

The Legal EHR: Beyond Definition

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1

Overview

- Definitions
- Federal Rules of Evidence vs. HIPAA Security Rule vs. Medicare Conditions of Participation
- The “Nearly New” Federal Rules of Civil Procedure and Application to ROI
- Sarbanes-Oxley
- “Loss of Chance”
- Problem Areas



Definitions

- Legal Health Record
 - The record that is generated **at or for** a healthcare organization as a *business record* that documents the clinical activity respecting a patient and is the record that will be disclosed upon request
- Electronic Health Record
 - Health information recorded on any digital medium that is evidence of transactions or events that (1) has legal or business value and (2) indicates an intention to be memorialized
- Legal Electronic Health Record
 - Which aspects of these 2 definitions do we pick?
 - Is it the legal health record created and maintained in an electronic format, or is it the electronic health record further defined to make it “legal”?
 - It is not a distinction without a difference (here he goes again)



Evidence 101

- To be admissible, evidence must be
 - Relevant as determined by Rule 401
 - Authentic under Rule 901
 - Either not hearsay under Rule 801(d) or subject to an exception under Rules 803, 804, or 807
 - In original form or accompanied by admissible secondary evidence to prove content (Rules 1001 to 1008)
 - Of a type that the probative value outweighs any danger of unfair prejudice as determined by Rule 403



Rules 901 and 902 - Authentication

- Rule 901 requires a foundation of evidence sufficient to prove that the information sought to be introduced is what it purports to be
 - Testimony of a witness with knowledge
 - Lay (handwriting only) or expert comparison
 - Distinctive characteristics
 - Voice recognition
 - Public record or report – “authorized by law to be recorded and filed”
 - Proof of the function of a process or system – evidence describing a process or system used to produce a result and showing that the process or system produces an accurate result



Rules 901 and 902 - Authentication

- Rule 902 permits self-authentication; that is, without a foundation of extrinsic evidence
 - Official publications
 - Trade inscriptions
 - Certified domestic records of regularly conducted business activity (using FRE 803(6)):
 - made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, *a person with knowledge of those matters*;
 - kept in the course of the regularly conducted activity; and
 - made by the regularly conducted activity as a regular practice.



Authentication under the HIPAA Security Rule

- First concern is with *integrity* – that the record has not been altered or destroyed in an unauthorized manner
 - 45 CFR § 164.312(c) – protect ePHI from alteration or destruction in an unauthorized manner (at rest)
 - 45 CFR § 164.312(e)(2) – implement security measures to ensure that electronically transmitted ePHI is not improperly modified without detection until disposed of (in motion)
- Secondary concern is *authentication* – making sure that you know who is accessing, making entries in, and modifying records in the data set
 - 45 CFR § 164.312(a)(1) – implement technical procedures to allow access only to those persons or programs that have been granted access rights
 - 45 CFR § 164.312(d) – implement procedures to verify that a person or entity seeking access to ePHI is the person claimed (i.e., who he, she, or it purports to be)
 - 45 CFR § 164.312(b) – implement mechanisms that record and examine activity in information systems that contain or use ePHI.



Medicare Conditions of Participation

- Medicare CoPs (42 CFR § 482.24(c)(1)) are concerned that a practitioner accept responsibility for each entry in the medical record by authenticating the entry
 - All entries in the medical record must be dated, timed, and authenticated, in written or electronic form, by the person responsible for providing or evaluating the service provided. For authentication, in written or electronic form, a method must be established to identify the author. ***A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed, is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created.***
 - Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. (Interpretive Guidelines)



Authentication vs. Authentication

- HIPAA Security Rule explicitly requires both integrity and authentication
- Medicare CoP explicitly requires both integrity and authentication
- FRE implicitly requires both integrity and authentication
 - You can't get self-authentication under FRE 902 unless the business record was created by or with information transmitted from a person with knowledge under FRE 803(6)
 - What does “person with knowledge” mean?



Rule 803(6) - “Person With Knowledge”

You can't be a “person with knowledge” in your own facility

- This has NOTHING to do with the objective truth of the information or whether the person recording the information did it right
- FRE doesn't require this for the exception to be met
- You don't know whether any recorder in your facility is a “person with knowledge”
 - FRE doesn't require this for the exception to be met
- You don't know who the recorder is
 - FRE doesn't require this for the exception to be met



Rule 803(6) - “Person With Knowledge”

- It's a question of *reliability*
 - Exceptions to hearsay (of which Rule 803(6) is one) are based on the intrinsic reliability of the information
 - YOU RELIED ON IT to provide care AS IF IT WERE MADE BY A PERSON WITH KNOWLEDGE
 - You included the information in the medical record as a part of your ordinary duties - i.e., to provide patient care
 - It doesn't mean that the information is true, just that it is *admissible*
 - Records of drug dealers and Al Capone are admissible as business records, because even criminals keep records of transactions



Rule 803(6) - “Person With Knowledge”

- Official Comments to FRE 803(6):
 - “Sufficient foundation for the introduction of such evidence will be laid if the party seeking to introduce the evidence is able to show that it was **the regular practice of the activity to base such memorandums, reports, records, or data compilations upon a transmission from a person with knowledge**, e.g., in the case of the content of a shipment of goods, upon a report from the company's receiving agent or in the case of a computer printout, upon a report from the company's computer programmer or one who has knowledge of the particular record system. In short, the scope of the phrase “person with knowledge” is meant to be coterminous with the custodian of the evidence or other qualified witness. **The committee believes this represents the desired rule in light of the complex nature of modern business organizations.**”
- In short, using 803(6) to exclude external information that you used to treat a patient from your legal EHR is chasing a rabbit down the hole into Wonderland
- What are you going to do when an interoperable EHR hits your facility – not testify to anything at all?
- Doesn't this effectively torpedo AHIMA's own PHR initiative?



Why Is This Important?

- Are you using authentication under the FRE as a surrogate for record retention decision purposes?
- Are you using it as a surrogate for compliance with a federal or state records maintenance standard?
- Are you unable to determine whether external information was used in clinical decision-making?



Rule 1002 – The Original Document Rule

- Commonly referred to as the “best evidence” rule
- The original of a document is always the best way to prove what the contents of that document are
- Certain documents don’t need to be produced as an original
 - Duplicates (which is what a facility’s certified paper copy is)
 - Certified copies of filed public documents
 - Summaries - but only if the original is available for inspection and copying, perhaps in court



What is a “Duplicate” of an EHR?

- Is it what the clinician observed at the time the records were created?
- Is it a paper chronological record of every relevant entry?
- Is it inclusive of metadata and other things that the clinician never saw or could see?
- What if there is a difference between these?



FRCP and Application to ROI

- FRCP apply differently depending on whether the person or entity producing the information is a party or a non-party
- Rule 26 outlines the basic discovery process for parties; Rule 45 governs the production of documents by non-parties
- Both Rule 26 and Rule 45 have been updated to take into account the new e-discovery concepts



FRCP and Application to ROI

- The “litigation hold” generally means something entirely different to non-parties
 - Non-party has no obligation to maintain the hold after the production requirement has been fulfilled
 - A “hold” is only established upon receipt of the subpoena or some notice that a subpoena will issue
 - No abstract duty to preserve evidence that third parties may want, until a hold is instituted
 - You don’t have to keep things that you wouldn’t ordinarily keep in your business
 - EKG machine readouts
 - Post-it® Notes
 - BUT, you can create this obligation by contract
 - Third party payor contracts surely, but also others – you should check



FRCP and Application to ROI

- “Undue burden” and “significant expense” might actually mean something if you are a non-party
 - Use a sampling strategy to see what it really will take to produce what is requested – within the time to object
 - Know what it takes (both time and money) to find your most requested data types
 - Know how to retrieve things that you may not use but that may be requested
 - Even though requesting parties may ask for data in a specific format, you have no obligation to create new data
 - You don’t have to keep anything you don’t intend to use in the ordinary course of your business, unless the law says so.



FRCP and Application to ROI

- The Power of an Objection
 - Objection is the only way to narrow the scope of the subpoena, because ignoring it won't make it go away
 - The objection process triggers the equivalent of the Rule 26 “meet and confer” requirement – or it should
 - Redaction and summary may allow the production of necessary information (not what was asked for) at a lower overall cost and time burden
 - Patient privacy concerns can be addressed by altering the scope of the subpoena and the response
 - Make the requesting party show how it is entitled to the information sought



Sarbanes Oxley

18 U.S.C. § 1519:

Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States or any case filed under title 11, or in relation to or contemplation of any such matter or case, shall be fined under this title, imprisoned not more than 20 years, or both.



Sarbanes Oxley

- “Any matter within the jurisdiction of any department or agency of the United States”
 - **Tracks language of 18 U.S.C. 1001 and has been interpreted very broadly**
- “In relation to or contemplation of any such matter or case”
 - **Again, a very broad standard**



“Loss of Chance”

- Massachusetts law now allows recovery for a misdiagnosis or malpractice that lowers the chance of a person’s surviving an acknowledged fatal disease, even if the disease likely would have caused the patient’s death regardless of the physician’s negligence
- Case would argue for more inclusion and use of medical information rather than less
- How do you tell the story of care?
 - Can your system provide a coherent chronology of care in human perceivable form?
 - Do you voluntarily produce the whole story?
 - If you rely on a patient’s PHR, doesn’t this help insulate the provider from liability?



Problem Areas

- External Information and the FRE 803(6) Test
- The “Source-Output” Gap
- Growing Out vs. Shrinking In
- Record Retention/Destruction Policies
- Risk Management Issues – “Telling the Story”



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