ELECTRONIC HEALTH RECORDS SYSTEMS:
TESTING THE LIMITS OF DIGITAL RECORDS’ RELIABILITY AND TRUST

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ANNOTATION

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The United States healthcare system accounts for nearly twenty percent of our nation’s Gross Domestic Product. Its vast information ecosystem comprises nearly 700,000 physicians;1 over fifteen million healthcare workers;2 5,900 hospitals;3 16,000 nursing homes,4 and numerous other facilities; enormous insurance interests; mandated, untested national technology strategies; and hundreds of millions of critically concerned actors—all combining in interlocking, information networks. It is a system

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2. Id.


worthy of examination. Is the evidence created by this vast information ecosystem reliable?

The following Article summarizes systemic defects in our nationally mandated healthcare information systems. The authors examine the critical doctrines animating our current evidentiary rules. Time after time our medical records systems are revealed to be defective. Authenticity is suspect as an endemic matter, just as is trusted reliability for clinical and business purposes. Certainly there is a looming evidentiary defect undermining the very purpose for the records’ existence.

Why are there such catastrophic failures? Here, the authors make their original and lasting contribution. Viewing the issue as more than the reliability of discrete records, the authors examine the invisible societal processes causing records-systems’ dysfunctionality. They demonstrate our current system is unrealistic in that it ignores the complexity in our economy. As one example, our system purposefully ignores the fact that healthcare records are used arguably as much to obtain payments as they are to document clinical facts. The authors demonstrate that a more realistic approach is necessary if we are not to delude ourselves. In this regard, the Article is an example of an updated empiricism—informed by more advanced, appropriate, and prudent ideas about technology.

INTRODUCTION

Electronic records systems are bringing unprecedented changes to the United States Healthcare Industry. As an objective of economic stimulus legislation, under the American Recovery and Reinvestment Act of 2009 (ARRA),5 billions of taxpayer dollars are leveraging additional billions of private dollars to accelerate clinicians’ and clinical organizations’ uptake of these as yet non-standardized and minimally regulated systems. The history and the rationale for the uptake stimulus, as well as risk considerations, have been thoroughly reported elsewhere.6 Of particular note is that the stated objectives of ARRA address the security and exchange of information from Electronic Health Records (EHRs),7 and are effectively silent on whether the information originates from a reliable and trustworthy source.


This Article is unique from prior summaries, including those detailing risks, in focusing specifically on EHRs as sources of records for United States legal proceedings and processes, and therein offering exemplary illustration of how EHRs can pose unique challenges to those legal proceedings. The resulting challenges derive from, generally speaking, fundamental operational characteristics of these systems that can vary widely from records management and digital records norms, giving rise in turn to potential impeachability on grounds of unreliability and untrustworthiness, as well as unfitness for the stated business of the industry itself, clinical care, whether by design or by use, known or unknown. The Article will also note direct and indirect market forces for preferentially selecting “unfitness” in the evidentiary capacities of electronic health records management systems.

BACKGROUND AND CONTEXT

It is important to note that the path traced by digital records in United States healthcare has been substantially influenced by interests and market forces that may vary from those of other industries. For example, medical records themselves play a substantial role as intermediate artifacts for payment, with the record of care demonstrating and affirming “care necessity” as the stated object of insurer’s payment policies. Since third-party (public or private insurer) payment requires records of care as artifacts whose content explains or justifies services, then records themselves behave as a primary determinant of payment and, at least implicitly, the objective of the service. Generally speaking, the results of the service do not influence payment for service. In effect, the record of care has a greater role in determining payment than the service work-product itself or its benefit to the patient. In contemporary parlance, past and current payment systems emphasize quantity over quality, with evolving and future payment models aiming to shift “from payments based on volume to payments based on performance,”8 reorienting payments toward care quality and improved clinical outcomes of patient care services.

In (oversimplifying) sum, previous payment systems brought the United States a phenomenon representing the logical result of payment for volumes of records detailing volumes of care of unknown value or benefit, rather than payment for care results. Current Federal Health Information Technology policies, such as incentive payments for EHR implementations and limited use, are intended to speed the uptake of information systems that are

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presumed to, among other projected or potential benefits, report the clinical quality measures (CQMs) that form the basis for ongoing development of these transitional and future payment models.\footnote{See Clinical Quality Measures (CQMs), CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 24, 2014, 10:30 AM), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.}

However, in this construct, given that EHRs are non-standard, variant, and even aberrant records systems, there is a substantial financial incentive to attuning the record systems’ functional priorities to assure that the resulting record artifact leverages the maximum payment, dissociated from its accuracy and reliability as a business record of patient care events. Furthermore, the oft-noted litigious atmosphere in healthcare offers a second and separate incentive for records systems that can represent events, or amend representations of events, according to considerations other than accuracy and reliability as legally sound records.

Nonetheless, recognizing that better, cheaper, faster work-product records data systems were necessary, the United States’ initiative for following Western European leads in digitizing healthcare records got further underway in earnest with the Institute of Medicine’s\textit{ Computer Based Patient Record: An Essential Technology for Health Care} report in 1991, which included a forecast that all would be on EHRs by 2001.\footnote{See generally INST. OF MED., COMM. ON IMPROVING THE PATIENT RECORD, DIV. OF HEALTH CARE SERVS., THE COMPUTER-BASED PATIENT RECORD (Richard S. Dick & Elaine B. Steen eds., 1991).} The 1997 update, as a “progress check,” noted little movement forward and attributed the lag to a lack of common data standards and privacy rules, among other things.\footnote{See generally \textit{Inst. of Med., Comm. on Improving the Patient Record}, Div. of Health Care Servs., \textit{The Computer-Based Patient Record} (Richard S. Dick et al. eds., rev. ed. 1997).}

The vigor of the United States’ efforts then renewed under policies promulgated by the George W. Bush and Obama Administrations. Healthcare organizations have been encouraged to adopt new health information technologies (HIT) via regulation, incentive programs, and future penalties.\footnote{Section 1848(a)(7) of the HITECH Act provides that beginning in Calendar Year 2015, eligible professionals who do not demonstrate that they are meaningful users of certified EHR technology will receive an adjustment to their fee schedule for their professional services of ninety-nine percent for 2015, ninety-eight percent for 2016, and ninety-seven percent for 2017 and subsequent years. See American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 472 (2009).} The stated purposes of these programs are in line with broad national interests in improving the healthcare industry’s effectiveness and costs as represented in the oft-referenced Triple Aim of better care for individuals, better health for populations, and lower per capita costs.\footnote{The IHI Triple Aim, \textit{Inst. for Healthcare Improvement}, http://www.ihi.org/offerings/Initiatives/TripleAim/Pages/default.aspx (last visited Mar. 2, 2014).} Many others have presented the presumed future benefits of EHRs, particularly, the

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oft-cited and respected EHR authorities Sharona Hoffman and Andy Podgurski. However, even their generally positive inventory includes reference to presumptive benefits’ dependency on fundamentals of system fitness: “The benefits of EHR systems will outweigh their risks only if these systems are developed and maintained with rigorous adherence to the best software engineering and medical informatics practices and if the various EHR systems can easily share information with each other.”

In prioritizing records systems’ derivative end-uses ahead of their reliability, the United States has created consequences for presumptions of fitness as reliable records without affirmation, testing, or standardization against existing applicable international EHR Systems Standards or Business Records requirements.

Recent publicly available statements have further substantiated the reality of system aberrancies’ risks. One was the 2012 published letter signed by U.S. Attorney General Eric H. Holder, Jr., and the Secretary of the Department of Health and Human Services, Kathleen Sebelius, regarding EHR mediated falsification of records for the purpose of getting paid improperly. Another was a Request for Proposal from the federal government to purchase services to study how to mitigate errors in quality incentive payments, including errors arising from “gaming” the EHR-data submissions reporting systems. In late 2011, General Electric published a letter that acknowledged defects in its EHR’s reporting functions that could lead to improper payments. More recently, the Office of the Inspector General for the U.S. Department of Health and Human Services, reported its

15. Id. at 107.
hospital survey results showed that “nearly half of hospitals (44 percent) reported that they can delete their [EHR] audit logs.”

In the following sections, we will introduce the bases for addressing EHR systems as a general class of records management systems providing evidence that digital records systems require special treatment when called upon to support business records requirements in legal proceedings.

I. “RELIABILITY” AS THE OVERARCHING AND KEY NECESSARY ATTRIBUTE FOR BUSINESS RECORDS PROCESSES AND SYSTEMS

A. 901(b)(9) Evidence About a Process or System

In Rule 901(b)(9) of the Federal Rules of Evidence, it is stated that a requirement for validating business records is “[e]vidence describing a process or system and showing that it produces an accurate result.” Rule 901(b)(9) is designed for circumstances and systems where ongoing experience with evolving information technology gives cause to review or revisit questions of reliability. Over the years, many types of machines, such as cash registers and fax machines, have sufficiently demonstrated their general fitness for eventual presumptions of accuracy, which some have “criticized as an attitude of agnosticism . . . presenting only a slight obstacle to the introduction of forgeries . . . .” In healthcare, X-ray machines and clinical laboratory blood chemistry machines are examples of systems that have, through user demand and experience as well as rigorous regulatory oversight, been affirmed as reliable systems producing accurate results. EHRs, however, are not subject to regulatory oversight that validates

21. FED. R. EVID. 901(b)(9).
22. Id. 901 advisory committee’s note.
23. See id.
24. Example (9) is designed for situations in which the accuracy of a result is dependent upon a process or system which produces it. X-rays afford a familiar instance. Among more recent developments is the computer, as to which see Transport Indemnity Co. v. Seib, 178 Neb. 253, 132 N.W.2d 871 (1965); State v. Veres, 7 Ariz. App. 117, 436 P.2d 629 (1968); Merrick v. United States Rubber Co., 7 Ariz. App. 433, 440 P.2d 314 (1968); Freed, Computer Print-Outs as Evidence, 16 Am. Jur. Proof of Facts 273; Symposium, Law and Computers in the Mid-Sixties, ALI-ABA (1966); 37 Albany L. Rev. 61 (1967). Example (9) does not, of course, foreclose taking judicial notice of the accuracy of the process or system.

accuracy or reliability in an array of their functions, including those of direct patient care information capture and management, including care record reporting. In contrast, EHRs are notable for being subject to “gaming” payment systems. This illustrates one of the sources of variance in EHR systems, where unreliable or inaccurate results may actually be deemed desirable market factors insofar as they can, through false representation, facilitate an unearned or otherwise improper gain, such as increased payment for services not rendered or rendered unnecessarily, or to falsify records in order to appear to meet clinical or administrative guidelines for medical practice.26 In possible contrast to fundamental case law references on machine-generated reports,27 EHRs can be designed, configured, implemented, and used to render false representations in the course of “regular business.” This, then, is a principal distinguishing aspect of EHRs that tests the boundaries of current evidentiary procedures that presume their reliability and trustworthiness is no worse than other records management systems. In their current unregulated, non-standardized states where the current primary market drivers of their use exclude prior inspection against long-standing records management requirements, they illustrate the necessity of scrutiny of all outputs produced for rendering into legal proceedings. This necessity arises not simply from substantial possibility of legally dubious record management processes, but also the possibility that reliability supports, such as audit trails and near and long-term records management functions, may themselves be missing, difficult to use, or of uncertain veracity as verified by the OIG survey cited earlier.28 In further support of the references noted in the introduction, additional examples are sampled from the authors’ collections of representative records in Appendices A, B, and C.

In Appendix A, we have an Emergency Department episode of care record provided by a patient who, also a noted Compliance authority, affirms that those marked elements of the record in fact never occurred. Note that


As Chief of Radiation Therapy and Radiology respectively, Dr. Manning and Dr. Barth encountered a number of problems with Dr. Hussain’s performance. One of the issues of most concern was his failure to conduct adequate follow-up with radiation therapy patients. . . . Upon review of the required documentation in August 2003, Dr. Barth and Dr. Manning found “an alarming pattern . . . that Dr. Hussain finds it appropriate to copy and paste other physicians [sic] assessment into electronic patient record without giving evidence that he has actually seen and examined the patient prior to, during, or after treatment.”

Id. (second alteration in original) (citations omitted).


28. LEVINSON, supra note 20, at 15.
the EHR system itself appends to each segment within those elements the initials of the individual who affirmed them. This illustrates one of the attributes of EHRs that distinguish it from paper records, which can, of course, be falsified as well. In this instance, though, it is further likely that any audit trail, if not deleted or corrupted, will show that those false elements were created at the same exact instant and, insofar as they may be programmed into the system as default “boilerplate” in the absence of true patient-specific, unique, and human-authored elements, may provide ready evidence of challengeable assertions of reliability, depending on the circumstances of care. In this particular record, though, we have the benefit of the patient’s own testimony that these examinations did not happen. The fact that they were included is a result of the added value the record gains as a financially determinant artifact, potentially increasing the payment to the facility due to the additional services (falsely) represented.

In this system, if used to represent such records as reliable representations of attempts to maximize reimbursement as the primary purpose of the enterprise, then, so presented, they might be indeed accurate representations of the business activity of that particular Emergency Department. However, if the records are intended to accurately represent the patient and the care services provided, they are clearly defective and so will require further explanation for asserting reliability in the form of, as in Rule 901(b)(9), an accurate result.

In Appendix B, we see two Episode of Care records for the same patient, with a number of indications of unreliability. First, the patient’s temperature, blood pressure, and weight (to the one-hundredth of a pound) are identical. For the weight to be absolutely identical is unlikely to the degree of near-impossibility. To then have all vital signs’ factors identical represents additional impossibilities. The tortured phrasing, syntax, and content of the presenting reason for the visit (Chief Complaint) appears to be most likely partially or wholly machine-generated without review or validation by a human operator, representing another form of inaccuracy resulting from a casual, at best, attentiveness to accuracy in this entity’s course of business.

B. Rule 803: Exceptions to the Rule Against Hearsay—Regardless of Whether the Declarant Is Available as a Witness

Similarly, in assessing reliability per Federal Rule of Evidence 803(6)(E), EHRs can be easily demonstrated to fall afoul of the necessary attributes, including “[n]either the source of information nor the method or
circumstances of preparation indicate a lack of trustworthiness."

29 The extensive commentaries on Rule 803(6), especially those aspects addressing issues of informant motivation, appear particularly pertinent to the evidentiary support variances and errors found in EHR-sourced records. In particular, the comment notes that the “absence of motivation to misrepresent has not traditionally been a requirement of the rule.”

30 However, the context of the comment appears to indicate that the misrepresentation may have at least two origins: processes “tuning” a record output specifically to prejudice litigation, and processes tuned to other factors deemed nonetheless, upon examination, non-prejudicial to the litigation at hand.

31 It does not appear to speak to the unusual state of EHRs, where processes may be designed to misrepresent records and impair detection or illumination of misrepresentation, to the point of introducing the concept of evaluating systems for what might be termed “auto-spoliation.” The discretion of admissibility processes, though, are rendered broad enough by being “subject to authority to exclude if ‘the sources of information or other circumstances indicate lack of trustworthiness.’”

32 Earlier in the exception 6 commentary, we find:

The element of unusual reliability of business records is said variously to be supplied by systematic checking, by regularity and continuity which produce habits of precision, by actual experience of business in relying upon them, or by a duty to make an accurate record as part of a continuing job or occupation.

33 This treatment then focuses on the achievement of “unusual reliability” that arises for business records under certain regimes. These regimes include when records are systematically checked, when habits of precision are rendered by conscientious execution of the given enterprise’s definitions or requirements for preciseness in records practices, by the experience of their continuous reliability for tasks at hand, or the regime where a dedication to accuracy is actually practiced and enforced. Insofar as a given enterprise’s use of the EHR systems is becoming increasingly “routine,” their unique vulnerabilities reside in the absence of systematic accuracy testing, in imprecision, problematic use, and user experiences of clinical and

30. Id. 803 advisory committee’s note.
31. Id.
32. Id. (quoting FED. R. EVID. 803(6)(E)) (emphasis added).
33. Id. (citing MCCORMICK ON EVIDENCE §§ 281, 286, 287 (Kenneth Broun ed., 6th ed. 2006); Charles V. Laughlin, Business Entries and the Like, 46 IOWA L. REV. 276 (1961)).
Amplification of the kinds of activities producing admissible records has given rise to problems which conventional business records by their nature avoid. They are problems of the source of the recorded information, of entries in opinion form, of motivation, and of involvement as participant in the matters recorded.

Sources of information presented no substantial problem with ordinary business records. All participants, including the observer or participant furnishing the information to be recorded, were acting routinely, under a duty of accuracy, with employer reliance on the result, or in short “in the regular course of business.”

These dependencies for reliability on accuracy, and a presumptive “duty of accuracy,” become a special source of substantial difficulty in systems, such as EHRs, where factors of design, configuration, implementation, and use, as well as non-market incentives, can knowingly or unknowingly support inaccuracies and their obfuscation at extremes of variance from records management practices. We have seen how the masking of errors can impact financial institutions, even those subject to scrutiny and regulation, with far-reaching effects. Thus, such problems are not unique to healthcare. Nonetheless, since EHRs have no primary assurer of reliability,
and have substantial evidence of non-reliability, the risks of untested submission as evidence appears to be without justification and unlikely to exceed the benefits. As reflected in Federal Rules of Evidence 901 and 803 noted above, the systems must by other means be pressed to show evidence of producing accurate results and not indicate a lack of trustworthiness.

II. EXAMPLES AND ILLUSTRATIONS

As noted above, EHR systems are designed, configured, implemented, and used to create records that can appear to be both accurate and complete for a number of end uses. The evidentiary challenge is when “appearance” is at odds with the truth of the matters represented, when the records are not authentic. There are many variants to this. This Article will provide focus and examples constrained to two general areas: (1) Clinical—the record wrongly represents the patients’ medical information and/or condition; and (2) Operational/Financial—the record wrongly represents clinical personnel’s actual work or services performed.

For both of these areas, a contemporary EHR record system may generate outputs, in digital or in print form, that are intended to represent the appearance of accurate, reliable records of patient care services or events, but are neither accurate nor reliable for that purpose. They can, instead, represent accurate records of how a system was employed to achieve different business aims agnostic or contrary to patient care benefit, such as misrepresenting the patient’s condition or the patient care service work product to gain greater payment.\footnote{37. See RTI INT’L, RECOMMENDED REQUIREMENTS FOR ENHANCING DATA QUALITY IN ELECTRONIC HEALTH RECORD SYSTEMS 3–6 (May 2007), available at http://www.rti.org/pubs/enhancing_data_quality_in_ehrs.pdf (“EHR-S[ystems] provide a new opportunity for fraudulent behavior, and on ever-increasing scales, although they also provide opportunities to discourage those that would use these systems for personal gain. Development of common standards and regulations that increase accuracy and discourage fraud has the potential to make the health care system more efficient . . . .”); OFFICE OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., WORK PLAN: FISCAL YEAR 2012, at I-20 (2012), available at https://oig.hhs.gov/reports-and-publications/archives/workplan/2012/Work-Plan-2012.pdf (“Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service based upon the content of the service and have documentation to support the level of service reported.”).} In the absence of an entity that regulates or authoritatively asserts records systems’ evidentiary fitness qualifications, courts will be burdened with verifying each instance of an EHR-sourced record for evidence of the source EHR system to show that, as in 901(b)(9), the system’s processes have produced an accurate result, been properly retained, and not misrepresented the clinical or the operational/financial events in question.
The further bases for EHR records’ admissibility can be examined point by point to determine their validity as a Statement Made for Medical Diagnosis or Treatment; 38 Recorded Recollection; 39 and Records of a Regularly Conducted Activity. 40

Rule 803(6) states:

A record of an act, event, condition, opinion, or diagnosis [is admissible] if:
(A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;
(B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;
(C) making the record was a regular practice of that activity;
(D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
(E) neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness. 41

Condition A is not as easily attested to when the EHR’s event tracking system, designed to capture key events and their times of occurrence (time stamps), can show that the record was created either before the patient was appointed or arrived for the service (medical visit) or many days or weeks after the date of the visit. 42 Conditions B and C have been addressed earlier, where the dependencies for reliability and meanings of systematic testing, “regularly conducted activity” and “regular practice” are intended to also support the concept of reliability along with a presumptive duty of accuracy. 43 Condition D presents substantial challenge insofar as, in current minimally-to-non-regulated EHRs, the simple attestation of a custodian or qualified witness, but without presentation of a testing regime showing adherence to a duty of accuracy, would appear to fall short. Condition E is also problematic when the systems are promoted, advertised, trained and/or used in a manner that indicates a possible lack of trustworthiness. 44 Conversely, if an event tracking system operates in such a way that its time

38. FED. R. EVID. 803(4).
39. Id. 803(5).
40. Id. 803(6).
41. Id.
42. See infra Exhibit 1.
43. FED. R. EVID. 803(6) advisory committee’s note (citing MCCORMICK ON EVIDENCE §§ 281, 286, 287 (Kenneth Broun ed., 6th ed. 2006); Charles V. Laughlin, Business Entries and the Like, 46 Iowa L. Rev. 276 (1961)).
44. See infra Exhibits 1–4.
settings are configured without synchronization to the system it is tracking, every record event will appear wrong.

Rule 803(5) states that a recorded recollection is:

A record that:
(A) is on a matter the witness once knew about but now cannot recall well enough to testify fully and accurately;
(B) was made or adopted by the witness when the matter was fresh in the witness’s memory; and
(C) accurately reflects the witness’s knowledge.\(^{45}\)

The Recorded Recollection exception could be asserted as a reason to allow the EHR documentation, and Condition A would appear to be a valid element. Conditions B and C may be more difficult to attest to when referencing the accompanying Appendices and Exhibits as exemplifying problematic variances from “regular” business records practice. If a document has been “created” in a way that does not reflect the patient’s actual signs and/or symptoms, how could a case be made that it “reflects the witness’s knowledge”? A record that has been created before the patient even arrives or created weeks after the patient’s appointment or uses a random notes generator, or uses an authorship substitution function, also, at the minimum, requires further queries to deem “made or adopted by the witness when the matter was fresh in the witness’s memory.”\(^{46}\)

Rule 803(6) defines Records of a Regularly Conducted Activity as:

A record of an act, event, condition, opinion, or diagnosis if:
(A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;
(B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;
(C) making the record was a regular practice of that activity;
(D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
(E) neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness.\(^{47}\)

As shown above, the reliability of the medical record can be subject to impeachment for several reasons. The Exhibits show a number of examples that would negate elements (A) and (E). In addition, there are multiple other

\(^{45}\) Federal Rule of Evidence 803(5).

\(^{46}\) Id.

\(^{47}\) Id. 803(6).
elements that would thwart the use of EHR documentation as reliable, which are discussed below:

Electronic Records: Additional Rules for Records on Computers

1. The type of computer used and its acceptance as standard and efficient equipment
2. The record’s method of operation
3. The method and circumstances of preparation of the record, including:
   [a] the sources of information on which it is based
   [b] the procedures for entering information into and retrieving information from the computer
   [c] the controls and checks used as well as the tests made to ensure the accuracy and reliability of the record
4. The information has not been altered.

The computer has become accepted and “standard” (here meaning “normal”) equipment, but how the software is used and how reliably it performs is the issue for the admissibility of records created with the wide variety of software programs representing themselves, and being represented, as appropriate for use as an EHR system. As discussed earlier, this acceptance appears to be based on assumptions of reliability that include a presumptive adherence to a duty of accuracy, which as illustrated by this Article, is not consistently present. The ability to duplicate, replicate, copy, or “clone” records from one patient to the next, or from one visit to the next, requires scrutiny due to the risks of insult to accuracy and integrity documented elsewhere, which are compounded when auditing functions are limited,

49. Cloning has several definitions in authoritative sources. They appear to have in common the concept of using functions built into the EHR itself (not the operating system, such as simple use of common software “Copy” and “Paste” functions) that captures a substantial amount of a prior record of patient service for a given patient and then duplicates that same record on a different date of service for the same patient or a different patient, misrepresenting the record as if it was a uniquely created original record for the later date of service. The outcome is a sequence of records for a given patient or several different patients, with substantially identical, if not entirely identical record content. See generally Robert Lowes, Cloned EHR Notes Jeopardize Medicare Payment, MEDSCAPE MED. NEWS, Sept. 25, 2012, http://www.medscape.com/viewarticle/771548; Nina Youngstrom, Medicare Watchdogs, Compliance Officers Investigate ‘Carry Forward’ (with Two MACs’ Policies on Cloning Electronic Medical Records), AIS HEALTH (Aug. 15, 2011), http://aishealth.com/archive/rme081511-03. Also note that the term “cloning” appears to have been in decreasing use and subsumed under broader references to copy functions in recent years.
impaired, or non-existent. Such abilities, when employed, invite closer assessment to determine how they were actually used. Means and results of retrieving information are also difficult issues when there are multiple ways to create artifacts represented as documents where the “output” does not resemble the way the information was entered. For example, see Exhibit 2, which indicates that extensive information was rendered into a record at a single moment, perhaps at a single click or keystroke, and not necessarily as a result of documenting findings in an exam or gathering information about the patients’ actual current symptoms or complaints. In such circumstances, further investigation and testing of records functions may be required to support an assertion of reliability.

The element 3(c), “the controls and checks used as well as the tests made to ensure the accuracy and reliability of the record,” could be verified by performing an audit of the date and time stamps and other metadata from the EHR system. Unfortunately, not all EHR systems have the ability to perform and/or record this level of data. Systems exist with the ability to turn off the audit functions partially, intermittently, or completely. As noted in the previously cited OIG report of hospital interviews, a very high proportion of hospitals reported the ability to disable audit functions. Some systems do have all of the capabilities necessary to validate the methods and timing of documentation entry, but the time and expense to retain, manage, and mine this information may be cost-prohibitive.

The fourth element—the information has not been altered—may be one of the easiest items to impeach in the EHR system. A substantial number of EHR systems, including those widely used, allow the user(s) to maintain the record as “open” or “pending” for days, weeks, months, and years even though a claim for the service has been submitted for reimbursement. This is intended as a convenience and workflow necessity to allow a provider to return and finish his or her documentation at some point in the (near) future. Examining date/time anomalies, such as odd-interval dates/times of record initiation and of record completion are important, especially when such anomalies point to late completion and back-dating of completions. The specific issue with the ability to keep the record open for an unlimited amount of time is more onerous when the EHR software or system allows the user the ability to overwrite the originally rendered documentation.


52. Information Integrity in EHRs, supra note 48.

53. LEVINSON, supra note 20, at 15.
indefinitely until finalization and there is no record maintained of the originally rendered documentation.

Completion, closing, or other “signature-like” functions also present challenges for assuring EHR record integrity. When the provider finalizes the record and affixes his or her “electronic signature,” the specific encounter’s documentation is, presumably, not subject to any form of surreptitious alteration. However, presumptions about the actual “signature” function, especially with regard to non-alteration, must be tested due to variability in systems’ fidelity to accepted signature principles. As shown in Appendix C, the representation of the who “signed” a clinical record and who actually provided the component elements of the clinical services can also be problematic and free of indirect indicators like handwriting changes.

Many systems do support administrative controls that mitigate or eliminate some impeachment hazards such as automated administrative closure twenty-four to forty-eight hours after record origination. This function, if enabled and not overridden ensures that amendments or corrections to the record thereafter are performed correctly and preserving the originally rendered information intact. Examining the system’s capabilities and settings for final closure of the record is one way of determining the ability of a source EHR system to make unaccounted alterations.

Examination of the documentation event metadata capture and management capabilities, if available, is another way to determine if alterations can occur. If health information can be altered without a reliable audit trail to indicate that the information has been modified, documentation capture reliability and documentation management integrity cannot be assured. In an article from the Journal of the American College of Surgeons it was stated:

Unlike paper records, detection of an EMR alteration by visual inspection is not possible. Rather, the only way to tell if an EMR has been altered is to use its metadata to track the changes made to the document. Metadata will tell who accessed the medical record, which information was viewed, and how and when the document was modified. Without the underlying

54. See, e.g., R.D. Gelzer & Patricia Trites, Using Test Vignettes to Assess EHR Capabilities, J. AHIMA, May 2006, at 56–59. Author Gelzer reports that testing signature functions in four leading EHR products at a national trade show in 2009 showed that “signed” records that were then altered and re-“signed” gave no indication in screen view outputs nor in print outputs that the record had been changed after the signature function had been applied.
metadata, an EMR is merely hearsay, because there is no way to prove the integrity of the document.\(^{55}\)

Even the federal government has identified the presence of risk of integrity shortfalls in computer systems. The *Publication of the OIG Compliance Program Guidance for Third-Party Medical Billing Companies* stated:

Among the risk areas the OIG has identified as particularly problematic are

- Billing for items or services not actually documented . . .
- ‘Upcoding’ . . .
- Lack of integrity in computer systems.\(^{56}\)

### III. AUTHENTICITY\(^{57}\)

“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.”\(^{58}\) This command lays the down the challenge of authenticity, proving that an artifact is what it is claimed to be. In digital records, the difficulties represented by this have been captured in discussions of our current “authenticity crisis.”\(^{59}\) In support of that perspective, EHRs demonstrate that there are substantial difficulties with the inclusion of all EHR records uncritically as candidates for asserting self-authentication under Rule 902.\(^{60}\) Regarding Rule 902(11)’s reference to hearsay exceptions 803(6)(A)–(C),\(^{61}\) this Article has already demonstrated reasons to assess EHRs’ fidelity. At the same time, the hearsay exception for Statements Made for Medical Diagnosis or Treatment\(^{62}\) has also been undermined by the examples of a falsified Emergency Department record and of nonsensical-to-impossible outpatient clinic records of presenting patient complaints and vital signs.\(^{53}\) Without further supporting analysis, those record elements purported to be authentic must be tested, because they

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58. FED. R. EVID. 901(a).


60. FED. R. EVID. 902.

61. FED. R. EVID. 902(11).

62. FED. R. EVID. 803(4).

63. See infra App. A.
may be inauthentic as, for example, records of patient care, but entirely authentic for the purpose of demonstrating records falsification to secure improper payment.

These difficulties with EHR authenticity appear especially acute with our renewed understanding that the concept of “regularly” intends to also reflect expectations of reliability deriving from multiple business regimes or attributes, including a presumptive (and exercised) duty of accuracy. This Article illustrates the growing recognition of the ubiquity, approaching commonality, of dubious EHR functions as a specific challenge to authenticity. These illustrations include the ability to manipulate or disable authenticating audit trails or document completion functions and to generate corrupted record times, along with functions that copy forward content that, at origination, may have been authentic but with propagation became inauthentic in its “new” context, or that alter apparent authorship. Given these challenges to authenticity, the Rule 901(a) prerogative to require proof for processes or systems producing (acting as source for) evidence, seems to reasonably demand procedural testing to EHR-sourced records, since currently no other entity provides reference evidence showing that any given EHR produces an accurate output or result.64 The necessity of considering such a demand will persist until there is an effective regulatory or standards-recognized “certification” regime that specifically and comprehensively tests and assures EHRs and EHR-sourced records’ reliability. For the purposes of referencing EHRs in legal proceedings, this regime must include testing fidelity to established business records requirements in design and in use.

In sum, EHRs currently cannot be equated with accepted technologies such as fax machines, cash registers, or regulated devices as necessarily capable of reliable production of authentic records. Evidentiary testing or other means of authentication of EHR-sourced records are therefore necessary for their validation.

IV. SUMMARY

EHRs represent unique challenges to evidentiary practices because their current state includes substantial variability in their fitness as business and clinical records. In addition, the extensive discretion allowed different enterprises in configuration and use of a given brand of system means that demonstration of soundness in one setting is not necessarily applicable in another setting. This variability invokes those cautions against presumptions of reliability and trustworthiness present in current evidentiary rules, directs
evidentiary proceedings to apply special cautions to EHRs, and, eventually, 
develop and apply system validation requirements to digital records to assure 
that presumptions of proper processes are not simply good-faith based.

CONCLUSION

Our subject here has been to introduce the concept of EHR systems as an 
illustration of why digital records systems, most especially EHRs, may, as a 
matter of routine, merit testing for reliability and trustworthiness as a 
precondition for, as an example, accepting the validity of records systems 
under Rule 901(b)(9) or deeming their outputs admissible under Rule 803(6). 
Other industries, with simpler business rules, more systematic auditing 
guidelines, and external references for credibility may share some or all of 
the vulnerabilities of EHRs as sources of truth. In all instances though, 
organizations are obliged to make certain that their records systems originate, 
retain, and preserve records by such means and for such lengths of time as 
required by the rules, regulations, and common practices deemed pertinent to 
their line of business.

Currently there are no regulatory health information technology 
requirements or Federal HIT program qualifications for these systems that 
assure, or reference, their fitness as business or clinical records. While some 
regulatory reference exists to supportive functions, such as “audit trails,” at 
this writing, their use is not required in deployed systems, meaning that 
evidentiary non-reliability will persist as a challenge to e-Discovery and to 
all business record-supported or dependent processes in the healthcare 
industry for a long time.

There is a substantial body of resources for due-diligence in records 
management systems for supporting reliability and trust. Eventually, 
federal oversight entities, or accumulating case law, will assert their 
influence on assuring reliability in IT in general, perhaps beginning with 
Healthcare IT. Thereafter, trustworthy EHRs will, all patients hope, become 
a norm as the marketplace gains increasing transparency to reliability defects 
so that superior systems and superior applications of those systems can 
accelerate. In the meantime, in the absence of an authoritative source of

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65. See generally BALDWIN-STRIED REICH ET AL., supra note 7; PAUL, supra note 57; LAURA A. 
ZUBULAKE, ZUBULAKE’S E-DISCOVERY: THE UNTOLD STORY OF MY QUEST FOR JUSTICE (2012); 

66. See, e.g., Zubulake v. UBS Warburg LLC, 382 F. Supp. 2d 536 (S.D.N.Y. 2005); Lewy v. 
Remington Arms Co., 836 F.2d 1104 (8th Cir. 1988) (supporting organizations’ duties to assure that their 
systems provide reasonable retention of and access to past records).

67. See, e.g., Gelzer, supra note 54, at 56–59.
meaningful EHR reliability regulation or certification, health care enterprises, which represent nearly twenty percent of all United States business activity, must exercise additional institutional rigor and discipline in achieving digital business records reliability. The benefits to business records are the subject here. Great value will accrue through other means, such as displacing inferior systems and stimulating better systems, while also lowering patient, organization, and provider/user risk through improvements in clinical care, patient safety, and healthcare enterprise effectiveness.
EXHIBIT 1: MAJOR VENDOR PATIENT RECORD SCREENSHOT

Redacted screen shot from an in-use EHR, used in an American Bar Association presentation, from the professional archives of author Patricia A. Trites.
EXHIBIT 2: IMMEDIATE CREATION OF MULTIPLE CHART COMPONENTS

This screenshot, from the archives of author Patricia A. Trites, is provided to illustrate functions that may or may not have problematic implications but nonetheless are useful to show potential risks. This output from an auditing function shows that an extensive list of chart components, which seem to include Office Note, Follow-up Letter, and Past Medical History, were created at the same instant. This “creation” could have been a volitional act by the user, by clicking on an icon for example. Or it could be that the system automatically generates a partially populated record when the system originates a patient record for subsequent editing or modification. In any case, since these functions are created as if unique to a specific patient and for specific date and time of clinical care, this helps illustrate how automated functions, if not tested and understood, could generate substantial “default” information that may or may not represent actual events represented as unique to this specific patient, this patient service, at this date and time.
Chiropractic Note System web-based advertising projects insights into documentation challenges potentially represented by, for example, automated notes generators. “Our chiropractic EMR software is very simple to use and it will generate more income for your chiropractic office while providing you with more time for yourself.”

“You can, however, customize virtually every screen to fit your specific needs including designating preferred items or pre-defined scenarios to call up at any time to completely fill out your screens.”

“The heart of the program is the random text generation for your SOAP Notes. CNS uses a unique methodology to generate complex sentence structures.”

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69. Id.

70. Id.

71. Id.
EXHIBIT 4: PROMOTIONAL MATERIALS ON ADAPTIVE AUTOMATED NOTES AND PAYER/PAYMENT ORIENTED CONSIDERATIONS

These materials, captured from the company’s website on January 26, 2014, are not to be construed as necessarily problematic. They are offered here to show illustrations of promotional materials that address topics of documentation process variation as well as how EHR vendors may represent documentation objectives.

Promotional Website Content

Our clients report that it takes them less than 45 seconds to complete a chart. Praxis is that fast. This is because with Praxis, you literally chart as fast as you think. How is this possible? Praxis learns directly from you as you chart in your own words. Therefore, with Praxis, you are interacting with your own words and medical concepts. In effect, instead of you having to adapt to templates developed by an EMR vendor (that presumably knows more about treating a certain condition than you do!), Praxis adapts to you, getting smarter and faster the more you use it. Before you know it, you are charting at the speed of your mind!  

Praxis does three things for you that no other program can:

3. Your chart comes alive!
   ...and completes itself...
   ...and runs your practice...
   ...and becomes your best partner...

Narrative excerpt for “Benefits” slide:

Praxis is an Electronic Medical Record program based not on templates but on a unique technology that instantly searches for and displays the most similar encounter you have ever documented in your practice in relation to the one you are about to start on right now, so that you may use that similar text to generate the current one at the speed of your mind.  

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Thus, Praxis knows how to play the third-party payers’ game better than anything else on the market, and wins every time, simply by learning all the requirements variations easily and painlessly. For the cases shown here, for example, Praxis will handle and charge each one differently even though they share the same diagnosis. Praxis learns how to accommodate to all third-party requirements better than any template could.  

74. *Id.* at Frequently Asked Questions.
Narrative excerpt:

In addition, Praxis plays the Level of Service game on your behalf. I mean really, why should a more complex case be more difficult to chart? Indeed if you have charted it before, you now have the text instantly at your fingertips so you need not recall what the bullets should be. It is far easier to do what you wrote than to chart what you did. And you can see that it is all quite effortless.  

75. *Id.*
This is an excerpt from an Emergency Department physical examination record.76 All elements outlined in blocks were fabricated as these elements of the examination were never actually performed. (One block does enclose part of the Abdomen exam report, the second line, which was performed.) Most notable is the Back exam statement: “There is no CVA Tenderness” which was actually both fabricated and false, insofar as the patient had a kidney stone which results in exquisite tenderness in the Costo-Vertebral Angle (CVA).

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76. Used with permission.
APPENDIX B: ANOMALOUS EHR-GENERATED NOTES

Note 1:

Subjective:
Chief Complaint: 52 year old came for follow up for chronic low back pain not improving with medicines unable to do routine workup pain allergy to following meds: the time

Objective:
HEENT: patient is alert, oriented, smiling. Soft ears and nostrils, no rhinorrhea. No head, neck or ear symptoms.
LUNGS: S: r/t spine rl, r/t chest. No rhonchi.
BJE: Tenderness to palpation in paraspinal muscles in L5 spinous region. SLR negative. Pain is greater in extension more so than flexion. No clubbing, cyanosis or edema. Pulses intact. Kerr's: Wt.
NEURO: Alert DTR's equal no sensory motor coordination changes.
SKIN: No rash or lesions.

Assessment:
Low Back Pain: #724.2.
Asthma: (airway constrictions) #493.9.

Plan:
Instruction given in detail if has any question feel free to call

Prescriptions & Medication Changes:

1. Refills: 1 year.

Follow Up:
Return if problem develop or worsen or go to emergency room.
A series of ten outpatient clinic notes for the same patient were provided for a specified time as part of a data quality and information integrity study and subsequent presentation. The notes originated as printouts from an EHR-system. Prior to providing the scanned versions of the notes in PDF format, the source record was screened for protected health information and de-identified both for patient and source information. The rings highlighting information were added for the purposes of rendering support for this Brief.

Comparing Note 1 and Note 2 for this same patient: The most readily apparent anomalies are (1) the nonsensical phrasing in the Chief Complaint on Note 1, with a blank space where the patient’s age should be (blacked out in Note 2); (2) the two Notes’ identical vital signs, to the tenth of an ounce in the weight, and (3) the blank space in Note 1 for the breadth, in centimeters,
for the liver span. Eight additional visits ending “12/23/08” showed another visit pair with identical vitals and one triplet set with identical vital signs, all to the tenth of an ounce on weight. Three of these visits also had the identical nonsense Chief Complaint phrasing as Note 1, with one having one added word at the end, another having two added words at the end, still rendering nonsense.

The blank spaces for missing data (age, liver span) give an indication of how much of the Note is auto-populated, with the missing elements demonstrating that it is unlikely that the clinician intended the content as she or he did not read the note and correct the deficiencies, then authenticated and attested to deficient records.
APPENDIX C: “MAKE ME THE AUTHOR” FUNCTION USE CAUTION
SCREENSHOT

January 14, 2014:

The Office of Physician Billing Compliance has this web-displayed caution about problematic uses of a function that replaces the original author on the note with a subsequent author. Per the instruction, “MMTA generates a physician note consolidating both the resident/NPP note with an attending, without visible edits and corrections. An audit trail of the resident/NPP note is retained. The signature indicates MMTA has been used, appending “last edited by” in the signature block but does not print original author’s name. When the original author is a Resident, Teaching Physician documentation requirements still apply. The attending must continue to append his or her teaching physician attestation, describing his or her participation in the services. The attestation must appear in the final version of the note.

Limitations.
MMTA functionality is only available in the Epic Ambulatory application (it is not available in Inpatient). MMTA only works with a “perked” note. It does not work for closed notes, so it cannot be used for prior notes from the same patient, or a note from another patient. Medical Students, Non-physician practitioners, and Residents do not have access to this functionality.

MMTA has only been approved for use in notes that will be used as correspondence to physicians outside of our practice. Its purpose is to generate a “clean” consultation/referral note, without visible edits of the resident’s documentation.

Do NOT use MMTA for billable services when the Physician did not see and evaluate the patient personally, including the Primary Care Exception and “incident to.” These services must be submitted in the NPP billing number.

Future versions of MMTA will indicate previous authorship. Regularly scheduled audits will include review of the entire document trail and testing for the appropriate use of MMTA.

The attending, as always, is responsible for the entire content of his or her documentation and is personally responsible for its accuracy and medical necessity.

Any questions? The Office of Physician Billing Compliance contact information: (352)392-3359 or e-mail Nina Tarnowczyk (ntarnowczyk@ufl.edu).

78. Id.
79. Id.
Dear Centricity Practice Solution and Centricity™ EMR customers:

GE Healthcare recently became aware of inaccuracies with reports in Centricity Practice Solution and Centricity Electronic Medical Record (EMR) that may affect customers who have attained or are currently planning to attain Meaningful Use through the Medicare EHR Incentive Program. As your trusted partner in electronic medical records, we want to make you fully aware of the situation and of the steps we are taking to address it. GE Healthcare is moving quickly to correct these inaccuracies, and we expect to have the affected reports fixed no later than the end of November 2011.

The inaccuracies that we have identified may affect the results you obtained from the Crystal Reports or Medical Quality Improvement Consortium (MQIC) reporting tools for Meaningful Use. This inaccuracy affects some of the Meaningful Use reporting measures. The underlying clinical data and logic of the electronic medical record system remain sound.

If you have already attested in 2011, we recommend that you run the reports again for your particular attestation period after we provide the updates. If your results are different from those used for attestation, you may need to evaluate if you have already met applicable Meaningful Use threshold for the original period or would meet the thresholds for all applicable measures (not only those that may have changed in the initial reporting period) for a later reporting period in 2011. We are working with CMS to identify what you may need to do if the data used to support your attestation have changed, and we will provide you with this information when we release the updated reports. You may also wish to consult your own resources. Please note that eligible professionals may attest with 2011 data until February 28, 2012.

If you have not yet attested and you use only GE Healthcare’s reports for your Meaningful Use attestation, we recommend that you delay your attestation until the updated reports are released.

We have identified a series of immediate steps that you need to take on these specific measures to ensure that your progress towards Meaningful Use can be assessed accurately by our reports. Please click here to access these steps. For MQIC customers, please see the separate communication on MQIC for additional details on how you may be affected.

We remain committed to providing you with the tools that you need to achieve Meaningful Use. We understand the complexities of healthcare and apologize for any inconvenience that this may cause you. We will keep you apprised of any changes as we become aware of them.

If you have further questions, I invite you to reach out to me, your value-added reseller, or your account executive.

Michael Friguletto

Vice-President and General Manager
GE Healthcare

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E-mail from Michael Friguletto, Vice President and General Manager, GE Healthcare, to Centricity Practice Solution and Centricity EMR customers (2011), available at http://view.exacttarget.com/?j=fe5d1678756d027c67314&m=fe6c1672746303&l=fe3c3157172650375537137361&u=fe5c1577706506757311&s=fe251072e600174751479&jb=fe4c14&jw=fe2177274630075771677.