HL7 EHR WG – "EHR as Legal Record" Project – Benefits and Savings (as fact and prospect) 17 May 2016			
	Benefit	Savings (to Whom)	Reference(s)
Supporting priority "legal" attributes of: (a) Audit Trail Usability, (b) Export Distortion Reduction and (c) eDiscovery.			
1	Ensuring common methods of capturing, retaining and rendering evidentiary metadata in EHR systems and records, across providers, across geographic locations Attributes supported: a, b, and c	• Savings from consistent EHR record management functionality • Savings from consistent audit events and audit trails • Savings from common traceability functions • Savings from consistent evidentiary practices Accruing to: all parties and especially auditors, providers, claimants, defenders	• ISO/HL7 10781, EHR System Functional Model Release 2 • ISO 21089, Trusted End-to-End Information Flows (ISO DRAFT Technical Specification, submitted for ONC review, with permission of ISO TC215 Secretariat) • HL7 Fast Interoperable Resources (FHIR) EHR Record Lifecycle Event Implementation Guide
2	"Minimum Standard" Audit Trail reporting relative to entry origination and provenance over time Attributes supported: a, b, and c	• Support industry consistency for audit trail content and rendering (usability) • Support requirements for consistency and accuracy of accounting for the fundamental attributes of authorship and timeliness • Reduction of errors arising from mis-attribution of source data (medication errors arising from machine-generated rather than clinician originated care. • Reduction of litigation costs and time associated with trying to prove or disprove idiosyncratic, filtered or non-usable audit trails. Accruing to: Adopters of EHRs, Vendors, Litigants, Judiciary, Professional Liability Insurers	Federal Rules of Evidence - Rule 803 Business Records Exception
3	Support for Federal Rules of Civil Procedure (FRCP) – Requirements for cooperation between parties. Objectives: just, speedy and inexpensive. *Requires standards supporting basic formats and content for Release of Information processes. Example: As a basic starting point, a "minimum necessary" or "minimally fit" Release of Information report output including content for episode-of-care records and other records an organization stipulates as its "designated record set" for patient care.* Attributes supported: b and c	• Savings from uniformity and common legal practice • Savings from widespread adoption Accruing to: plaintiff and defense	US Federal Rules of Civil Procedure

4	Reducing negative impact of EHRs on eDiscovery and Litigation
	
	Attributes supported: a, b, and c
		• Savings from potential reduction in rates providers pay for insurance through use of certified EHR Systems providing accuracy and authenticity as collateral benefits of supporting legal process requirements
		• Savings from uniform EHR record system functionality:
		  • Capture audit events
		  • Capture and maintain audit entries in audit trails
		  • Extract and render audit trail content, detail and summary
		• Preserve original displays of EHR data (Consider assuring technical means to capture, render, at the least those as used in course of direct patient care and medical decision-making)
		• Encourage development of read-only production of EHR display screens to reduce discovery and litigation costs trying to access screen clinicians saw and used during origination.
		
		Accruing to: plaintiff and healthcare defendants, malpractice insurers, clinical decision making and patient safety analysis of risks and first-cause in errors or "near-miss" events.
			• Doctors Company Claims Study (Closed Claims)
			• CRICO Malpractice Claims Analysis
			• AHIMA - EHR Systems a Difficult Witness in Court
			
			Numerous eDiscovery impact references in Appendix A

5	Enabling Provisions of Healthcare Fraud and Abuse Control Act (HCFAC) • Absence of recommended data quality/anti-fraud safeguards in EHRs have impact. Attributes supported: b and c	• Savings from efficiency and effectiveness of WFA programs: Rolling three year average for most recent FY 2015, submitted 2/2016, was $6.10 per $1.00. Accruing to: providers, payers	HHS OIG Compendium of Unimplemented Recommendations and Enforcement Actions (p. 9 of 84) "Health Information Technology: ONC and CMS should collaborate to develop a comprehensive plan to address fraud vulnerabilities in electronic health records."
6	Developing a formal reference establishing accountability, key tenets, uniform and common practices for managing and preserving electronic health data/records, similar to the Generally Accepted Accounting Principles (GAAP) standards Attributes supported: a, b, and c	• Savings from system functionality ensuring consistent EHR record management practices • Savings from interoperability improvements based on broad-based commonalties Accruing to: providers, claimants, defenders	GAAP Accounting Standards ARMA's GARP Guidelines AHIMA's Information Governance models

7	False Claims Act: Example-absence of documentation attribution requirements (who actually provided what services) means clinical services of lower value (less qualified, possibly unqualified personnel) get paid at rate of "apparent" provider. Attribute supported: c	• Savings from proper attribution of documentation • Reduction of errors arising from mis-attribution of source data (medication errors arising from machine-generated rather than clinician originated care). • Accurate report • Accurate clinician workload attribution for improving resource distribution for patient care, efficiency and risk analysis (Calculation done for a upper Midwestern org based on assumption of 20% of encounters at $5500 to $11,000 per "event" quickly rose to hypothetical billions in fines.) Accruing to: patients, payers	(Example: Unpublished report submitted to HHS OIG 2008)
8	Data Quality management costs: Recent presentation at a Northeastern HIMSS meeting by an HIE, CEO noted that, "data quality normalization is their biggest headache and highest cost" because they have no way of evaluating, much less controlling, the reliability of source systems' abilities to support record authenticity and data quality. Their exchange has had to expend much effort and expense to assure that a given data set from one organization is compatible with the expectations for data quality at the other HIE participants. Without a uniform set of EHR functional requirements to reference, these efforts remain ad hoc. Attributes supported: a, b, and c	• Savings from assured reliable systems, record authenticity and data quality. • Savings from assured uniformity of EHR system functionality Accruing to providers, all record users	Recommend contact with Micheal L. Gagnon, CTO for Vermont Information Technical Leaders (operating the regional HIE) who spoke for Northeastern US HIMSS Chapter,
9	Normal business operations costs: Contacts in healthcare organizations note (anecdotally) a 10X+ cost increase in establishing and producing Release of Information outputs for responding to normal and recurring requests for records for non-clinical purposes (not for patient care services supports) Attribute supported: b	• Savings from uniform outputs related to Release of Information requests Accruing to: providers (record-keepers)	At Kathy Kenyon's request last year, a number of attorneys conveyed their direct experiences in summary to ONC. These, presumably, are available to ONC for review. (This initiative could be restarted and advanced if of interest.)

Regarding Patient Safety...			
10	Patient Safety – Preventing Data Integrity Failures [ECRI recommendations] • Use a computer-user interface that is visible, readable, understandable, and consistent. • Clearly display all patient information on all computer screens. • Limit the number of patient records displayed on a screen at one time. • Require a patient identification check at various points in the care process. • Provide evidence-based order sets for common tasks and conditions. • Minimize free-text entry of orders. • Minimize interruptions from alerts to high-risk, high-priority conditions. • Fully test a health IT system, including any upgrades and system improvements. • Provide comprehensive training to health IT system users. • Support event reporting and other methods to identify and address health IT problems.	• Savings from avoidance of harm to patients • Savings from avoidance of unsafe conditions and practices • Savings by promoting clarity and consistency in computer-user experience • Savings from avoidance of identity errors • Savings from fully tested systems and thus avoidance of errors, downtime and other adverse incidents • Savings from knowledge transfer (training) and better practice resulting therefrom • Savings from prevention, based on event reporting and corrective responses to identified errors, omissions or anomalies • Accruing to: patients, providers, payers, vendors, employers	ECRI Patient Safety Top 10 ECRI Study - Data Errors in Health IT HL7 EHR WG – EHR System Usability Project
Regarding Federal Policy...			
11	Alignment of ONC (US) regulations, policies and inspection/testing programs with international standards allows US-based EHR System vendors (and their conforming systems) a competitive advantage in international markets	• Savings: Reduced cost of system design, development, testing, implementation and ongoing support across national boundaries • Savings: Reduced risk if developed/proven elsewhere Accruing to: provider, EHR system developer	Standards Boost Business
12	Use of voluntary consensus standards, whenever practicable and appropriate, is intended to achieve the following goals: • Eliminate the cost to the government of developing its own standard • Decrease the cost of goods procured and the burden of complying with agency regulation • Provide incentives and opportunities to establish standards that serve national needs • Encourage long-term growth for U.S. enterprises	• Savings as cited (← in left column) Accruing to: US federal agencies, US taxpayers	US Office of Management and Budget (OMG) Standards Policy OMB Circular A-119, published 27 Jan 2016

	• Promote efficiency and economic competition through harmonization of standards • Further the policy of reliance upon the private sector to supply government needs for goods and services		
Regarding US and International Standards...			
(1)	Ensuring common methods of capturing, retaining and rendering evidentiary metadata in EHR systems and records, across providers, across geographic locations	[See Row 1 above.]	• ISO/HL7 10781, EHR-S FM R2 • ISO 21089, Trusted End-to-End Information Flows
13	Ensuring common definitions of key terms, e.g.: accountability, event, action, actor, agent, author, enterer, role, audit, audit trail, audit report, evidentiary record, record entry, record lifespan and lifecycle, persistence, indelibility, fidelity to source, access, authorization, authentication, authenticity, traceability and more	• Savings from common community of expression in terms, concepts and knowledge Accruing to: all parties	• ISO/HL7 10781 • ISO 21089
Generally...			
14	Standards and related compliance programs help save money and improve performance, quality, safety, and reliability	• Savings from investment in standards and compliance programs as cited (in left column) • Savings from cross-border interoperability • Savings to R&D budget with less investment • Savings by incorporation of standardized technologies and terminologies Accruing to: all parties	Standards Boost Business
15	Standardization and conformity assessment activities lead to lower costs by reducing redundancy, minimizing errors, and reducing time to market		
16	Standards make cross-border interoperability possible, ensuring that products manufactured in one country can be sold and used in another		
17	Businesses reduce the economic risk of their research and development activities by participating in standardization		
18	Businesses lower their overall R&D costs by relying on previously standardized technologies and terminologies		

Appendix A

Federal and State Laws Regarding E-Discovery and Production of Electronic Records A new set of amendments to the Federal Rules of Civil Procedure (FRCP) were enacted on December 1, 2015 that are significantly changing the process of discovery and production of electronic health records at the Federal, State and Local Court Levels	Source(s): FRCP Amendments Enacted 12-1-2015 http://www.supremecourt.gov/orders/courtorders/frcv15_5h25.pdf Impact of 2006 FRCP Amendments at Federal and State Court Level: http://www.bna.com/uploadedFiles/Content/Products/Legal_and_Business/Subscriptions/Litigation/Allman%20EDiscovery%20Rules.pdf Enactment of EDiscovery rules at State level: http://www.ediscoverylaw.com/state-district-court-rules/ http://www.law360.com/articles/600393/tips-for-managing-e-discovery-in-state-courts EDiscovery at the Local Court level: http://abovethelaw.com/2015/07/e-discovery-update-know-your-courts-local-e-discovery-rules/

EDiscovery rules regarding proportionality and the preservation of information along with the widespread adoption of EHRs and exchange of clinical information are mandating the development of new standards and processes by which to value electronically stored clinical information.	See: 2015 FRCP Amendments – What You Need To Know http://abovethelaw.com/2015/12/everything-you-need-to-know-about-the-new-frcp-amendments/ 2015 Amendments – "The Dawning of the Goldilocks Era" Discussion on Proportionality Rule, Preservation and Costs https://e-discoveryteam.com/2015/11/11/2015-e-discovery-rule-amendments-dawning-of-the-goldilocks-era/ Proportionality Rule In E-Discovery – Impact of 2015 Amendments http://blog.kcura.com/relativity/blog/3-implications-of-the-frcp-changes-to-proportionality https://www.hunton.com/files/News/95a86cf8-e593-4c14-8210-8b5eab82435c/Presentation/NewsAttachment/a3ce6cea-9f97-41a9-b965-8c49b85bc548/new-federal-rules-aim-to-promote-proportionality-in-discovery.pdf http://businessoflawblog.com/2015/11/frcp-changes-proportionality/ Preservation – New Rule 37(e) https://www.law.cornell.edu/rules/frcp/rule_37 http://www.rpb-law.com/images/pdf%20folder/RPB_Rule37(e)_WhitePaper.pdf http://www.exterro.com/blog/frcp-amendments-breakdown-of-newly-revised-frcp-37e/ ARMA Paper Article on Rule 37(e) https://www.arma.org/r1/news/newswire/2015/12/22/what-does-frcp-rule-37(e)-mean-now 2015 EDiscovery Caselaw Trends http://www.insidecounsel.com/2015/12/28/2015-e-discovery-case-law-trends

Federal Rule 26(c) Gives a Court Discretion to Order Cost-Shifting or Cost Sharing	Sedona Conference – Zubulake Decisions – Allocation of Costs https://thesedonaconference.org/node/4317 Zubulake I-IV Cost Allocation for EDiscovery http://www.arkfeld.com/articles/Zubulake%20I%20through%20IV.pdf Sedona Commentary on Preservation and Sources Not Reasonably Accessible file:///C:/Users/Kim/Downloads/Commentary%20on%20Preservation,%20Management%20and%20Identification%20of%20Sources%20of%20Information%20that%20are%20Not%20Reasonably%20Accessible.pdf Ineffective EDiscovery Raises Cost of Healthcare http://www.recommind.com/ediscovery/ineffective-ediscovery-raises-the-cost-of-healthcare American Bar Association EDiscovery Book Chapter http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2015-sac/written_materials/5_2_chapter_12_cost_shifting.authcheckdam.pdf
In *Zubulake v. UBS Warburg LLC,* 2004 *U.S. Dist. LEXIS 13574, (S.D.N.Y. 2004)* *(* Zubulake V),the court established that the duty to preserve relevant evidence begins at the moment, litigation or a regulatory investigation can be 'reasonably anticipated.'	Duty to Preserve: http://www.ediscoverylaw.com/2004/12/zubulake-v-court-grants-adverse-inference-instruction-and-outlines-counsels-role-in-locating-preserving-and-producing-relevant-evidence/ http://www.americanbar.org/content/newsletter/publications/law_trends_news_practice_area_e_newsletter_home/obligationpreserve.html http://www2.law.columbia.edu/johnson/ediscovery/zubulakecase.htm ABA – Looking Back on Zubulake – 10 Years Later http://www.abajournal.com/magazine/article/looking_back_on_zubulake_10_years_later

The ability of providers and other stakeholders, to establish, implement an effective legal hold that would meet court requirements is virtually non-existent.	EDiscovery Basics: Legal Hold http://www.gibsondunn.com/publications/Documents/E-DiscoveryBasics-LegalHolds-Vol1No4.pdf Relevant Caselaw: Baker vs. Community Health Systems https://www.crowell.com/files/US-ex-rel-Baker-v-Community-Health-Sys-Inc-Opinion.pdf Fees and Costs Associated With Discovery and Legal Hold http://www.law360.com/articles/464395/skadden-gets-initial-nod-on-fees-in-hospital-fraud-case 'Lackadaisical' Litigation Holds by Federal Government Undermines Medicaid Fraud Case https://www.zapproved.com/united-states-ex-rel-baker-v-community-health-systems/

APPENDIX B

Note: If ONC is anticipating an outreach or educational resource in conjunction with this work, there is growing interest in and encouragement of attorney's proactively gaining discovery knowledge in digital records systems in general		
Facilitating American Bar Association (ABA) Model Rule 1 – Competence. Given the convergence of FRCP and State eDiscovery Rules with the ROI Process, Courts are Recognizing (and Citing) the Duty of "Competence" Counsel has: "A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation".	• Savings from system functionality to aid competent practice (knowledge, skill) • Savings from preparation aids in system functionality • Savings from measures/indicators of record completeness Accruing to: plaintiff and defense counsel	ABA Model Rule 1