Electronic Medical Records Legal Requirements

Are your electronic records legal?

Lists of required attributes & questions to ask before buying a system:

Monday, October 6, 2008 4:49 AM From: "Ken Pope" <ken@kenpope.com>View contact details

To: "Ken Pope" <ken@kenpope.com>The new issue of the American Medical Association's *American Medical News* (vol. 51, no. 38) includes an article: "Is your EMR legal? A document can look like a medical record, but not meet the legal definition. System design and user error can contribute to vulnerabilities that increase your liability" by Pamela Lewis Dolan.

PLEASE NOTE: At the end of this article, under "Additional Information* is (a) a list of attributes that electronic medical records must have when presented as evidence in court must, and (b) questions to ask before buying an electronic medical record system.

Here are some excerpts:

You might find your electronic medical record to be an efficient way to store patient data, but is that record legal? If it were subpoenaed, would it help you or hurt you in court?

These kinds of questions are emerging as more physicians go electronic. Federal Rules of Civil Procedure, approved by the U.S. Supreme Court in December 2006, not only make any electronically stored data discoverable in a trial, but also open up physicians to several new liabilities inherent in the detail electronic data provides.

While EMRs are touted as a way to make life easier for physicians, health IT and legal professionals say they can make life miserable for a doctor who buys the wrong system, or uses it in the wrong way.

"Where these issues can raise their heads is somewhat unpredictable," said Reed Gelzer, MD, co-founder of Advocates for Documentation Integrity and Compliance, an advocacy and consulting group that educates physicians and health care entities on the legal EMR.

But, as some recent cases of snooping hospital employees have proven, EMRs can also detect when someone violates HIPAA. And, just because an EMR creates something

that looks like a medical record doesn't mean that document fits the legal definition of a medical record. Few protections exist.

Minneapolis health care attorney Gerald Deloss, vice chair of the American Health Lawyers Assn.'s Health Information and Technology Practice Group, says safeguards, including system certification, help vendors design systems that meet certain legal criteria relating to the Health Insurance Portability and Accountability Act and the civil procedure laws. But as certification requirements evolve, safeguards can end up lacking.

"There are currently very few standards for EMRs, and the certification process is just now getting under way. ... [It] still allow[s] behavior that would disqualify the EMR as a legal record if challenged in court," said Jonathan Tomes, president of EMR Legal, a consultancy firm based in Overland Park, Kan.

The Certification Commission for Healthcare Information Technology, which declined comment for this story, is the most well-known and widely used certifying body. The organization, founded in 2004, was contracted by the U.S. Dept. of Health and Human Services in 2005 to help further its goal of widespread EMR adoption. It released its first set of certification criteria in 2006.

Dr. Gelzer said there are three areas to consider when shopping for a legal EMR:

* How well the system shows authorship. Does it clearly show who entered what portion of the record?

* How the system deals with changes. Does it track alterations to the record as well as who made each change and when? Does it save the original?

* How well the system's audit function supports the accuracy and validity of the record. Are there cross-checks in place?

A system used incorrectly offers many ways to help a plaintiff prove the physician is negligent.

Attorney Lori-Ann Rickard, president of St. Clair Shores, Mich.-based Rickard & Associates, said there can be problems with systems that have **click-box features**, which allow physicians to select **pre-formatted boxes** to answer questions during the clinical exam. "When I am in litigation, they are always making the doctor look like this heartless guy that is trying to whip through patients, but 99% of the time that is not true."

She recommends systems provide an outlet for **free text**, so a doctor can click standard boxes, but still add notes to show the variations between each patient

exam. "I want a doctor who is thinking and I want the medical record to show he is thinking."

But even EMR notes that are written out come with risk. In the April 17 New England Journal of Medicine," Pamela Hartzband, MD, and Jerome Groopman, MD, a physician couple in Massachusetts, wrote about the dangers of errors being perpetuated when physicians **cut and paste previous clinical notes written by colleagues**. Similarly, cloned data -- copied **boilerplate language** -- is on the radar of insurers, and many are refusing to accept it as establishing medical necessity.

Physicians shouldn't give in to the pressures to go electronic until they have gone through a careful, deliberate selection process, he said.

"The idea that an EMR decision could actually be a step backwards is obviously not something the vendor is going to say," Dr. Gelzer said.

"And the government wants so badly for people to use these systems, but the government hasn't been forthright about the risk issue either."

ADDITIONAL INFORMATION:

Making it legal

Electronic medical records presented as evidence in court must have certain attributes.

* The record must be documented and kept in the normal course of business.

* The record has to be made at or near the time of the exam or event recorded.

* The record has to be made by a person with knowledge of the events. When dictation is used, the physician must review the report for accuracy and authenticate it.

* The computer used must be considered standard and efficient equipment.

* Authors and sources of information must be identified.

* Alterations must be noted and the original record preserved.

* Authors must be able to display the quality checks/audits used to ensure data integrity.

Sources: "The Legal EMR" presentation by Reed Gelzer, MD, and Patricia Trites; other resources

Ask the vendor if and how an EMR will protect physicians and produce legally sound records.

* Does the system assign authors to each new entry in a document? The system should not overwrite a prior author.

* Does the system record the time and identity of each user and what he or she looked at or changed?

* Are alterations to records obvious?

* How easily can an audit be performed? How accurate is the audit? The audit trails should not be alterable or easily disabled.

* Does the EMR allow "documentation by exception," which allows the determined norms to be entered into the record unless otherwise changed?

* Does the EMR allow "open item billing," which automatically bills when an order is made? If so, can it be disabled?

* Does the system have controlled access that provides different views dependent on the user's job title or department?

* Does the system allow cut-and-paste functions? If so, is the original source identified?

* If the system has click-box features, does it also allow free-text entry?

Sources: "The Legal EMR" presentation by Reed Gelzer, MD, and Patricia Trites; other resources