THE ELECTRONIC HEALTH RECORD: A DISCOVERY AND PRODUCTION NIGHTMARE

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I. INTRODUCTION

One of modern civilization's greatest achievements has been the dramatic increase in life expectancy.[1] The life expectancy for a United States citizen in 2014 was 78.8 years,[2] a considerable increase from the 49.3-year life expectancy in 1901.[3] Much of this increase in life expectancy can be attributed to improvements in medical technologies.[4]

Advancements in medical technology, from the magnifying glass to the ultrasound, the stethoscope to the artificial heart, and the x-ray to the M.R.I, have increased health care providers' knowledge of disease detection, prevention, and cure.[5] While there are countless examples of technological advances in medicine,[6] one of the most impactful changes occurred in how patient information is recorded and stored in the electronic medical record (EMR).[7]

EMRs were first developed in the 1960s.[8] As they evolved and gained widespread acceptance, paper records became all but obsolete in the modern practice of medicine.[9] As with any new technology, EMRs brought new

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[1] NAT'L INST. OF AGING, GLOBAL HEALTH AND AGING: LIVING LONGER (2015), https://www.nia.nih.gov/research/publication/global-health-and-aging/living-longer.

[2] CTR. FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR HEALTH STATISTICS: LIFE EXPECTANCY (2016).

[3] Max Rouser, *Life Expectancy*, OUR WORLD IN DATA (2016), https://ourworldindata.org/life-expectancy.

[4] *Snapshots: How Changes in Medical Technology Affect Health Care Costs*, KAISER FAM. FOUND. (Mar. 2, 2007), http://kff.org/health-costs/issue-brief/snapshots-how-changes-in-medical-technology-affect.

[5] Nicholas Bakalar et al., *Milestones in Medical Technology*, N.Y. TIMES (Oct. 10, 2012), http://www.nytimes.com/interactive/2012/10/05/health/digital-doctor.html.

[6] *Id.*

[7] *EMR: A New Era in Medical Technology - Survey Results*, NET HEALTH (Jan. 9, 2016), http://www.nethealth.com/emr-a-new-era-in-medical-technology-survey-results.

[8] Micky Tripathi, *EHR Evolution: Policy and Legislation Forces Changing the EHR*, BODY OF KNOWLEDGE (Oct. 2012), http://bok.ahima.org/doc?oid=105689#.Wa2w7sh95Go.

[9] ROBERT E. HOYT, HEALTH INFORMATICS: A PRACTICAL GUIDE (6th ed. 2014).

possibilities, opportunities, challenges, and difficulties not only for the medical profession, but also the legal profession.[10]

For the medical profession, EMRs' ability to record and store information is like a dream, albeit an imperfect one.[11] However, their impact on the legal system is more akin to a nightmare.[12] The complexity of EMRs has created challenges that our legal system has been slow to subdue.[13] The law has dragged painfully behind the technology only addressing a select few of the discovery issues that have arisen with EMRs.[14] To make matters worse, the few times that the courts have ruled on such issues the clarity hoped to be achieved is lost in a fog of inconsistent rulings.[15] To demonstrate some of the discovery issues created by EMRs, it is helpful to analyze a hypothetical medical malpractice case.

In the hypothetical case, Dr. Krueger has been served with a complaint as well as a request for production of documents. The request for production specifies that Dr. Krueger is to produce all medical records that he has pertaining to the care received by the plaintiff over the past ten years. Further, the plaintiff wants access to her EMRs' metadata and audit trails, a computer with the EMR software installed, and the EMR software's manual.

Dr. Krueger remembers the days when paper medical records with his illegible hand writing were kept in individual manila folders in his small family practice on Elm Street. Due to Dr. Krueger's reluctance to change, he did not implement an EMR system in his practice until 2009. Therefore, some of the plaintiff's requested records are in paper format while others are EMRs. Dr. Krueger inquires of his retained counsel in this matter whether he would be complying with the request for production if he printed the EMRs and produced all the records in paper format.

In addition to the format of production, Dr. Krueger is unsure what medical records to produce. The electronic health record (EHR) system utilized by his group is connected with the records of various other providers as well as the local hospital. Therefore, Dr. Krueger has access to various

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[10] Molly Gamble, *5 Legal Issues Surrounding Electronic Medical Records*, BECKER'S HOSP. REV. (Jan. 19, 2012), http://www.beckershospitalreview.com/legal-regulatory-issues/5-legal-issues-surrounding-electronic-medical-records.html.

[11] Peter Garrett & Joshua Seidman, *EMR VS EHR- What Is the Difference?*, HEALTH IT BUZZ (Jan. 4, 2011, 12:07 PM), https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference.

[12] Gamble, *supra* note 10.

[13] *Id.*

[14] *Id.*

[15] *See, e.g.*, Wyeth v. Impax Lab., Inc., 248 F.R.D. 169 (D. Del. 2006); Williams v. Sprint/United Mgmt. Co., 230 F.R.D. 640 (D. Kan. 2005).

medical records authored by different health care providers that he did not create.

To further complicate the matter, the EHR system utilized by his group does not organize records based on the provider. Instead, records are organized based on type of records such as laboratory results, office visits, and radiology reports. Therefore, Dr. Krueger cannot make a determination of what records he created without looking at each individual record. Dr. Krueger wants to know if he should produce the entire EHR containing various other providers' records, or if he should go through his entire system and manually select those records that he created.

Dr. Krueger did attempt to locate a few of the pertinent medical records to show his attorney. Unbeknownst to Dr. Krueger, he created additional metadata by accessing these records. Dr. Krueger does not know what metadata is, how it is created, or how to produce the metadata if he is so required.

Finally, Dr. Krueger is unhappy with the request by plaintiff to provide a computer for her to access the medical records. He believes this request is unreasonable. He wants to know if he must comply with that request and the request for the software's manual.

While the hypothetical presents a few seemingly simple questions that arise out of the use of EMRs, the answers are not simple. The hypothetical demonstrates some discovery and production issues associated with EMRs that were not previously encountered with paper records. Unfortunately, the current Federal Rules of Civil Procedure, as amended, do not adequately address these new issues.[16] Furthermore, the courts have provided little guidance for these issues as the vast majority have yet to be ruled upon.[17] To further complicate the situation, the courts that have ruled on some of these issues have issued conflicting holdings.[18]

The purpose of this Note is to analyze the production and discovery issues that arise with the use of EMRs and EHRs. Part II provides detailed definitions of medical records, EMRs, and EHRs, the history pertaining to all three, and an overview of the current Federal Rules of Civil Procedure in relation to electronically stored information (ESI) such as EMRs and EHRs.

Part III will examine the discovery and production issues created by the structure of EHRs and the imbedded metadata in EHRs. In regards to structure, there is an in-depth discussion of the lack of interface uniformity, the difficulties associated with printing the EHR, and the non-static quality

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[16] *See* FED. R. CIV. P. 34.

[17] Gamble, *supra* note 10.

[18] *See, e.g., Wyeth*, 248 F.R.D. 169; *Williams*, 230 F.R.D. 640.

of the EHR as a living document. Part III also will also discuss how courts are currently deciding whether to order the production of metadata.

Part IV argues that the discovery and production issues currently plaguing the legal system can be alleviated by enacting legislation and amending the Federal Rules of Civil Procedure. Legislation that mandates a universal EHR structure would alleviate many issues that are created by the current EHRs' structure. Furthermore, an amendment to the Federal Rules of Civil Procedure would provide further guidance in the production of all ESI including EHRs.

II. BACKGROUND

A. What Are Medical Records?

In order to understand the discovery and production issues created by EMRs, one must first have a basic understanding of what constitutes a medical record. Courts have used various different sources to define medical records.[19] One such source is the Merriam-Webster's Dictionary.[20] It defines a "medical record" as "a record of a patient's medical information" such as past medical history, treatment provided, and diagnosis.[21]

Another available source for the definition of medical records can be found in state statutes such as the Ohio statute which defines medical records as any form of data that "pertains to a patient's medical history, diagnosis, prognosis, or medical condition and that is generated and maintained by a health care provider in the process of the patient's health care treatment."[22]

Moreover, courts in some states have defined medical records in their court rules like the Supreme Court of Minnesota which defines medical records as "any records that relates to the past, present, or future physical or mental health or condition of an individual including but not limited to medical history, examination, diagnoses, and treatment."[23]

Alternatively, other courts have provided their own definition of medical records in their opinions like a court in Ohio which defined medical records

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[19] *See, e.g.*, Griffith v. Aultmann Hosp., 54 N.E.3d 1196, 1205 (Ohio 2016); Perry v. Bullock, 761 S.E.2d 251, 253 (S.C. 2014).

[20] *See Perry*, 761 S.E.2d at 253.

[21] *Medical Record*, MERRIAM-WEBSTER DICTIONARY, http://www.merriam-webster.com/medical/medical%20records (last visited Sept. 16, 2016).

[22] OHIO REV. CODE ANN. §3701.74(A)(8) (LexisNexis 2014).

[23] MINN. R. 4 (2014).

as records created and maintained by a medical provider while administering the patient's health care treatment.[24]

Congress has also provided a definition of medical records contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[25] HIPAA defines health information as "any information . . . recorded in any form or medium, that: (1) [i]s created or received by a health care provider . . . and (2) [r]elates to the past, present, or future physical or mental health or condition of an individual."[26]

Understanding the requirements for medical records can also aid in understanding the definition. A health care professional is required by state licensure laws, regulations, accreditations standards, professional association guidelines, and reimbursement programs to keep records for his or her patients.[27] Medical records provide the ability to document aspects of patient care, communicate between health care providers, identify problems, monitor the effectiveness of treatments, provide data for research and education, and keep records for legal documentation.[28]

The content required for medical records varies from state to state.[29] These requirements can be found in statutes, regulations, municipal codes, and accreditation standards.[30] The Joint Commission provides one such example of medical record requirements.[31]

The Joint Commission is the "nation's predominant standards-setting and accrediting body in health care."[32] In order to be accredited by the Joint Commission, hospitals are required to create and maintain medical records for each individual treated.[33] Each entry must be signed by an authorized individual, contain identifying patient information, support the diagnosis and treatment, and document the hospital's course and result of treatment.[34] The medical records must also promote continuity of care among health care providers.[35]

While there is no one universally accepted definition, a combination of these sources makes it clear that medical records are created by health care

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[24] *Griffith*, 54 N.E.3d at 1205.
[25] 45 C.F.R. §160.103 (2014).
[26] *Id.*
[27] WILLIAMS H. ROACH, JR., MEDICAL RECORDS AND THE LAW 29 (3d ed. 1998).
[28] KRISTYN S. APPLEBY & JOANNE TARVER, MEDICAL RECORDS REVIEW §1.2 (4th ed. 2006).
[29] ROACH, *supra* note 27, at 31.
[30] *Id.*
[31] APPLEBY & TARVER, *supra* note 28, §1.3.
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*

providers to aid in the treatment of patients and provide a way to document said treatment.[36]

B. The History of Medical Records

To further understand the definition of medical records, it is helpful to analyze the history behind the recording of medical information. The recording of medical information dates back as far as a papyrus text on surgery from 1600 B.C. Egypt.[37] In the seventeenth century, the increased knowledge of human anatomy by way of dissection resulted in an increased impulse to record the information ascertained.[38] By the mid-eighteenth century, physicians in Western Europe began keeping case books recording their practices of bleeding and purging.[39]

The first hospital in the United States to keep patient medical records was New York Hospital in 1793.[40] However, these "medical records" contained only line items of admissions and discharges.[41] In the 1800s, qualitative measures in clinical medicine were emerging creating a desire to systematically record the data.[42] By 1880, the usage of medical records as a legal document motivated the New York Hospital to supervise the content and quality of the information they were recording.[43] However, medical records were not used to aid in the treatment of patients until 1898.[44]

In 1918, the American College of Surgery required hospitals to keep patient records that contained a summary of care and outcomes.[45] By the late nineteenth century, medical records contained sections for history, present illness, physical examination, and progress notes.[46] From that point forward, the system of maintaining detailed patient records became the norm.[47]

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[36] *See supra* notes 19–35 and accompanying text.

[37] Richard F. Gillum, *From Papyrus to the Electronic Tablet: A Brief History of the Clinical Medical Record with Lessons for the Digital Age*, 126 AM. J. MED. 853, 853 (2013).

[38] *Id.*

[39] *Id.* at 853–54.

[40] *Id.* at 854.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.*

C. What Are EMRs and EHRs?

Electronic medical records (EMRs) are medical records that document, monitor, and manage the health care administered by a health care provider that are stored in an electronic format.[48] According to the National Coordinator for Health Information Technology, EMRs are digital versions of the traditional paper medical records.[49] EMRs differ from electronic health records (EHRs) in that they consist of only the records of one provider.[50] Therefore, a health care provider's ability to exchange information with another provider is not significantly enhanced by the mere use of EMRs.[51]

However, many providers have an EHR system that provides a heightened amount of interoperability between health care providers.[52] These systems combine the EMRs of various providers into a comprehensive record for each patient called an EHR.[53] According to the National Coordinator for Health Information Technology, the EHR contains the records of various health care providers for one particular patient.[54] The National Alliance for Health Information Technology stated that EHR data "can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization."[55]

The EHR is distinct from the EMR by its interoperability, the type of information it contains, its intended use, and its ownership.[56] Unlike the EMRs, the EHR is not limited to just health care information.[57] It also includes administrative and financial data that is relative to that particular patient.[58]

The intended uses of EHRs and EMRs can also be differentiated. EHRs were designed to be used by all health care providers, irrespective of which

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[48] Dave Garets & Mike Davis, *Electronic Medical Records vs. Electronic Health Records: Yes, There Is a Difference*, HIMSS ANALYTICS (Jan. 26, 2006), https://app.himssanalytics.org/docs/WP_EMR_EHR.pdf.

[49] Garrett & Seidman, *supra* note 11.

[50] *Id.*

[51] *Id.*

[52] *What Is EHR Interoperability and Why Is It Important?*, HEALTH INFO. TECH., https://www.healthit.gov/providers-professionals/faqs/what-ehr-interoperability-and-why-it-important (last updated Jan. 15, 2013).

[53] Garets & Davis, *supra* note 48.

[54] *Id.*

[55] *Id.*

[56] *See infra* Section III.A.

[57] APPLEBY & TARVER, *supra* note 28, §1.9.1.

[58] *Id.*

health care provider authored the particular record.[59] They were created to share information amongst health care providers in an effort to reduce fragmented care in the health care system.[60] EHRs' design permits health information to be accessed by all those involved in the patient's care, including the patients themselves.[61]

Another important distinction between EMRs and EHRs is ownership.[62] EMRs are owned by the physician or facility that created that particular record.[63] In contrast, the overall EHR with the information from various providers "belongs" to the patient.[64] This distinction in who owns a particular set of information can have implications when determining what records are required to be produced in response to a request for production of documents.[65]

D. The Emergence of EHRs

Just as the history of medical records is helpful to understanding the definition of medical records, so too is the history of EMRs and EHRs helpful in the understanding of their definitions. The history of EMRs goes back to the late 1960s.[66] The creators of these early health information systems wanted to make records immediately available to the user anywhere and reduce the work of clinical bookkeeping.[67] However, it wasn't until the 1990s that data exchange in health care began to gain acceptance.[68]

In 1990, the Institute of Medicine (IOM) began a study analyzing paper medical records.[69] In 1999, it published the results of that study titled *To Err is Human: Building A Safer Health Care System*.[70] This report stated that using EHRs would improve patient outcomes.[71] In performing the study, the IOM found that between 44,000 and 98,000 Americans die in hospitals each

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[59] Garrett & Seidman, *supra* note 11.

[60] *Id.*

[61] *Id.*

[62] Garets & Davis, *supra* note 48.

[63] *Id.*

[64] *Id.*

[65] *See id.*

[66] Tripathi, *supra* note 8.

[67] *Id.*

[68] ROBERT D. BELFORT ET AL., BLOOMBERG BNA HEALTH LAW & BUSINESS PORTFOLIO SERIES, HEALTH INFORMATION TECHNOLOGY: EMERGING LANDSCAPE: LEGAL ISSUES AND OPPORTUNITIES §1150.0101 (2014).

[69] Jim Atherton, *Development of the Electronic Health Record*, AMA J. OF ETHICS (Mar. 2001), http://journalofethics.ama-assn.org/2011/03/mhst1-1103.html.

[70] BELFORT ET AL., *supra* note 68.

[71] *Id.*

year due to medical errors.[72] The report also found that preventable adverse outcomes cost the United States somewhere between $17 billion and $29 billion per year.[73]

The report attributed these preventable errors to the fragmented health care delivery system.[74] The study revealed that patients see multiple providers each year.[75] Based on the EMR systems in place at the time of the study, those providers did not have access to the records of the other treating providers.[76] This fragmented system made it more likely for information to be missed leading to adverse outcomes.[77] The IOM's report asserted that until there was an organized EHR system, the population would pay the price of unsafe care.[78]

With its study, the IOM laid the groundwork for creating policy and increasing investments in health information technology.[79] The data from its study, collected in 1990, helped lay the foundation for the creation and passage of HIPAA in 1996.[80] In turn, HIPAA was a driving force behind the widespread use of EHRs.[81]

In 2001, the IOM published another study: *Crossing the Quality Chasm: A New Health System for the 21st Century*.[82] This study advocated for the investment of resources into health information.[83] Through the use of both reports and studies, the IOM advocated for increased interoperability of health care providers' EHRs.[84]

Despite the two IOM studies and the passage of HIPAA, the use of EHRs by health care providers remained low.[85] There are many factors that have been attributed to the reluctance of health care providers to adopt EHR systems including high costs, lost revenues during the time of transition, the challenge of choosing a system, lack of protection standards, and conflicting federal and state privacy policies.[86]

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[72] INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 3 (Linda T. Kohn et al. eds., 2001).

[73] *Id.* at 27.

[74] *Id.* at 3.

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] BELFORT ET AL., *supra* note 68.

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.* §1150.0101-02.

In 2004, President George W. Bush created the position of National Health Information Technology Coordinator to develop a nationwide interoperable health information technology system.[87] In June 2004, the National Coordinator published *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care - Framework for Strategic Action.*[88] It was the first strategy document relating to the use and adoption of health information technology.[89] It provided specific actions to "accelerate the adoption of information technology in health care."[90] The strategic framework contained four goals: to inform clinical practice, interconnect clinicians, personalize care, and improve population health.[91] These goals remain the foundation of our current system of health information technology.[92]

In 2009, Congress passed the American Recovery and Reinvestment Act (ARRA).[93] The Health Information Technology for Economic and Clinical Health Act (HITECH) was enacted as part of the ARRA.[94] HITECH developed federal policy and provided stimulus funds to aid in the design, development, and adoption of a nationwide health information technology system that would enable electronic exchange of medical records.[95] HITECH contained a Medicare and Medicaid incentive program for the "meaningful use" of EHRs by providers who met the federal established objectives.[96] In 2015, these incentives changed to penalties for healthcare providers not meaningfully using EHRs.[97]

Since its passage in 2009, HITECH has stimulated the use of EHRs by health care providers.[98] In 2013, a study published by the Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology found that eight in ten office-based physicians reported they used

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[87] *Id.* §1150.0102.

[88] *Id.*

[89] *Id.*

[90] TOMMY G. THOMPSON & DAVID J. BRAILER, DEP'T OF HEALTH & HUMAN SERV., DECADE OF HEALTH INFORMATION TECHNOLOGY iv (2004).

[91] *Id.*

[92] BELFORT ET AL., *supra* note 68, §1150.102.

[93] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

[94] *Id.*

[95] BELFORT ET AL., *supra* note 68, §1150.102.

[96] *Id.*

[97] *Id.*

[98] Press Release, U.S. Dep't of Health & Human Serv., More Physicians and Hospitals are Using EHRs than Before (Aug. 7, 2014), https://www.hhs.gov/about/news/2014/08/07/more-physicians-and-hospitals-are-using-ehrs-than-before.html [https://wayback.archive-it.org/3926/20170127160706/https://www.hhs.gov/about/news/2014/08/07/more-physicians-and-hospitals-are-using-ehrs-than-before.html].

an EHR system.[99] The HHS continues to provide resources to increase the use of health information systems in the United States.[100] In September 2016, HHS awarded over $87 million for health care information technology improvements in health care facilities across the nation.[101] HHS's current strategic plan is focused upon strengthening health care, advancing scientific knowledge and innovation, advancing the health, safety, and well-being of the American people, and ensuring efficiency, transparency, accountability, and effectiveness of the HHS programs.[102]

As time passes, the usage of electronic health information will continue to increase.[103] The interoperability between physicians that both the government and the medical community are advocating for will continue to expand.[104] While the desired interoperability has the potential to improve patient care and medical treatment outcomes,[105] it does present the risk of continuing to create discovery and production issues in the legal system that the current Federal Rules of Civil Procedure, as amended, do not address.[106]

E. The 2006 Amendment to Civil Procedure Affecting Discoverability of EHRs

Rule 34 of the Federal Rules of Civil Procedure governs requests for production of documents.[107] As originally adopted, Rule 34 focused on the production of documents and things.[108] In 1970, Rule 34 was amended to include data compilations.[109] Since then, the amount of electronically stored information (ESI) has increased dramatically.[110]

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[99] *Id.*

[100] Press Release, U.S. Dep't of Health & Human Serv., HHS Awards over $87 Million for Health Centers' IT Enhancement (Sept. 15, 2016), http://www.hhs.gov/about/news/2016/09/15/hhs-awards-over-87-million-health-centers-it-enhancements.html [http://wayback.archive-it.org/3926/20170127190136/https://www.hhs.gov/about/news/2016/09/15/hhs-awards-over-87-million-health-centers-it-enhancements.html].

[101] *Id.*

[102] *HHS Strategic Plan*, HHS.ORG (Mar. 10, 2014), http://www.hhs.gov/about/strategic-plan/index.html.

[103] *See id.*

[104] Press Release, Am. Med. Ass'n, AMA Continues Efforts to Improve Electronic Health Records (Feb. 29, 2016), http://www.ama-assn.org/ama/pub/news/news/2016/2016-02-29-ama-improves-ehr.page.

[105] *See id.*

[106] *See* FED. R. CIV. P. 34.

[107] *Id.*

[108] *Id.* (advisory committee's note to 2006 amendment).

[109] *Id.*

[110] *Id.*

Prior to the 2006 amendment, judges interpreted "documents" to include ESI.[111] Those judges reasoned that it would be unfair to the requesting party to allow the responding party not to produce relevant information just because it was stored electronically.[112] However, it became increasingly difficult to fit all types of ESI within the definition of documents.[113]

In 2006, the Federal Rules of Civil Procedure were amended to address discovery issues caused by ESI.[114] The newly-amended Rule 34(a) labeled ESI as its own category of discovery.[115] Judges would no longer have to try to fit all the various types of ESI into the definition of a document.[116]

The 2006 amendment to Rule 34(b) permits the requesting party to designate the form in which the requested ESI should be produced.[117] Rule 34 recognizes that different forms of discovery may be appropriate for different types of ESI.[118] Therefore, Rule 34 allows flexibility by not prescribing one set form of production; it instead leaves the determination of the appropriate form up to the parties.[119] Furthermore, Rule 34(b) does not require the requesting party to choose a form of production.[120]

In the response to a request for the production of ESI, the responding party must state the form it intends to produce the information in if the form was not specified or if the responding party objects to the form specified by the requesting party.[121] If the form is not specified, the information must be produced in the form in which it is "ordinarily maintained or in a reasonably usable form."[122] However, the responding party's option to produce in a reasonably usable form does not entitle the responding party to convert the ESI into a form that that makes it more difficult or burdensome for the requesting party to use.[123] If the requesting party is not satisfied with the form stated by the responding party or the responding party objected to the form requested, the parties must attempt to resolve the matter before the requesting party can file a motion to compel with the court.[124]

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[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] SHIRA A. SCHEINDLIN, MOORE'S FEDERAL PRACTICE, E-DISCOVERY: THE NEWLY AMENDED FEDERAL RULES OF CIVIL PROCEDURE 1 (2006).

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] *Id.*

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] *Id.*

The Advisory Committee Notes for Rule 34 state that the responding party may need to provide technical support, software information, or other assistance to enable the requesting party to use the ESI.[125] Also, the Advisory Committee Notes clarify that the same ESI needs only to be produced in one form.[126]

While the 2006 amendment to Rule 34 did address some of the complex issues created by the production of ESI,[127] it did not address many pertinent issues that arise from the production of EHRs.[128] EHRs are complex living documents.[129] As such, their discovery leads to many complex questions regarding how to produce and what to produce in response to a request for production of documents.[130]

III. ANALYSIS

While EMRs and EHRs cause many different discovery and production issues, the following section focuses on two issues that are frequently encountered by the legal system. First, the discovery and production issues created by the structure and interface of EHRs is explored. Within that section, the lack of interface uniformity, the difficulties associated with printing the EHR, and the non-static quality of the EHR as a living document are discussed. The second discovery issue discussed is metadata. In that section, metadata is defined and case law that relates to its production is analyzed.

A. Discovery and Production Issues Created by the Structure and Interface of EHRs

EHR software refers to the program that allows authorized users to access the EHR from a variety of devices including laptops, tablets, and smartphones.[131] Different software providers of EHRs structure patient information differently, creating interfaces that are unique to each EHR system.[132] An EHR interface refers to how the patient's information is

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[125] *Id.*

[126] *Id.*

[127] *See* FED. R. CIV. P. 34.

[128] *Id.*

[129] Robert Hudock & Jason Christ, *Electronic Health Records Pose Several Challenges*, NAT'L L. J. (Dec. 14, 2009), https://www.law.com/nationallawjournal/almID/1202436239813.

[130] *See id.*

[131] Stephen O'Connor, *How Do EHR Systems Work?*, ADVANCED DATA SYS. CORP. (Apr. 5, 2017), http://healthcare.adsc.com/ blog/bid/195876/How-Do-EHR-Systems-Work.

[132] *Id.*

presented to a physician while utilizing the EHR.[133] The fact that the structure and interface varies depending on the EHR software program creates discovery and production issues in the legal system.[134]

The hypothetical medical malpractice case discussed in Part I provides an illustration for some of these issues.[135] Fist, Dr. Krueger's EHR software did not contain a print function. Second, his system had a source-oriented structure without a sort function to enable him to only see the records that he had authored. Finally, his particular EHR system did not allow him to view the information as it would have looked at the time he provided the treatment in question. All of these present barriers to production created by Dr. Krueger's particular EHR system's software. To fully understand why many of these barriers exist, it is beneficial to return to the discussion of the history of medical records and the history of EMRs from Part II.[136]

The desire to keep detailed paper records of medical treatment was motivated, at least in part, by the need of the legal system to have detailed records for litigation purposes.[137] In contrast, EMRs were not created with such a focus in mind.[138] Instead, EMRs were created to reduce errors, improve patient outcomes, and increase communication between providers.[139] In essence, the EMRs were not designed with litigation in mind.[140]

Early versions of EHRs had software which structured the medical records either as time-oriented, problem-oriented, or source-oriented.[141] Time-oriented records were structured in chronological order.[142] However, problem-oriented records were structured based upon problems with each problem located in its own section of the interface containing subjective information, objective information, assessment, and plan information for that particular problem.[143] While source-oriented records were organized based on where that particular record's information was gathered such as office

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[133] DAN ARMIJO, ELECTRONIC HEALTH RECORD USABILITY 8 (James Bell Associates et al. eds., Oct. 2009).

[134] Gamble, *supra* note 10.

[135] *See infra* Part I.

[136] *See infra* Part II.

[137] Gillum, *supra* note 37.

[138] *See infra* Section II.D.

[139] *See id.*

[140] *See id.*

[141] Kristiina Hayrinen et al., *Definition, Structure, Content, Use and Impacts of Electronic Health Records: A Review of the Research Literature*, 77 INT'L. J. OF MED. INFO. 291, 294 (2008).

[142] *Id.*

[143] *Id.*

visits, hospital records, and radiology reports.[144] While the first EHRs were structured based on one of the three orientations,[145] most modern EHR systems utilize a combination of the three different orientations.[146]

While there are many different issues created by EHR software, this section focuses upon the lack of uniformity in interface designs, the difficulties associated with printing the EHR, and the inability of the software to display the information as it would have appeared to a particular physician at a particular point in time.

1. Interface Uniformity

Unfortunately, there is no universal EHR system that is utilized by all health care providers.[147] To make matters more complex, there is also no set structure, interface, or set informational requirements for EHR systems;[148] meaning that the more than 300 EHR system used by health care providers in the United States could, theoretically, each be structured differently, have different interfaces, and contain different pieces of health care information.[149]

Moreover, each one of those 300 systems can offer countless different combinations of orientations, interfaces, and information to different health care providers.[150] In fact, it is fairly common for different health care providers, even within the same health care facility, to have different interfaces based on what information is most relevant to their particular role on the patient's health care team.[151] While this type of structural tailoring may lead to reduced error rates and improvements in patient outcomes,[152] it definitely creates a discovery nightmare.[153]

The impact of a complex discovery process extends further than the client's bill.[154] It can also have serious implications for the underlying case.[155] When health care providers struggle to provide the EMRs pertaining to a

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[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] Hudock & Christ, *supra* note 129.

[148] *Id.*

[149] Farrah Jolly, *So Many Electronic Health Record Choices*, INFORMATIONWEEK (Jan. 28, 2011, 12:35 PM), http://www.informationweek.com/healthcare/electronic-health-records/so-many-electronic-health-record-choices/d/d-id/1095743.

[150] Hudock & Christ, *supra* note 129, at 1–2.

[151] *Id.*

[152] *Id.*

[153] Matthew P. Keris, *A View from the Trenches: Discovery Issues with Electronic Medical Records*, RISK RX (2011).

[154] *See id.*

[155] *Id.* at 2.

particular patient, the focus of a medical malpractice case can easily shift from a breach in the standard of care to the structure and interface of an EHR system.[156]

It is difficult for the fact-finder to grasp that how the information is being presented to them may not have been how it was viewed by the particular physician at the time in question.[157] Health care providers can find themselves under an increased level of scrutiny when they cannot easily locate the information due to a difference between how the information is presented to them while testifying and how it is presented in the interface to which they have grown accustomed.[158] Judges and jurors can get lost in such details, resulting in undue delay and confusion of the issues as litigators spend time trying to explain complex technical concepts in terms that the lay juror can understand.[159]

2. Integrated Print Function

Whether or not an EHR system contains an integrated print function can also impact the ease of production of an EHR.[160] Luckily, many EHRs have an integrated print function. [161] Yet, the resulting printout comes with some drawbacks.[162] The printed document may not provide an adequate representation of how the information is portrayed by the physician's interface.[163] As discussed previously, this can be an incredibly difficult concept for jurors to grasp and accept.[164]

And while an integrated print function may not be the ideal method of production, there are still some EHR systems that are not equipped with such a print function making the task of production that much more problematic.[165] Without such an integrated print function, providers must respond to a request to produce his or her EMRs via screenshots of each and every screen in the EMR.[166] Screenshots make it increasingly difficult to interpret and

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[156] Chris Dimick, *EHRs Prove a Difficult Witness in Court*, J. AM. HEALTH INFO. MGMT. ASSOC. (Sept. 24, 2010), http://journal.ahima.org/2010/09/24/ehrs-difficult-witness-in-court.

[157] Keris, *supra* note 153.

[158] *Id.*

[159] *See id.*

[160] *Id.* at 4.

[161] Gamble, *supra* note 10.

[162] *Id.*

[163] Keris, *supra* note 153.

[164] *See infra* Section III.A.1.

[165] Gamble, *supra* note 10.

[166] Dimick, *supra* note 156.

organize the information contained in the EMRs.[167] Not to mention the fact that it is incredibly time consuming to capture all the information from an EMR in such a manner.[168]

Time is not the only cost of a lack of an integrated print function.[169] If a provider cannot produce the EMRs in a comprehensive format, it may raise suspicions that the record is faulty or the physician is intentionally withholding information.[170] Which leads to another hurdle that must be explained to a juror.[171]

Northshore University Health System (Northshore) provides an example of the impact on both the requesting and responding parties when the EHR lacks an integrated print function.[172] Since its EHR system did not contain an integrated print function, Northshore was forced to use screenshots to print its EMR.[173] Hours of diligent work went into capturing every piece of medical information.[174] The result was four boxes worth of pages that were incredibly difficult to decipher.[175]

These boxes were produced to the requesting attorney.[176] Not surprisingly, he was very suspicious of how the medical records had been produced.[177] He filed a motion to compel with the court requesting access to the EHR system.[178] The court granted his motion and ordered Northshore to provide the attorney offsite access to the EHR.[179] However, even with the offsite access, the plaintiff's attorney found the interface of the EHR to be severely limited.[180] He felt that the interface impeded the ability of the EHR to tell the patient's medical story.[181]

Northshore provides an example of the real discovery issues that are felt by both the requesting and the responding parties when the EHR lacks an integrated print function.[182] Yet, even with such a function, the printout

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[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Id.*
[171] *See supra* notes 157–59 and accompanying text.
[172] Dimick, *supra* note 156.
[173] *Id.*
[174] *Id.*
[175] *Id.*
[176] *Id.*
[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] *Id.*
[181] *Id.*
[182] *Id.*

created can lead to its own discovery issues.[183] Nonetheless, an integrated print function is superior to the alternative.[184]

3. Static Document

Finally, the software of EHRs is not currently equipped with a filtering function that allows the EHR to be produced with only the information that would have been available at a set point in time.[185] EHRs were designed to be fluid in nature.[186] As such, they exist as "abstractions composed of thousands of data elements."[187] They are considered to be living documents that are ever-changing with each patient encounter.[188]

Current EHR systems make it impossible, or at least cost prohibitive, to produce a patient's EHR as it would have appeared to the physician on a particular date.[189] Every time new information is added, the EMR reflects the information in various different locations making it impossible to recreate the medical records as they would have been at the time in question.[190]

The lack of a filtering feature can have devastating implications for a medical malpractice case.[191] The standard of care required of a physician is predicated upon what information was available to the physician at the time of treatment.[192] If counsel is not able to ascertain what information was available, it could have serious implications for determining whether a breach in the standard of care has occurred.[193]

4. Conclusion

Returning to Dr. Krueger's questions regarding the source-oriented structure of his EHR, the most assurance that can be given to him is that it is common for EHRs to have a predominately source-oriented structure.[194] As designed, the current EHRs do not contain a sort function that would allow

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[183] *Id.*
[184] *Id.*
[185] Hudock & Christ, *supra* note 129.
[186] *Id.*
[187] *Id.*
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *See id.*
[192] *See* Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12 W. J. EMERGENCY MED. 109, 112 (2011).
[193] *Id.*
[194] Hayrinen et al., *supra* note 141.

him to view and produce only those records which he authored.[195] With the source-oriented structure, Dr. Krueger has two options in regards to producing the documents. He can produce the entire EHR, including his EMRs as well as the EMRs of other physicians, or he can sort through each individual record manually making a determination if that particular record was authored by him. Both options have significant disadvantages. Unfortunately, the current EHR software does not provide an attractive option for the production of source-oriented EHRs.

Since Dr. Krueger's EHR does not contain an integrated print function, he will be required to use screenshots to produce his EMRs.[196] This can make it even more burdensome to produce the enormous amount of information contained in the EHR.[197] It will lead to a tremendous amount of paper that is incredibly tedious to decipher.[198]

Finally, Dr. Krueger's current EHRs' structure does not allow him to view or produce the information as he would have seen it at the time of treatment. This can lead to many issues. It can be difficult to determine whether or not he violated the standard of care, if the information available to him at the time of treatment is unknown.[199]

The hypothetical demonstrates the frustration that can be felt by both the medical and legal professions when trying to produce EMRs. The simple truth of the matter is that EHRs, as currently structured, are not adequately equipped with the proper functions to enable ease of production for litigation purposes. Until a change is made by the industry, these production and discovery issues will continue to be felt by the legal system.

B. Determining the Required Format to Produce EHRs

Returning to the hypothetical from Part I,[200] Dr. Krueger inquired of his counsel whether it would satisfy the request for production of documents if he produced his EMRs in print format. The answer depends upon the language of the request.[201] In Dr. Krueger's case, the request for production specifically requested the EHR's metadata, audit trails, a computer with the EHR software installed, and the EHR software's manual. Rule 34 of the

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[195] *Id.*
[196] Dimick, *supra* note 156.
[197] *Id.*
[198] *Id.*
[199] *Id.*
[200] *See infra* Part I.
[201] *See* FED. R. CIV. P. 34.

Federal Rules of Civil Procedure governs whether Dr. Krueger is required to comply with those requests.[202]

1. The Request for Production of Metadata

As discussed in Part II,[203] Rule 34 of the Federal Rules of Civil Procedure requires electronically stored information (ESI) to be produced in the format in which "they are kept in the usual course of business."[204] Rule 34 also permits the requesting party to specify the form in which the ESI is to be produced.[205] If the request does not specify a format, the ESI must be produced in a form "in which it is ordinarily maintained or in a reasonably usable form."[206] If a format is requested, the responding party may object to the format requested and instead state the format in which the ESI is being produced.[207]

A mere printout of the EHR may be insufficient to satisfy the request for production of documents[208] because it lacks the EHR's metadata.[209] Metadata is ESI that describes the "history, tracking, or management of an electronic document."[210] Metadata is in essence data about the data.[211] The EHR's metadata can show when a medical record was created, by whom, and any edits that were made to the record after its initial entry.[212]

Audit trails are a type of system metadata that are particularly relevant in EHRs.[213] Audit trails provide verification of the activity that has occurred in the EHR.[214] Federal regulations require that audit trails be maintained in all EHRs.[215] Specifically, regulations require that information be recorded of any person accessing the medical record, the time and date of the access, the record that was accessed, and any action taken by that individual.[216]

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[202] *Id.*

[203] *See infra* Part II.

[204] FED. R. CIV. P. 34(b)(2)(E)(i).

[205] *Id.* at 34(b)(1)(C).

[206] *Id.* at 34(b)(2)(E)(ii).

[207] *Id.* at 34(b)(2)(D).

[208] *See id.* at 34.

[209] *See* Mark R. Bower et al., *Another Trip Down the Audit Trail*, 18 PROFESSIONAL NEGLIGENCE (Am. Ass'n for Justice, Washington D.C.), no. 2, 2011.

[210] Aguilar v. Immigration & Customs Enforcement Div. of U.S. Dep't of Homeland Sec., 225 F.R.D. 350, 354 (S.D.N.Y. 2008).

[211] *Id.*

[212] *Id.*

[213] Vargas v. Lee, 2015 N.Y. Misc. LEXIS 2176, at *4 (N.Y. Sup. Ct. June 5, 2015).

[214] Bower et. al., *supra* note 209.

[215] *Id.*

[216] *Id.*

Audit trails and metadata can be particularly useful in cases where the veracity of the record is questioned.[217] On the other hand, if the authenticity of the record is not in question, the production of metadata can cause an undue burden to the producing party with little to no gain to the requesting party.[218] These competing interests often lead to disagreements between parties on the discoverability of metadata.[219]

Therefore, if the parties cannot come to an agreement regarding the production of metadata, the requesting party can file a motion to compel its production.[220] The courts must then step in and determine if the metadata should be produced.[221]

Unfortunately, courts have not been consistent in determining whether or not metadata is required to be produced.[222] In fact, there is not a bright-line rule regarding even which party has the burden of proof in a motion to compel the production of metadata.[223] To make matters hazier, different courts have also looked at different factors to determine whether the burden has been met.[224]

2. Determining Which Party Has the Burden of Proof

There is conflicting case law on which party has the burden of proof on the issue of the discoverability of metadata.[225] Some courts have held that the requesting party has the burden of proof in order to prevail on a motion to compel.[226] However, several courts have held that the burden is upon the producing party to provide evidence to prevent an order compelling the production of metadata.[227] Unfortunately, as the law stands, there is no bright-line rule on which party has the burden of proof when the court is ruling on a motion to compel metadata.[228]

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[217] *See Vargas*, 2015 N.Y. Misc. LEXIS, at *4.

[218] *Id.*

[219] *See id.*

[220] FED. R. CIV. P. 34 advisory committee's note to 2006 amendment.

[221] *Id.*

[222] *See generally* Wyeth v. Impax Lab., Inc., 248 F.R.D. 169 (D. Del. 2006).

[223] *See id. See generally* Williams v. Sprint/United Mgmt. Co., 230 F.R.D. 640 (D. Kan. 2005).

[224] *See Wyeth*, 248 F.R.D. at 171; *Williams*, 230 F.R.D. at 652.

[225] *See Wyeth*, 248 F.R.D. at 171; *Williams*, 230 F.R.D. at 652.

[226] *See* Kentucky Speedway, LLC v. National Ass'n of Stock Car Auto Racing, No. 05-138-WOB, 2006 WL 509735, at *4 (E.D. Ky. Dec. 18, 2006); *Wyeth*, 248 F.R.D. at 171.

[227] *See generally* Linnebur v. United Tel. Ass'n, No. 10-1379, 2011 WL 5103300 (D. Kan. Oct. 27, 2011); Romero v. Allstate Inc. Co., 217 F.R.D. 96, 107 (E.D. Pa. 2010).

[228] *See Wyeth*, 248 F.R.D. at 171; *Williams*, 230 F.R.D. at 652.

3. Determining What Must Be Proved

Irrespective of which party has the burden of proof, there is no clear requirement for what must be proved to either prevail on a motion to compel or prevent an order compelling.[229] Some courts have held that the requesting party must show a "particularized need" for metadata.[230] Other courts have held that the producing party must show undue hardship or expense.[231] Others still have adopted a blanket rule that, where the parties cannot agree on the format, the default standard is a PDF format devoid of any metadata.[232]

4. Determining if the Burden of Production Has Been Met

Courts have held that there is a general presumption against the production of metadata.[233] The *Wyeth* court held that the requesting party could rebut the presumption by demonstrating a particularized need for the data.[234] There, the court denied the requesting party's motion to compel the production of metadata,[235] because the requesting party did not make a demonstration that there was a particularized need for the metadata.[236] Likewise, in *Kentucky Speedway*, the court refused to compel the production of metadata, because the requesting party had not made a showing of particularized necessity.[237]

The *Williams* court also stated that there is a general prohibition against the production of metadata.[238] Yet, the court did not look at if there was a particularized necessity to overrule that general presumption.[239] Instead, the court hinged its determination of whether the metadata should be produced on whether the metadata was viewable in the ordinary usage of the requested record.[240] The court also clarified that metadata should only be produced in the absence of a prior agreement to the contrary.[241] Also, the court specified that a producing party should not have to make a special effort to preserve or

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[229] *See Wyeth*, 248 F.R.D. at 171; *Williams*, 230 F.R.D. at 652.

[230] *See Kentucky Speedway, LLC*, 2006 WL 509735, at *8; *Wyeth*, 248 F.R.D. at 171.

[231] *See Linnebur*, 2011 WL 5103300, at *20-21; *Romero*, 217 F.R.D. at 107.

[232] *Wyeth*, 248 F.R.D. at 171.

[233] *See id.*; *Williams*, 230 F.R.D. at 652.

[234] *Wyeth*, 248 F.R.D. at 171.

[235] *Id.*

[236] *Id.*

[237] Kentucky Speedway, LLC v. National Ass'n of Stock Car Auto Racing, No. 05-138-WOB, 2006 WL 509735, at *23-27 (E.D. Ky. Dec. 18, 2006).

[238] *Williams*, 230 F.R.D. at 652.

[239] *Id.*

[240] *Id.*

[241] *Id.*

produce metadata.[242] However, the court held that when the responding party has been ordered to produce the document in the form it is ordinarily maintained in, it must produce them with the metadata intact.[243]

And while the court in *Williams* required the production of metadata in that case,[244] the court recognized that the production of metadata would not be justified in certain instances.[245] Such instances include both when the parties agree that metadata should not be produced[246] and when the responding party obtains a protective order to prevent the metadata from being produced.[247] Additionally, the responding party can make a timely objection to the request for production of metadata.[248]

Other courts have looked to the relevancy of metadata to determine whether or not they should compel its production.[249] *Gilbert* is an example of a court allowing the production of an EHR's audit trail in medical records.[250] In *Gilbert*, the plaintiff requested the production of the audit trail because the medical records as produced did not indicate whether or not an emergency department physician had ever reviewed plaintiff's medical records prior to her discharge.[251] There, the court permitted disclosure of the audit trail, because it was relevant to the plaintiff's allegations.[252]

Vargas provides an example of the court utilizing a relevancy determination to deny a motion to compel metadata.[253] In *Vargas*, the plaintiff sought to have the court compel the hospital to produce its EHR with the audit trial intact to identify what time treatment was received by the plaintiff.[254] The court denied the motion to compel.[255] It found that the details of treatment could be ascertained from the EMRs which had previously been produced, making the production of the audit trail unwarranted.[256]

The court in *Vargas* provided an explanation of when audit trails should be produced.[257] The court reasoned that audit trails would be relevant to a

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[242] *Id.* at 650.
[243] *Id.* at 652.
[244] *Id.* at 657.
[245] *Id.* at 652.
[246] *Id.*
[247] *Id.*
[248] *Id.*
[249] Vargas v. Lee, No. 507923/2013, 2015 N.Y. Misc. LEXIS 2176, at *4 (Sup. Ct. June 10, 2015).
[250] Gilbert v. Highland Hosp., 31 N.Y.S.3d 397, 401 (Sup. Ct. 2016).
[251] *Id.* at 399.
[252] *Id.* at 400.
[253] Vargas, 2015 N.Y. Misc. LEXIS 2176, at *4.
[254] *Id.* at *2.
[255] *Id.* at *5.
[256] *Id.* at *4–5.
[257] *Id.*

determination of the process in which a document was created or when a document's authenticity is questioned.[258] The *Vargas* court ruled that metadata should not be produced merely because it contains relevant information.[259] Instead, the court stated that the metadata should only be required to be produced if the information was not readily obtainable from the records produced to the requesting party.[260]

5. Conclusion

While the case law is definitely not set,[261] the Federal Rules of Civil Procedure allow a requesting party to request metadata.[262] The responding party can object to the request of metadata[263] or file a motion for a protective order for the metadata.[264] Courts are split on which party has the burden of proof,[265] what they must prove,[266] and what factors are considered in the determination of whether the production of metadata will be required.[267]

As such, there is no clear answer for Dr. Krueger's question regarding whether or not he must produce his EMRs' metadata. Due to the fact that the plaintiff specifically requested the form for production of the EMR, Dr. Krueger has three options. He can comply with the request,[268] object to the requested format[269] and produce the EMR in a format devoid of metadata,[270] or he can file for a protective order for his EMRs' metadata.[271] Considering the inconsistent rulings regarding metadata,[272] no further clarification for whether or not he is required to produce the metadata can be given to Dr. Krueger.

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[258] *Id.*
[259] *Id.*
[260] *Id.*
[261] *See infra* Section III.B.1.
[262] FED. R. CIV. P. 34(b)(2)(E).
[263] *Id.*
[264] *Id.*
[265] *See infra* Section III.B.1.
[266] *Id.*
[267] *Id.*
[268] FED. R. CIV. P. 34(b)(2)(E).
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] *See infra* Section III.B.1.

IV. RESOLUTION

In analyzing Dr. Krueger's hypothetical medical malpractice case, it is clear to see the nightmare created in his small practice on Elm Street. Both the judicial and legislative bodies need to take steps in order to prevent future nightmares. Legislation is needed to create a universal EHR structure equipped with various features that eliminate many of the production issues identified in Dr. Krueger's hypothetical. In addition, the Supreme Court should amend the Federal Rules of Civil Procedure in order to provide further guidance regarding the production of all ESI including EHRs.

A. Resolving the Discovery and Production Issues Created by the Structure and Interface of EHRs

The first step in resolving discovery and production issues caused by EHR software is the creation of a universal EHR structure. In order to achieve a universal EHR structure, Congress needs to pass legislation with the guidance of organizations such as The Joint Commission, The Institute of Medicine, and The Health and Human Services Office of the National Coordinator for Health Information Technology. The universal EHR structure should be aimed at creating a uniform interface that all EHR software providers must adhere to in order to be used by health care providers that treat either Medicaid or Medicare patients.[273] A universal EHR structure would alleviate many of the discovery nightmares currently plaguing the legal system.

The new legislation should follow a similar implementation schedule as the one utilized by the HITECH Act.[274] Specifically, there should be a predetermined amount of years where physicians are compensated for their use of the new universal EHR structure.[275] After the incentive years have passed, a fee should be assessed to each physician who receives reimbursement from either the Medicare or Medicaid programs that is not using such a system.[276]

As part of the new required structure, EHR systems should be required to have an integrated print function. The print function should provide the option to only print those records authored by a particular physician or facility. The print function should also provide the option to print the

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[273] *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).
[274] *See id.*
[275] *See id.*
[276] *See id.*

information based on either of the three orientations, time, problem, or source.

Finally, the system should allow the authored user to see how a particular EHR appeared as of a certain date. Likewise, the system should also enable the EHR to be printed including only the information that would have been available at that date. A universal EHR structure will not solve all of the discovery or production issues associated with EHRs. However, it will be an important step towards quashing the nightmare.

B. Resolving the Ambiguity in Requests for Production of Metadata

In addition to legislation, the Federal Rules of Civil Procedure should be amended in an effort to address issues pertaining to the production of metadata. Specifically, Rule 34 dealing with requests for production of documents should be so amended.[277] Currently, the standard of when metadata will be required to be produced[278] and which party has the burden of convincing the court of its necessity varies depending on which judge is ruling on the case.[279] These inconsistent court holdings make some guidance on when and if metadata needs to be produced essential.[280] This guidance is especially needed in regards to EHRs.[281] A national standard is needed to prevent confusion of the issues and undue delays in litigation in the production of EHRs.

Specifically, the Supreme Court should amend Rule 34 to require the production of metadata only when the requesting party provides evidence to the court that metadata would aid in the clearing up a specified ambiguity in the EMRs as produced or if there is a question of the validity of the said records.[282] The presumption should be that metadata should not be produced unless there is a showing of a particularized need.[283] That burden should rest with the requesting party.[284]

Unless the requesting party can convince the court that metadata is needed, the responding party should not be required to produce it.[285] The Advisory Committee Notes regarding the new amendment should provide

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[277] *See* FED. R. CIV. P. 34.

[278] *See infra* Section III.B.1.

[279] *Id.*

[280] *Id.*

[281] *Id.*

[282] *See* Vargas v. Lee, No. 507923/2013, 2015 N.Y. Misc. LEXIS 2176, at *4–5 (Sup. Ct. June 10, 2015).

[283] *See* Wyeth v. Impax Lab., Inc., 248 F.R.D. 169, 171 (D. Del. 2006).

[284] *See id.*

[285] *See id.*

examples of situations in which the requesting party could show a particularized need for the metadata. Such situations include when the veracity of the ESI is in question[286] or when the metadata is central to the ligation such as when it hinges upon when the document was created or by whom it was authored.[287]

If Rule 34 was amended so that the default was to exclude metadata, it would prevent undue delay and confusion of the issues in cases while still providing an avenue for production when it is essential to the case. Metadata has been held by various courts to be a waste of litigation resources and to be of limited evidentiary value.[288] Therefore, the newly amended rule should have a general presumption against the production of metadata, unless the requesting party can demonstrate a particularized need for the data.[289]

Likewise, audit trails should not be permitted, unless there is a question of validity of the document or its creation that cannot be answered by the documents as produced to the requesting party.[290] Audit trails have the potential to cause a great amount of confusion to the fact finder in what they are, what they do, and more importantly what they mean.[291] In most cases, they are of little evidentiary value.[292] As such, they should not be required to be produced except in extraordinary circumstances.

Rule 34 should also permit the responding party to prevent an order to compel the production of metadata by showing undue hardship or expense.[293] The current rule's stance that parties should also be permitted to agree to the production of metadata or non-production of metadata should be preserved in an effort to prevent litigation on the issue.[294] While another amendment may not resolve all the ambiguity associated with the production of EHRs, it would provide more guidance to courts as they rule upon various discovery and production issues relating to EHRs.

V. CONCLUSION

As more and more issues are raised regarding the discovery and production of EMRs, the need for clear uniform rules will increase. If the legal community worked with the medical community, the combined effort

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[286] *See Vargas*, 2015 N.Y. Misc. LEXIS 2176, at *4.
[287] *Id.*
[288] *See Wyeth*, 248 F.R.D. at 171.
[289] *Id.*
[290] *See Vargas*, 2015 N.Y. Misc. LEXIS 2176, at *4.
[291] *See* Gilbert v. Highland Hosp., 31 N.Y.S.3d 397, 400 (Sup. Ct. 2016).
[292] *See id.*
[293] *See* Wyeth, 248 F.R.D. at 171.
[294] *See* FED. R. CIV. P. 34.

could lead to the passage of legislation that would require a uniform structure for EHRs that would benefit both litigants and health care providers. Until then, litigants will be forced to wade through the fog of uncertainty and contradicting precedents to determine what to produce and in what format.

Unfortunately, many questions raised by Dr. Krueger's hypothetical cannot be answered by the existing law. Many of them would result in hard fought litigation with no clear guidance resulting in something akin to a coin toss on which side will prevail. Our legal system cannot continue to let such ambiguity in our discovery process of EHRs continue unchecked. Action is needed to provide guidance to attorneys so that, when Dr. Krueger walks through the door with questions regarding the production of EMRs, counsel can give a more meaningful answer than "it depends."