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IN THIS ISSUE

Health care providers have to continually adapt to the evolving landscape of health information technology. This article provides a brief history of the movement toward a nationwide electronic health record system; reviews common issues seen in using electronic health records; and discusses whether metadata is part of a patient's health record, so as to be subject to production in litigation.

Keeping Up with the Technology: Constant Changes Perpetually Impact the Practice of Medicine and Create Liability Risks

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Introduction

Typically, the most important piece of evidence in any medical malpractice case is the medical record. An accurate and well-documented record can demonstrate the practitioner exercised reasonable judgment and met the standard of care. Incomplete or inaccurate medical records or records which appear to be altered, can create uncertainty and doubt. This, in turn, serves as an immense obstacle to overcome at trial.

Before electronic records, the medical record typically consisted of a single folder with a manageable amount of paper. Since the push for nationwide implementation of electronic health records, medical records can be thousands of pages. Litigators who prefer hard copies often find themselves hidden behind stacks of five-inch binders. In addition to the typical documents found in a paper chart, electronic health records provide more detailed information and are often formatted in a way that can be repetitive and difficult to follow. Electronic health records not only increase the amount of material at issue in medical malpractice cases but expose health care providers to liability risks that were virtually non-existent prior to introduction of the electronic health record.

Programs encouraging use of health information technology change from year to year with recurrent updates to rules and requirements—the most recent being the Office of the National Coordinator for Health Information Technology's Cures Act Final Rule scheduled to go into effect June 2020.[1] This paper briefly outlines the origins of this movement toward a health care technology ecosystem and discusses liability concerns associated with electronic health records.

Moving Toward an EHR Centered World

Over ten years since its passage, the Health and Information Technology for Economic and Clinical Health (HITECH) Act of 2009 remains an influential force in the delivery of health care in the United States. HITECH set out to promote the meaningful use of electronic health records; a task considered to be a critical national goal.[2] Often used interchangeably, electronic health records (EHR) and electronic medical records (EMR) are not one in the same.[3]

The Office of the National Coordinator for Health Information Technology (ONC) refers

[1] Department of Health and Human Services, *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*, https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification (published May 1, 2020; effective June 30, 2020).

[2] Centers for Disease Control and Prevention, *Public Health and Promoting Interoperability Programs*, https://www.cdc.gov/ehrmeaningfuluse/introduction.html (page last reviewed Sept. 9, 2019).

[3] Garrett, Peter et al., Health IT Buzz, *EMR v. EHR – What is the Difference?* https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference (Jan. 4, 2011);

to EMRs as the digital version of paper charts from a provider's office.[4] EMRs can be difficult to share or exchange. [5] Providers have many options when it comes to EMR software, which can be incompatible with software used by other providers. Instead of exchanging the information electronically between compatible EMR systems, providers often print EMRs to send via scan, fax, or mail.[6] Printing EMRs can be troublesome, especially when a provider mistakenly believes they printed a complete copy of the record but the EMR system printed an incomplete version. By contrast, EHRs go beyond record maintained by a single provider to include to information gathered from every provider involved in a patient's care.[7] All authorized providers have access to this information, allowing a patient's EHR to move fluidly between specialists, hospitals, nursing homes, and laboratories.[8]

In 2011, the Centers for Medicare and Medicaid Services (CMS) established the Medicare and Medicaid EHR Incentive Programs to encourage health care professionals and hospitals to adopt and demonstrate meaningful use of certified electronic health record technology (CEHRT) in the delivery of health care.[9] CMS and the ONC established standards and criteria EHRs must meet in order to qualify for these programs.[10] These standards have been updated several times throughout the years. We can expect to see continued updates as technology advances.

The concept of meaningful use comes from five health care policy priorities: (1) improving quality, safety, efficiency, and reducing health disparities; (2) engaging patients and families in their health; (3) improving care coordination; (4) improving population and public health; and (5) ensuring adequate privacy and security protection for personal health information.[11] The EHR Incentive Programs set forth a three-stage plan to phase-in nationwide compliance.[12]

Stage 1 established requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.[13]

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[4] HealthIT.gov, *What are the differences between electronic medical records, electronic health records, and personal health records?* https://www.healthit.gov/faq/what-are-differences-between-electronic-medical-records-electronic-health-records-and-personal (page last reviewed May 2, 2019).
[5] Garrett, *supra* note 3.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Centers for Medicare & Medicaid Services, *Promoting Interoperability Programs*, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html (page last reviewed April 10, 2020).
[10] Centers for Medicare & Medicaid Services, *Certified EHR Technology*, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification (page last reviewed April 15, 2020).
[11] CDC, *supra* note 2.
[12] CMS, *Promoting Interoperability Programs*, *supra* note 9.
[13] *Id.*

Stage 2 expanded upon the Stage 1 criteria with a focus on advancing clinical processes and encouraged the use of CEHRT for continuous quality improvement at the point of care and structured exchange of information.[14]

Stage 3 focused on using CEHRT to improve health outcomes and updated meaningful use requirements to be implemented in 2017 and subsequent years.[15]

In 2018, the EHR Incentive Program was renamed "Promoting Interoperability Programs," signaling a new focus on the interoperability of health care data and improving patient access to health information.[16] Interoperability refers to the connection of EHR systems that allows health care providers to seamlessly share their patients' records regardless of the software being used.[17]

The ONC's Cures Act Final Rule, going into effect June 2020, furthers this focus on interoperability by promoting innovation in the health care technology ecosystem to deliver better information, more conveniently, to patients and providers.[18] In addition to promoting interoperability, adoption of standardized application programming interfaces (API) is encouraged to allow patients and providers to securely and easily access structured electronic health information using smartphone applications.[19] The Cures Act also seeks to prohibit information blocking, which involves interference with the access, exchange, or use of electronic health information.[20] As with previous changes that came before it, these new rules and requirements continue to impact the daily practice of medicine and introduce new risks of liability.

Recurring EHR Problems and SAFER Guides' Recommended Solutions

Recognizing the safety concerns created by the changing landscape in healthcare technology, the ONC created the SAFER Guides, which help health care organizations conduct self-assessments to optimize the safe use of EHRs.[21] Working together, health care providers, health IT vendors, and various stakeholders identify recurring problems and find solutions.[22] Recurring problems are seen in electronic communication, documentation and user errors, and clinical decision support tools.

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[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] Reisman, Miriam, *EHR: The Challenge of Making Electronic Data Useable and Interoperable*, Pharmacy & Therapeutics, Vol. 42, No. 9 (Sept. 2017).
[18] HealthIT.gov, *About ONC's Cures Act Final Rule*, https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule (last viewed April 28, 2020).
[19] *Id.*
[20] HealthIT.gov, *Information Blocking*, https://www.healthit.gov/topic/information-blocking (last viewed April 15, 2020).
[21] HelathIT.gov, *SAFER Guides*, https://www.healthit.gov/topic/safety/safer-guides (page last reviewed Nov. 28, 2018).
[22] Graber, Mark et al., *Electronic Health Record-Related Events in Medical Malpractice Claims*, Journal of Patient Safety, 15:77-85 (June 2019).

Electronic Communication. Promoting Interoperability Programs require coordination of care through patient engagement via CEHRT.[23] To meet this criterion, eligible professionals must show, among other things, use of patient portals and APIs (smart phone applications) to interact with patients via electronic messaging.[24] Increased availability and access to health care providers through APIs and patient portals multiplies the number of patient encounters.[25] The content and timeliness of these remote encounters can expose providers to liability. For example, offering medical advice without conducting a physical examination or failing to respond to a patient message can expose providers to liability risks.[26]

Electronic communication overload can also cause problems when high volumes of information, some of which is not clinically relevant, become intermingled with high urgency communications, causing important information to be overlooked.[27] The SAFER Guides recommend that providers schedule sufficient non-face-to-face time into their daily schedules to allow them to appropriately manage electronic communications.[28] Organizations can also delegate duties to other employees for matters not requiring physician involvement and utilize systems of sorting messages by urgency and type.[29]

Communication breakdown between providers is one of the most common causes of medical errors and patient harm.[30] EHRs integrate communication tools for referrals, consultation orders, and discharge related communications.[31] The SAFER Guides recommend implementation of mechanisms to monitor timeliness of acknowledgement and response to messages, including categorizing the status of communications as sent, delivered, opened, and acknowledged.[32] Additionally, it is recommended that the EHR contain copies of provider-to-provider communications,[33] further adding to the volume of discoverable materials available during litigation. Providers should particularly be mindful of advances in telemedicine and increased volumes of electronic communications due to the coronavirus pandemic.

Documentation Errors. Auto-filled templates can lead to inaccuracies in the record. For

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[23] Centers for Medicare & Medicaid Services, *Eligible Professional Medicaid EHR Incentive Program, Stage 3 Objectives and Measures, Objective 6 of 8, Coordination of Care through Patient Engagement* https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MedicaidEPStage3_Obj6.pdf (updated August 2017).

[24] *Id.*

[25] Paterick, Zachary et al., *Medical liability in the electronic medical records era*, Baylor University Medical Center Proceedings, 31:558-561 (Oct. 2018).

[26] *Id.*

[27] HealthIT.gov, *Clinician Communication*, SAFER Guides, https://www.healthit.gov/sites/default/files/safer/guides/safer_clinician_communication.pdf (Oct. 2016).

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.*

example, an automatic template for an annual OBGYN visit may list breast examination under services rendered. If the physician fails to perform the breast examination and fails to delete it from the automatic template, the record would incorrectly reflect that the breast examination took place.

Temptation to copy and paste can perpetuate documentation inaccuracies.[34] For example, identical progress notes documented on separate office visits can raise suspicions during litigation as to whether a physician conducted complete assessments on both visits. Additionally, copying and pasting can be problematic when providers rely on copied information as being accurate on the date in question. For example, a provider could incorrectly assume a patient is on certain medication by looking at a medication list that was automatically pulled from an outdated one.[35]

Documentation errors related to the administration of medication can have drastic effects. For example, medication measurements entered with incorrect decimal point placement could result in overdose.[36] The SAFER Guides recommend implementing re-authentication processes by requiring re-entry of a pin number or password to authenticate an order to help providers confirm the orders they entered are correct.[37]

User Errors. EHR systems often involve complex layers requiring several clicks of the mouse before entering a note or finding critical information. User error can occur when selecting from a drop-down menu too quickly or making the wrong selection by mistake.[38] For example, instead of ordering Flonase, the provider orders Flomax by clicking on the wrong drop-down selection.[39] Information overload from EHRs can lead providers to overlook important information.[40] The complexity of the EHR system, combined with the lack of appropriate training, can render an inexperienced EHR user unable to locate or access up to date imaging studies.[41] Moreover, less tech-savvy users may resist adapting to EHR systems, resulting in poor documentation.

Using EHRs in a clinical setting often reduces face time with patients. Providers are spending more time looking at screens, clicking through check points in the EHR, reducing eye contact with patients and hands on interactions during examinations. This can lead to patient dissatisfaction and increase the likelihood of allegations of negligence.[42]

[34] Paterick, *supra* note 25.
[35] Graber, *supra* note 22.
[36] *Id.*
[37] HealthIT.gov, *Computerized Provider Order Entry with Decision Support*, SAFER Guides, https://www.healthit.gov/sites/default/files/safer/guides/safer_cpoe.pdf (Nov. 2016).
[38] Graber, *supra* note 22.
[39] *Id.*
[40] Paterick, *supra* note 25.
[41] Graber, *supra* note 22.
[42] Paterick, *supra* note 25.

Clinical Decision Making. Promoting Interoperability Programs require eligible providers to implement clinical decision support (CDS) tools.[43] CDS tools enhance clinical decision-making through computerized alerts and reminders; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually-relevant reference information.[44] Although these tools can be viewed as standards, potentially impacting the definition of the standard of care in medical malpractice litigation, it is important to remember that the practice of medicine cannot be confined to an EHR system and CDS tools. That is, these tools cannot encompass, and may even ignore, all possible clinical scenarios providers may face.[45]

The SAFER Guides recognize CDS tools can introduce errors that adversely affect care.[46] Providers lose control over clinical decision-making if they fully rely on these tools, without constant monitoring and questioning to ensure that diagnosis and treatment are correct.[47] Out of date or incorrect information provided by CDS tools can result in patient harm.[48] The SAFER Guides recommend that current best practices and guidelines from national organizations and medical specialty profession associations be incorporated into CDS tools.[49] While this information can be helpful, physicians should ultimately rely on their education, training and experience, thereby utilizing clinical judgment based on the specific clinical scenario before them.

Eliminating and reducing useless or underutilized CDS advice can reduce overload and provider dissatisfaction.[50] The SAFER Guides recommend that EHR systems allow providers to remove alerts that do not make sense in the particular clinical context. For example, alerts for diabetic foot screening should not be presented for patients with bilateral lower extremity amputations.[51] Alert displays can also be modified to show only the most severe interactions with a specific drug versus a list of every single drug interaction.[52]

Although the SAFER Guides are only recommendations, providers should be cognizant of the issues previously discussed and consider implementing the ONC's recommended practices. It is important, however, for providers to remember that while CDS tools and technology support clinical judgment, they do not replace it.[53]

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[43] HealthIT.gov, *Clinical Decision Support*, https://www.healthit.gov/topic/safety/clinical-decision-support (content last reviewed April 10, 2018).
[44] *Id.*
[45] Paterick, *supra* note 25.
[46] HealthIT.gov, *CPOE*, *supra* note 37.
[47] Graber, *supra* note 22.
[48] HealthIT.gov, *CPOE*, *supra* note 37.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] Graber, *supra* note 22.

Patients' Rights to Medical Records: Including EHR Metadata and Audit Trails?

A common theme seen in HIPAA, HITECH, and the Cures Act, is a patient's right to the medical record. Given that EHRs increase the amount of health information gathered on a patient, an issue arises as to what information a patient is entitled to under these laws. Proponents of using metadata and audit trails in litigation argue the audit trail is metadata about the medical record and, therefore, undeniably part of the record.[54] However, the provisions that govern a patient's right to the medical record do not include metadata and audit trails in their definitions of patient health information.

Audit Trail Requirements. As a brief background, HIPAA requires covered entities to record and examine activity in the EHR.[55] This can be achieved through audit trails, which serve as a record of each action performed, when it was performed, and who performed it. Additionally, HITECH requires that EHRs provide capabilities for users to create an audit report for a specific time period and to sort entries in the audit log.[56]

Patients' Rights to Health Information. HIPAA's Privacy Rule requires covered entities to provide individuals with access to their protected health information (PHI) in one or more designated record sets maintained by the covered entity.[57] Given this requirement, it is first important to understand the various regulatory definitions of the information at issue.

Protected health information and electronic protected health information (PHI and ePHI) mean individually identifiable health information transmitted by electronic media; maintained in electronic media; or transmitted or maintained in any other form or medium.[58] "Individually identifiable health information," in turn, is defined as a subset of health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.[59]

"Designated record set" includes records maintained by or for a covered entity, including medical records and billing records; the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or records used, in whole or in part, by or for the covered entity

[54] Keel, Jennifer, *Follow the Audit Trail*, Journal of Nurse Consulting, 12:25-28 (Summer 2015).
[55] 45 C.F.R. §§ 164.308(a)(1)(ii)(D); 164.312(b).
[56] 45 C.F.R. § 170.210.
[57] Department of Health and Human Services, *Individuals' Right Under HIPAA to Access their Health Information 45 CFR 164.524*, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html (content last reviewed Jan. 31, 2020).
[58] 45 C.F.R. § 160.103.
[59] *Id.*

to make decisions about individuals.[60] The term "record" means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.[61]

Following the trend of HIPAA and HITECH, the Cures Act puts patients in charge of their health records.[62] According to the ONC, giving patients more power in their health care is key to implementing interoperability requirements.[63] The goal of the Cures Act is to promote transparency, providing Americans with the ability to regain visibility in the services, quality, and costs of health care.[64] Accordingly, the Cures Act prohibits information blocking. Information blocking is a practice by a health IT developer or health care provider that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI).[65]

EHI is ePHI, as defined in HIPAA, to the extent that the ePHI would be included in a designated record set regardless of whether the group of records are used or maintained by a covered entity.[66] In other words, EHI extends to records maintained by developers of certified health IT, a health information network, a health information exchange, or even a health care provider that might not be a covered entity or acting as a business associate of a covered entity.[67] In arguing patients are entitled to metadata and audit trails, opposing counsel may cite to these laws, arguing that the information is not only relevant to the case, but that the plaintiff has a right to the data under the spirit of these laws. This latter argument, however, fails to acknowledge the language used in the definitions set forth by the controlling laws.

According to the definition of designated record set, individuals do not have a right to access PHI that is not used to make decisions about them.[68] The Department of Health and Human Services gives the following example: "peer review files, practitioner or provider performance evaluations, quality control records used to improve customer service, and formulary development records *may be generated from and include an individual's PHI but may not be in the covered entity's designated record set(s) to which the individual has access*."[69] Although not used by the Department of Health and Human Services in its discussion, an analogy can be made to metadata and audit trails. Metadata and audit trails are generated

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[60] 45 C.F.R. § 164.501.
[61] *Id.*
[62] HealthIt.gov, *About ONC's Cures Act Final Rule*, *supra* note 18.
[63] *Id.*
[64] *Id.*
[65] HealthIT.gov, *Information Blocking*, *supra* note 20.
[66] Cures Act Final Rule, *supra* note 1.
[67] *Id.*
[68] Department of Health and Human Services, *What personal health information do individuals have a right under HIPAA to access from their health care providers and health plans?*, https://www.hhs.gov/hipaa/for-professionals/faq/2042/what-personal-health-information-do-individuals/index.html (content last reviewed June 24, 2016).
[69] *Id.* (emphasis added).

from an individual's PHI/EHR, but they are not included in a covered entity's designated record set, because metadata and audit trails are not used to make decisions relating to patient care. With regards to HITECH's requirement that the EHR give users the ability to create an audit report, the ONC explicitly clarified "users" does not include patients.[70] In sum, patients are not entitled to metadata or audit trails under these laws.[71]

Where do we go from here?

Health care providers must remain diligent and build endurance to face inevitable changes and advancement in technology. As technology continues to push boundaries, adapting will become a regular part of practicing medicine. Most litigators will face these issues at some point in their medical malpractice work. Lawyers should continue to recognize these issues in their cases and educate their clients how the EHR can expose them to liability.

[70] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, 77 Fed. Reg. 171, 54,163-54,292 (Sept. 4, 2012) (revising 45 C.F.R. Part 170).

[71] The question of whether metadata and audit trails are discoverable in litigation is an entirely different question. While courts are split on the issue, most find metadata and audit trails to be discoverable.

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