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Electronic Medical Records and E-Discovery



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Special to the Legal

Health care in the United States is rapidly evolving. Changes and new challenges are altering the way health care is perceived, organized and delivered. These changes affect health care providers, organizations and patients presenting new issues that impact medical malpractice litigation.

One of the most significant current developments is the transition from the paper chart system to electronic medical records (EMRs). The Patient Protection and Affordable Care Act and the Health Information Technology for Economic and Clinical Health Act have spurred the change to EMRs to occur rapidly in the coming years. Additionally, the Centers for Medicare and Medicaid Services have put in place incentives and compliance deadlines (otherwise known as meaningful use requirements) to further ensure that the vast majority of providers are moving in the direction of electronic health records. For many providers, the change from paper to electronic health records will occur quickly in order to meet required deadlines and thereby reap the benefits of the monetary incentives.

However, providers racing to adopt EMRs have an obligation to ensure that underlying reasonable procedures exist to avoid adverse events during this transition,



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as in the U.S. District Court for the District of South Carolina's 2000 ruling in *Smith v. United States*. Although these procedures have yet to be specifically delineated, judicial scrutiny of a transition to EMRs entails a fact-sensitive analysis. Providers must document this transition in the event it becomes the subject of litigation.

ESI AND EMR

Electronically stored information (ESI) is abundant in all hospitals. Much of this information will eventually be incorporated into a patient's EMR. Beyond passive ESI, EMRs will have an active role in patient treatment, from interfacing with providers to offering clinical decision support. EMR systems will share core functionalities, yet more sophisticated EMR systems may suggest courses of treatment upon an analysis of medical data, remind a provider of clinical practice guidelines or automatically warn of a patient's allergies or of a dangerous combination of medications.

Within the next few years, virtually all health care providers will operate within an EMR system. Many providers are already operating with only electronic record systems and are facing new discovery issues once patient care questions arise in the context of a medical malpractice lawsuit. However, this transition to EMRs has implications that reach beyond typical discovery inquiries. For both reasons, it is critically important that from the very onset of the conversion to an EMR system, providers and their attorneys are aware of



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the legal issues that EMRs can create, so as to avoid potential problems.

EMR AND DISCOVERY

In 2006, the Federal Rules of Civil Procedure were amended to include provisions specifically regarding ESI and many states have followed suit. EMR falls within that category of e-discovery that is subject to those requirements. Specifically, Fed. R. Civ. Pro. 26 requires parties to disclose the existence and location of any and all stored electronic information that the party intends to rely upon in support of its position. Note also that e-discovery is not limited to the medical record itself. EMR systems have additional discoverable information that is not included within the printed record. A typical example would be the metadata reflecting additions or changes to the medical records.

Fed. R. Civ. Pro. 26(b)(2) provides for discovery of ESI that the possessing party may not deem to be readily accessible due to undue burden or cost. Such information is likely to be subject to discovery if relevant to the claims asserted. System computers may be subject to hard-drive requests from the providers' computers, as well as the health care organization's computers. The analysis of system data and the depositions of IT personnel who are knowledgeable about a particular EMR system are likely to become more common.

An EMR can be a very useful tool in the discovery process, providing the capability to track the slightest alteration to a patient's record. This includes being able to document

when and by whom information was either entered or modified and how long a particular provider took to review a record or imaging results. Many EMR systems have a lockout control, which is a time after which a particular entry on a patient's chart is no longer open for alteration or modification. This prevents an entry from being added days later absent a system override requiring the provider to contact the administrator. EMR technologies can also help eliminate transcription errors necessitating later alterations of records. Many EMR systems will back up information off-site to prevent records from being damaged or lost. All of these advances in patient medical data preservation make EMRs a strong courtroom tool, for the EMR is arguably a piece of evidence laying its own foundation.

Of course, this is only the case when actual technical procedures and protocols that embody an EMR go unchallenged. As mentioned above, the use of EMRs can also greatly complicate the complexity and cost of discovery necessitating IT experts, which was one of the motivating factors behind the cost-sharing analysis of Fed. R. Civ. Pro. 26(b)(2). When an issue of a modification or alteration of a record does arise within the course of litigation, counsel for the opposing party can request the system information regarding any and all changes or alterations that have been made. This can become a very costly and time-consuming process if the system in place is not one that makes this information accessible and easy to provide. Also, an adverse inference to any modification or alteration in a patient's records will also result in an inability to effectively defend a matter, or at the very least, will present yet another obstacle to be overcome. This information should be accessible to the administrator for ease of discovery to avoid these issues.

In addition to record modifications and alterations becoming issues during the course of discovery, failing to ensure the integrity of EMRs can lead to spoliation of evidence, which is the intentional or negligent withholding, hiding, alteration or destruction of evidence relevant to a legal proceeding. This is one of the most serious issues that can occur with an incorrectly managed EMR. The result can be the imposition of extremely harsh penalties, including the preclusion of evidence, the dismissal of claims or an adverse inference being applied to the information in question. The inability of a health care provider or organization to use

the patient's EMRs at the time of trial ultimately results in the inability to best defend the matter.

EMR AND THE FUTURE

The widespread adoption of EMRs has the potential to aid in medical malpractice litigation by putting unwieldy amounts of information in a more user-friendly and searchable format, as well as by "definitively" providing the facts surrounding a patient's care, in theory. However, EMRs may also have a substantial impact on fundamental elements of medical malpractice litigation that force providers, patients and attorneys to re-examine pursuing and/or defending claims in the future.

One of these elements is the practical concern of the scope of a medical malpractice claim. EMRs may increase the scope of a claim in three key aspects: (1) the number of parties to pursue in a claim; (2) the amount of money needed to successfully litigate a claim; and (3) the amount of time a claim will require to resolve.

For instance, copying and pasting information from EMR to EMR is a basic capability shared by most EMR systems. The danger therein is that this allows for the perpetuation of an existing error or inaccuracy to follow a patient from provider to provider. An error, such as the omission of an allergy to a medication, never realized through one provider's course of treatment, may result in an adverse event through the course of treatment of another. The origin of this error may only be discovered well into the litigation of a claim necessitating amended complaints and/or answers and spawn disputes regarding liability. Another foreseeable event would be a technical error (software bugs, hardware malfunctions, etc.) resulting in an adverse event.

The extension of liability to an EMR vendor is an eventuality that necessitates significant technical discovery akin to a products liability action, yet framed within the nuanced complexities of a medical malpractice claim. Counsel for providers must educate clients regarding the importance of carefully choosing an EMR vendor and system. Also, health care providers should avoid contractual agreements that might immunize EMR vendors from technical errors leading to adverse events.

The use of EMRs may also change how standards of care are defined in a medical malpractice claim. Providers implicated in an adverse event may be weighed and measured against a sophisticated EMR system that

provides differential diagnoses or recommended courses of treatment. If a provider deviates from an EMR's recommended course of treatment, a jury may very easily equate that to a deviation from a legally defined standard of care. This would require that the focus of the defense be not only on the standard of care set forth by an expert, but also on a defendant's justification for deviating from the EMR-generated treatment recommendations. Also, standards regarding EMRs themselves may find traction; a hospital that does not utilize EMRs or uses a basic system may face liability if those systems utilized are deemed to be below an acceptable standard.

PROPOSED EMR LEGISLATION

Both the Pennsylvania State House and the House of Representatives have recently had legislation proposed regarding EMRs. In Pennsylvania, legislation has been proposed that provides immunity to suppliers of medical data to electronic databases with regard to medical malpractice claims. On the federal level, the Safeguarding Access for Every Medicare Patient Act, introduced by Pennsylvania Congressman Tom Marino, seeks to create legal protections for CMS providers if an adverse event occurs as a result of EMR errors.

TAKING CARE WITH EMR

Great care must be taken in selecting an EMR system and using that system to ensure the accuracy and integrity in the daily handling of patient medical records. Also, when records are produced in response to a specific claim or during discovery in litigated matters, procedures need to be in place to avoid needless evidentiary battles. The future of EMRs in medical malpractice litigation is uncertain, but being cognizant of potential issues and remaining educated with regard to advances in technology will afford the medical malpractice bar the level of preparedness necessary to avoid troublesome and costly issues during the course of case preparation. •