A Pandora's Box: The EMR's Audit Trail

By Matthew P. Keris
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It is safe to say that one of the most significant medical malpractice evidentiary developments since the widespread adoption of electronic medical records (EMRs) is the production of its "audit trail." By now, most who handle these types of claims know what the audit trail is, but for those who do not, it is a portion of the metadata (embedded computerized information about data entry) that can show the timing of chart entries and modifications done to it, if any. The audit trail can also show how long a portion of the chart was accessed and reviewed and whom was reviewing the entry. Sometimes the audit trail information is provided within a hard copy of the EMR record itself, or it can be produced separate and apart from the EMR record in another document, depending on the EMR system. Since the audit trail is available and saved with nearly every patient, the question in medical malpractice cases no longer is whether one can be produced. Rather, and as further discussed below, the current audit trail questions are (1) whether the audit trail should be produced; (2) if so, what parts should be produced; and, (3) how the information from the audit trail can be utilized at trial. The following will be an overview of how courts are handling these emerging audit trail issues.

No Fishing Expeditions: The Audit Trail Information Must Be for Legitimate Reasons

There is no clear precedent currently on the issue of whether a defendant health care provider must produce an audit trail as a matter of standard course as if it were the medical record itself. Courts surprisingly are deciding the issue primarily on relevance grounds, considering its broad definition. There are a number of decisions standing for the proposition that absent allegations of record alteration, "cover up" or improper health care provider access to the EMR, audit trail requests are irrelevant, overly broad and unduly burdensome to the defendant health care provider. See, Bentley v. Highlands Hospital, 2016 U.S. Dist. LEXIS 23539 (U.S.D.C., E. Dist. of KY)(Feb. 23, 2016) and Vargas v. Youssef, 2015 N.Y. Misc. LEXIS 2176, 2015 NY Slip Op. 31048 (U)(Sup. Ct. Kings Cty., June 10, 2015)("[g]eneral comments that the audit trail may provide discovery on the 'timing and substance of the plaintiff's care' are insufficient" and more needed to be shown before a defendant would have to turn over the audit trail).

In addition to medical malpractice cases where the content of the EMR is at issue, audit trails have also been ordered to be produced in instances where it was necessary to establish who received certain medical information that was important to the claims or defenses of a party. Gilbert v. Highland Hospital, 2016 N.Y. Misc. LEXIS 1672; 2016 NY Slip Op 26147 (March 24, 2016)("[w]hile the Vargas court concerned itself with the former consideration of relevance, it is the latter consideration [the who, what and when of chart access] which was at issue here."). See also, Moan v. Mass. General Hospital, 2016 Mass. Super. LEXIS 28 (Mar. 31, 2016) , where the defendant hospital was ordered to produce all audit trails or other documents sufficient to identify each person who accessed the patient's EMR; the periods of time they had accessed it; what they had accessed; and, all changes or additions made to the EMR by each person at each time in both paper and electronic form.

Further, audit trail information can be used to deny a summary judgment motion. In Prantner v. U.S., 2012 WL 2060632 (U.S.D.C. D. Minn. 2012), a hospital's EMR audit trail was cited as a main reason denying a defendant doctor's dispositive motion seeking dismissal from a medical malpractice case, where it was argued he had no duty to the patient. In that case, the critical issue for the defendant doctor was whether he was made aware of a critical laboratory value of a patient. The EMR was absent any specific reference or indication that the defendant physician had received, reviewed or even

considered the critical lab value. During his deposition, the defendant physician specifically denied knowing if he had or had not received the lab value, because he had no memory of it, and the EMR was not clear that he had received it. He was later confronted with the audit trail during his deposition, which indicated the lab value was available to him at a time when the patient was within the hospital. When asked, the physician admitted it was possible that he was aware of the lab value based on the audit trail information. At the conclusion of discovery, the physician filed a motion for summary judgment, arguing he had no duty to the patient, because the EMR did not reflect that he was given the critical lab results, nor did he know or admit that he was given the lab results. In denying the physician's dispositive motion, the court held that in considering the record most favorably to the plaintiff, the doctor's deposition testimony and the audit trail suggested the doctor was made aware lab value which was enough to deny his dismissal at that point procedurally.

At this point Pennsylvania law is absent any guidance on these audit trail issues, so the cases stated above are suggestive. That being said, these decisions provide guidance to the defense and objections to requests for the audit trail based on relevance should be considered if there are no issues pertaining to the contents and access to the EMR. Once the question of whether the audit trail should be provided is answered, the next issue deals with its production. Again, Pennsylvania courts are silent on these issues, but other jurisdictions can provide guidance on the production of the audit trail.

Know Your Role: Counsel Should Know What the Audit Trail Entails

Those lawyers who represent hospitals and large health care facilities know that plaintiff's document requests can result in significant time and expense to comply with those requests, not only to counsel, but also to the health care provider client. Some courts have considered cost-shifting arrangements in resolving issues of audit trail production on the basis that the request is "unduly burdensome" and "not likely to lead to relevant information." The Myers v. Riverside Hospital, 2016 VA Cir. LEXIS 53 (Cir. Ct. Newport News 2016)(April 21, 2016) case provides well-reasoned and practical guidance on how to handle the issue of producing an audit trail, when its production would assist plaintiff in advancing the claim, but result in considerable expense to the defendant.

In Myers, the plaintiff requested "any audit trails, metadata, EMR, or other identifiable health information" from the defendant hospital who conceded that plaintiff was entitled to this information, but the dispute was how to provide it. The plaintiffs specifically requested that the defendant load the EMR and metadata on USB drives and provide them to counsel, because they were not willing to sacrifice the convenience of accessing discovery materials on own terms, at any time. The defendant hospital suggested that plaintiff's counsel be given access to computer terminal at one of its locations at an agreed-upon time and that the request for the loaded USB be denied because it would expose it to undue expense.

As a way to resolve the issues, the trial court held that the defendant provide plaintiff with a good faith estimate of the costs associated to load a read-only EMR, including audit trails and metadata on USB drive. If plaintiff believed the estimate to be reasonable, then defendant would produce the USBs and bill plaintiff for the costs associated with its production. If plaintiff felt that the defendant overstated the costs associated with the USB production, a hearing on that issue would be held. The court reasoned "So long as plaintiff shoulders the expense of preparing the electronic materials in her preferred format, defendant does not incur any additional cost. And if plaintiff so values the ease of accessing the materials at her own convenience, plaintiff must be willing to pay for that right."

The Myers case represents an excellent example of expense cost-shifting for information that may be difficult, time-consuming and expensive. By shifting the costs of such an endeavor, it compels plaintiffs to seriously consider whether the potential gain of the metadata and audit trail is worth the expense in advancing their medical claim. In some instances, it just may not be worth it. Pennsylvania courts may be

persuaded by such an approach in handling the expense of audit trail production.

For defendant health care providers, another issue to consider when agreeing to produce the metadata and audit trail is knowing just what you will be producing. A complete understanding of what information is "out there" is necessary. Vague or incomplete understanding of the magnitude of the response to metadata discovery which results in partial or less than complete answers can lead to considerable additional time and expense to an endeavor that if done right the first time, would not have been as intensive. The case of Picco v. Glenn, 2015 U.S. Dist. LEXIS 58703 (U.S. Dist. Ct. CO 2015) is an example of what can happen when a half-hearted effort is placed in providing a "complete audit trail." In Picco, the defendant health care provider agreed it would provide a complete EMR audit trail as a part of a settlement agreement. Thereafter, during a hearing to enforce the terms of the settlement, the trial court held that the hospital had not complied with their agreement and was ordered to (1) produce a truly complete audit trail including all software applications, including independent systems that was excluded from the general EMR program (radiology department and EKG monitors); (2) permit entry by plaintiff's expert to conduct a forensic examination of the EMR in order to ensure that a complete audit trail was produced; (3) provide a database manager with knowledge, skills and credentials necessary to assist plaintiff's forensic examiner during the examination; (4) allow the plaintiff's forensic examiner at least 16 hours in the EMR; and, (5) bear the cost for providing a database manager to assist plaintiff's forensic expert.

Why so harsh a ruling on the defendant hospital? It appears from the case that despite agreeing to produce the "complete audit trail," the hospital failed repeatedly to do so. Instead, the hospital gave contradictory answers to audit trail responses and produced piecemeal audit trail information after repeatedly representing to the court and counsel that the audit trail was complete (in some instances limited by arbitrary date limitations). The hospital also was held to be in noncompliance with audit trail requests by not having someone available at hospital to assist with prior attempts to have plaintiff's forensic examiner review the EMR metadata. The court rationalized that the defendant hospital's production of "materials constituting 'building blocks' with which plaintiff might themselves assemble" as a complete audit trail was inconsistent with their rules of civil procedure which held that it was "the duty of the disclosing party, not the receiving party, to translate such information 'into reasonably usable form.'"

The Picco case is an example for hospital and health care system defense lawyers that courts may not take lightly issues of production of the complete audit trail. Defense counsel should know just what they are agreeing to produce before they agree to provide the "entire metadata" on a patient. Without knowing what is available, counsel may not know what they are agreeing to provide which may result in considerable time and expense borne by their clients.

Proper Experts Required for Introduction of Evidence of EMR Alteration

Once the audit trail is produced and counsel has had a chance to review it to the care rendered, plaintiff's counsel may seek to make an issue regarding the truthfulness of the information contained in the EMR at trial including allegations of alteration or wrongdoing. The limited precedent available indicates that prior to such attempts plaintiff's lawyers must support such factual charges with qualified expert testimony.

In Desclos v. Southern New Hampshire Medical Center, 2006 N.H. LEXIS 101 (July 11, 2006) the Superior Court of New Hampshire held that simple conjecture or inferences that an EMR record was altered based on a review of the audit trail is not enough, and expert testimony to support that position may be required. Absent expert testimony, a plaintiff patient was not permitted to present evidence to the jury that the EMR had been altered despite information that suggested after-the-fact changes to the record. It was specifically held that "[w]hether a medical record can be and has been altered on a computer, or on an electronic medical record system after having been transcribed is an issue requiring expert testimony." In that the

plaintiff did not submit an expert to support the argument that the defendant emergency room physician altered a treatment note, the plaintiff was not permitted to present evidence to establish the claim of alteration. The court concluded that as a matter of law, no rational juror could conclude from the evidence that there was a EMR record alteration.

Similarly, a Pennsylvania trial court concluded that proper expert testimony is required to prove an EMR alteration. The person providing testimony that a record was altered must be qualified prior to doing so. In Green v. Pennsylvania Hospital, 30 Pa. D & C. 5th 245 (2013), rev'd and rem'd other grounds, 123 A.3d 310 (Pa. 2015) , an informatics expert was precluded from offering expert testimony regarding EMR alterations because she lacked adequate qualifications and would provide testimony on a review of limited information.

In this medical malpractice case, the plaintiff sought to produce an informatics expert on EMR alterations against the defendant hospital, however after a voir dire hearing, the court determined it was appropriate to preclude the expert. During the voir dire hearing as to the proposed expert's credentials , it was learned that alterations expert had never worked with the specific EMR system either as a nurse or as an informatics consultant. Further, she had never seen the audit logs generated by this EMR system prior to this case. In precluding this expert based on her lack of qualifications, the court held that she was completely unfamiliar with the complex EMR and that "a passing entry level knowledge of the system was not enough given the seriousness of the conclusions she was alleging."

In addition, the court inquired as to the methodology of the informatics' expert's conclusions. When asked by the court as to how she reached her professional conclusion that the EMR was altered, the expert stated "I can't give you specifically what was altered, nor by whom. I can only look at what the audit trail shows as people having documented and then trying to track it back to the medical record and not being able to find entries that support that notation in the audit log." The court found the basis of the expert's opinions more troubling than her lack of experience with the EMR system and its audit trail. The court concluded that the expert came to her opinions "based merely on the fact that of a few records out of many hundreds of pages of hospital records being missing, that the record had surreptitiously been altered " was a "leap in logic [that] took it from the domain of expert testimony to pure unsupported assumption."

The Green trial court decision demonstrates that EMR experts whose testimony is proposed for purposes of proving an alteration must be both qualified and supported by proper methodology. From this case, it can be argued that the expert must have some prior working knowledge (either as a practitioner or expert) on the specific EMR system in use by the defendant and its specific audit trail. Further, a simple comparison of the audit trail to the EMR chart is not the proper methodology for proving a records alteration based on the complexity of the systems. For such a serious allegation to be presented to a jury for consideration, evidence of alteration or spoliation should be based on competent and qualified expert testimony.

Split Decisions: Application of Privilege to the Audit Trail

The audit trail is also problematic for hospital or health system defendants because the audit trail can reveal what information is being reviewed by those conducting a peer review and what information is being reviewed once a lawsuit is filed. The Hall and Moan decisions represents the first of what is anticipated to be several decisions regarding what portions of the audit trail should be discoverable and what should be protected by privilege.

In the first case that specifically dealt with the issue it was held that a peer review and attorney-work product privileges do not apply to an audit trail. In Hall v. Flannery, et. al., 2015 U.S. Dist. LEXIS 57454 (U.S.D.C., S. Dist. of Ill.)(May 1, 2015) the audit trail containing embedded information regarding what information the peer review committee viewed during a formal review and actions by the risk management team once litigation was anticipated was ordered to be produced to the patient's lawyer.

In Hall, the hospital defendant allegedly produced two "different" medical charts related to plaintiff's care. Believing there may have been records alterations, plaintiff's attorney requested manuals and instructional material and information regarding the EMR system vendor and an audit trail. The audit trail in this instance displayed embedded information from the peer review committee, including the identity of those on the peer review committee and what particular area of the plaintiff's EMR that was viewed. Similarly, it showed information viewed and utilized by risk management personnel and attorneys in anticipation of litigation.

The defendants collectively argued that these portions of the audit trail not be produced on the basis of the peer review and attorney work-product privilege. Plaintiff's counsel countered these arguments on several grounds. First, it was argued that the unredacted audit trail would be the best form of evidence to prove an alteration or after-the-fact change. It was further argued that the audit trail was a part of the medical record, and the peer review privilege would not protect it from disclosure as an "original source" document. Lastly, it was argued that the audit trail information produced as a result of defense counsel's review of the record was not considered "work-product" and subject to privilege because it was not solely created in anticipation of litigation.

The Hall court acknowledged that no legal precedent existed on this particular issue and was a case of first impression nationally. The court held that the audit trail and metadata was not peer review protected because: (1) the data was not specifically generated by a peer review committee in order to further its discussion of the medical care at issue; (2) it did not contain any information regarding the discussions held during the peer review committee meeting; (3) there was no evidence that the peer review committee looked at the audit trail during their discussions; (4) the audit trail only showed the time and portions a person viewed the EMR rather than interviews, memoranda or peer review meeting minutes; (5) it was generated n the normal and ordinary course of business and not for the specific use or consideration of the peer review committee; and, (6) there was no argument that the members of the peer review committee were to be kept secret or confidential.

Significantly, and in response to the defense's argument that the unredacted audit trail information would allow a "periscoping" of the peer review committee's concerns the court held that "to the extent that Plaintiff may acquire some advantage in knowing what documents were viewed by a committee member, such an advantage is negligible because the Plaintiff has already have had years to review the medical records themselves." Further, and in response to the defense's argument that the audit trail's information regarding the activities of the risk management department after the plaintiff requested a copy of the chart would violate the work-product privilege, the court held the audit trail was not protected by the attorney work-product privilege because: (1) the audit trail was not created in anticipation of litigation; (2) it was a part of the EMR; and, (3) it did not implicate the "mental impressions, conclusions, opinions or legal theories of a party's attorney or other representative concerning the litigation." The court concluded in this regard that he audit trail is only a reflection of who, when and what a person did in relation to the EMR and any additional knowledge or advantage to be gained from such information was negligible.

At least one court has specifically disagreed with the Hall ruling with respect to the application of privilege to the audit trail and the more narrow issue of whether the defendant health system would need to supply the names of those from a peer review committee who would be identified by the production of an audit trail. The Massachusetts trial court held in Moan, supra. that this information should not be produced, which acknowledges the privilege argument to the audit trail. The hospital defendant in Moan was excused from providing the names of the individuals who investigated the medical care on behalf of the peer review committee and to the extent that any of the information ordered to be provided was claimed to be privileged, it would produce a privilege log.

Hall and Moan are the first cases discussing the issue of privilege to the audit trail and for the defense and health care providers, this will be a considerable

issue moving forward. The Hall court's conclusion that the embedded information from the peer review committee as a part of the audit trail is of negligible advantage to the patient or their legal representatives is ripe for debate. There can be a very strong arguments made that the submission of embedded audit trail information recorded during a peer review analysis or after when litigation is reasonably anticipated reveals the thought process, work-product and medico-legal analysis that is otherwise privileged and protected. The audit trail from the peer review or attorney investigation could potentially show where there are concerns, weaknesses or deviations from accepted medical standards that would not have otherwise been made available. Further, the production of a completely unredacted audit trail could create a "chilling effect" discouraging frank and vigorous reviews by health care providers immediately after the care rendered which is contrary to why the peer review privilege was created. The lack of a thorough review by health care professionals because of the fear of litigation and discovery of their audit trail could contribute to health care providers repeating the same medical errors at the expense of quality patient care. It may also discourage early attorney investigations when memories are fresh and witnesses are available. It remains to be seen how Pennsylvania courts will decide this issue, and when it eventually comes before a court for consideration, it is anticipated to raise the attention of many.

Final Thoughts

For defense counsel, there are several considerations that need to be made with respect to the production of a health care client's audit trail. First, will the information advance the plaintiff's case in some manner, or is it a fishing expedition? A review of the plaintiff's complaint will provide guidance in this regard, and if there is no relevance for such a request, consideration should be made to object on these grounds. Second, know what the audit trail is and what its' production entails before producing it. Determine how labor intensive and expensive compliance with the request will be to the client and the professional liability carrier. If the time and effort are expansive, consider requesting a cost-shifting arrangement that bears costs upon the plaintiff. If the decision is made to produce the audit trail, make sure it is complete so as to avoid further criticism, scrutiny and cost to your client if it turns out that what was produced was incomplete. Third, demand that alteration evidence be precluded in the absence of qualified expert testimony. If it turns out the expert has no prior first-hand experience with the EMR system at issue or if they are simply comparing the audit trail to the record in coming to their conclusion, seek the preclusion of the evidence. Lastly, consider raising the appropriate privileges to audit trail entries by risk management (once litigation is anticipated) or if a peer review is conducted. By contemplating these issues, defense counsel will narrow the EMR's audit trail liabilities and keep the Pandora's Box shut. •

Matthew is a shareholder in the Health Care Department in the Scranton office of Marshall Dennehey Warner Coleman & Goggin.

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