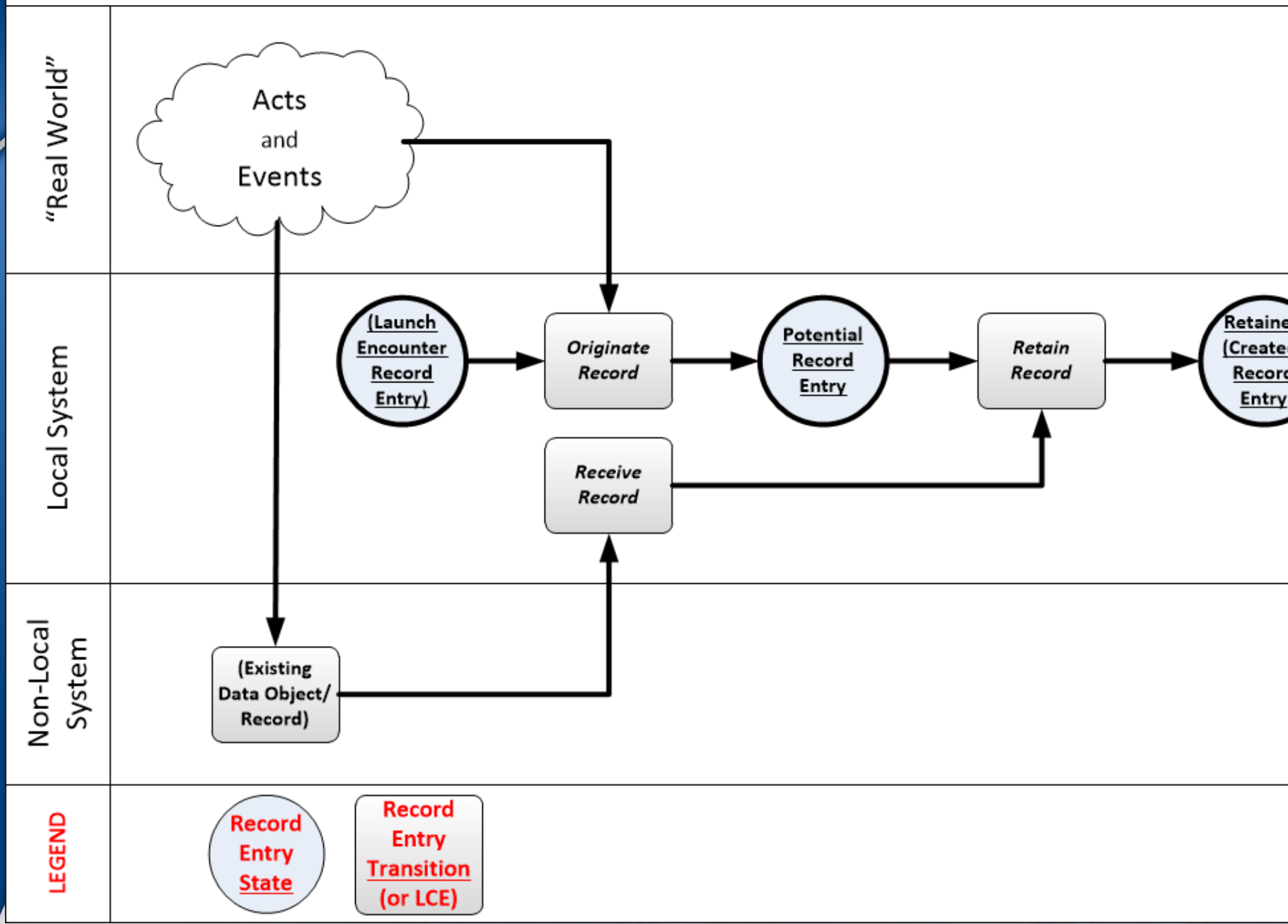
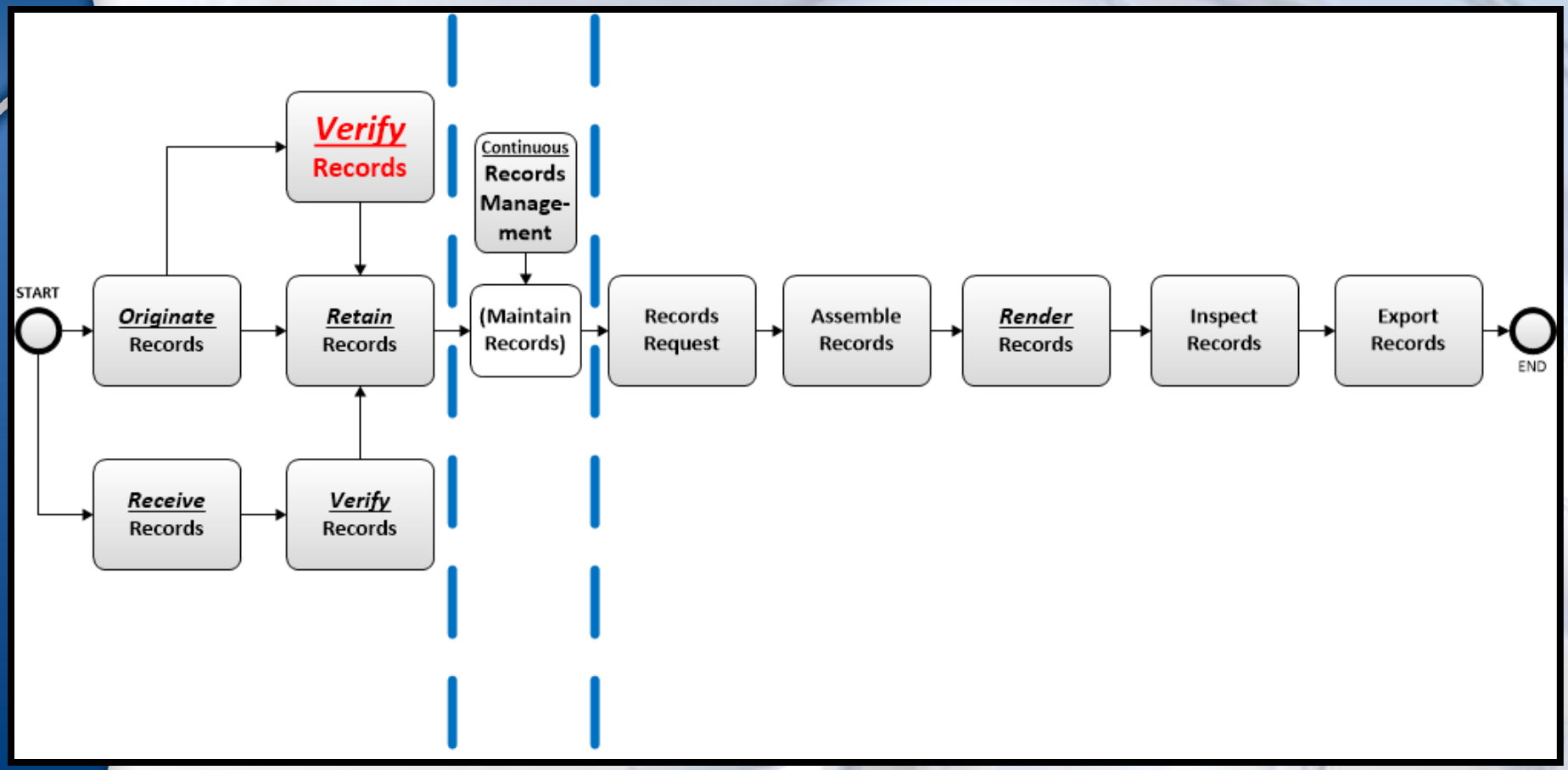
EHRs Capturing Real World *Acts or Events* into *Record Entries (REs)* via *Record Lifecycle Events (LCEs*



“To Verify” for “End-Use Export”



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To Verify End-Use Meaning Compliance

The accurate patient record

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To Verify End-Use Meaning Compliance

The accurate patient record
for _____

Presumes end-use specifications that align with end-use meaning

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“To Verify”

- Could be automated
- Could start with a very small, minor requirement
- Could initially be voluntary (or optional with benefit(s))
- Could become increasingly complex over time

Capability currently in progress (in nascent form) in upcoming version of FHIR* specification included in recent ballot.

*FHIR: Fast Healthcare Interoperability Resources

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To Verify, continued

- Now available as a linchpin and critical opportunity for Record Authenticity and its derivatives (Compliance and Program Integrity, Oversight)
- Leverages the ONC S&I Lab Results Interface Initiative
- Leverages the FHIR capability of managing diverse reference resources (ex: Specifications library)

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Background/References

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To Verify

- ISO/HL7 10781 - Electronic Health Record System Functional Model, Release 2
- Normative Standard for both HL7 and ISO
- aka FM R2 or R2

R2's Record Infrastructure (RI) Section utilizes "Lifecycle Events" from ISO 21089 (now in revision)

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RI.1.1 24 + 3 Lifecycle Events

Originate and Retain RI.1.1.1	Archive RI.1.1.14
Receive and Retain RI.1.1.8	Restore RI.1.1.15
Amend RI.1.1.2	Destroy or Identify Record Entries as Missing RI.1.1.16
Verify (Added Lifecycle Event #25)	Re-Activate RI.1.1.18
Translate RI.1.1.3	Merge RI.1.1.19 Function
Attest RI.1.1.4	Unmerge RI.1.1.20
View/Access RI.1.1.5	Link RI.1.1.21
Output/ Report RI.1.1.6	Unlink RI.1.1.22
Disclose RI.1.1.7	Legal Hold RI.1.1.23
Transmit RI.1.1.8	Legal Hold Release RI.1.1.24
De-Identify RI.1.1.10	Encrypt (New)
Pseudo-mynize RI.1.1.11	Decrypt (New)
Re-Identify RI.1.1.12	
Extract RI.1.1.13	

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“To Verify”

Going Forward…

- Advocates/End-users
- Use Case(s)
- Home Health, Lab, DME as CMS interest areas

Launch Opportunities

- FHIR Lifecycle Event Definitions
- Signal vendors: Building better EHRs as best option
- Signal users: Due-diligence required

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Contact Information

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