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To Whom It May Concern:

Statement from the defense

Much legal work is dependent on the review of medical documentation. For many litigation practice areas, analysis of medical documentation takes up a good part of pre-trial discovery, before a case ever reaches the courtroom. Whenever a potential plaintiff is injured, we rely on the plaintiff's medical records (both pre and post accident) to tell the story. We are assessing whether records should be submitted as evidence, or whether the records should be precluded from evidence because they are unreliable and do not meet the rigor of our long-held evidentiary standards. The implementation of electronic health records has not disrupted the majority of that work, although there are a number of issues, outlined below, which have greatly disrupted litigation when the issues increasingly arise due to the differences between traditional paper charting and electronic charting. The overarching theme is that electronic health records are not designed for a secondary legal use of records, but it must become an important design consideration, in order to avoid increasing litigation costs or distortion of the documented care.

1) ***Audit Trail usability*** -- Many legal counsel had hoped audit trails would serve as a provenance for the record and would be able to guarantee that the record was not modified or deleted because of litigation or some wrongful purpose. Most audit trails that exist as implemented fall far short. First, in practice, most vendors cannot certify that audit trail outputs are valid. Without this, audit trails are useless from a legal point of view. Audit trails cannot become evidence if their outputs cannot be validated. Second, all audit trails vary based on the choices made by the vendors designing the reports. Obviously some variation in audit trails is to be expected based on the needs of the software developers and implementing institutions, however, from a legal perspective a "bare minimum" standard logging timestamped changed and deleted values by users would make audit trails of more utility. It is frustrating going in circles with opposing counsel about whether after the fact changes were made to a record, and finding no clear support in an audit trail to resolve that issue. I have been involved in cases in which inquiry about audit trails have progress from in-house HIT staff through vendors with the end

result being no clear answer as to whether the record could be trusted. Increasingly, we can expect legal challenges to EHRs being used as evidence at all based on the lack of reliable audit trail support. Authentication of electronic documents is a key threshold that EHR data must meet if it will be considered reliable and trustworthy for evidentiary uses. A standardized “bare minimum” requirement for a legal audit trail will ensure EHR documentation will be allowed to be considered in the courtroom and relied on by litigants to tell their story.

2) ***Export distortion*** -- One issue important to medical liability matters is the often disconnect between native displays of EHR data and the exported print functions in either paper or electronic form. During production of EHR evidence, lawyers are often only provided with paper or imaged printouts which bear no resemblance to the native environments. The exported printouts are often cluttered, difficult to work with, and generate an enormous amount of unusable pages when compared to the paper chart equivalents (or the simple graphical interfaces clinicians are using in the native EHR). The most serious issue from a medical liability perspective is the difference between the paper print out and native environment in terms of design and the data accessible. It is not uncommon for medical professionals to have trouble recognizing the yield of a print function even when it is their own documentation. Often times the paper print out lacks and coherent organization, and almost never tracks the native electronic data display. Sometimes the paper printout lacks information displayed in the EHR, and sometimes the reverse is true. It is dependent on the templates created by the vendor to render a printed export. The design choices can have serious liability consequences. In one case, prior notes from one provider were jumbled together with another provider's notes, effectively making it seem to a jury as if one doctor's notes were another. A requirement for a read only display of a patient chart replicating the EHR native environment as a standard export would likely resolve many of these issues.

3) ***e-Discovery*** -- EHRs are tricky systems from a e-Discovery perspective as well. E-Discovery is a set of legal rules governing the production of electronically stored information or "ESI." Production of native ESI from an EHR system is problematic for a number of reasons. First, the data is generated in a proprietary system so is almost always unusable unless paired with the native EHR software which generated it. Most medical institutions cannot just share a copy of their EHR as implemented due to contractual limitations and exorbitant costs in replicating their native implementation. This has led some plaintiff's attorneys to successfully petition the courts for access to the live EHR in order to "see what it was the clinicians were seeing" at the time they delivered care. Some have gone so far to demand remote access at the time of trial in order for the native display to be put in front of the jury. Obviously from a security point of view, this is not an ideal scenario. Second, in EHRs the display of the data is just as important as the native ESI. Saving displays of the data is problematic as well. I am not aware of one system that preserves legacy displays which could be used during litigation. One additional complicating factor includes the tendency for EHR developers to push patches or upgrades which fundamentally change the display with no preservation of the historical display for any given time. Also it should be noted that several systems have role based displays of data (i.e. physicians, nurses and medical assistants have different data displayed when viewing the EHR) which further complicates production of authentic displays. Further, many systems rely on dynamic tables such that meta “problem lists” and “medications” are kept current, however the systems do not retain the historical versions of these tables if needed for litigation purposes. (i.e. wanting to know what the problem list looked like three years ago when certain care was rendered.) This inability to capture a frozen snapshot of a dynamic table in an EHR, caused one litigant to claim the health care provider spoliated evidence by using a system which did not preserve all of the data in a health care record in contravention of state and federal law.

Should you have any questions or comments, please do not hesitate to contact me.

Very truly yours,

Chad P. Brouillard