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## The Universe in the Palm of Your Hand: How a Universal Electronic Health Record System Could Improve Patient Safety and Quality of Care

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# The Universe in the Palm of Your Hand: How a Universal Electronic Health Record System Could Improve Patient Safety and Quality of Care

## I. Introduction

Electronic Health Records (EHR) have become an increasingly popular way for doctors and other practitioners to keep a record of their patient's health information. Historically, as access to information increases, the health care market lags behind.<sup>1</sup> The slow growth of technology in the health care market is not due to health care entities' lack of technological adoption. Rather, it is the type of technology being adopted that is the problem.<sup>2</sup> The type of technology that is used in hospitals has never had the ability to communicate with other technology creating "islands" of information.<sup>3</sup>

After the Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996, the health care industry saw a huge adoption of new technology.<sup>4</sup> However, the adoption of an electronic medical records system is a relatively new phenomenon.<sup>5</sup> During George W. Bush's presidency, the national budget for health-related information technology doubled.<sup>6</sup> This allowed for the development and implementation of new electronic medical record systems. After the transition of the presidency, President Barack Obama enacted the Health Information Technology for Economic and Clinical Health Act (HITECH). As a part of the American Recovery and

<sup>&</sup>lt;sup>1</sup> Paul Starr, Smart Technology, Stunted Policy: Developing Health Information Networks, HEALTH AFFAIRS, May-June 1997, 91, 93 (1997).

<sup>&</sup>lt;sup>2</sup> *Id*.

<sup>&</sup>lt;sup>3</sup> *Id*. at 94.

<sup>&</sup>lt;sup>4</sup> D'Arcy Guerin Gue and Steven J. Fox, Esq., Guide to Medical Privacy and HIPAA, ¶110 GROWING NEED FOR DATA STANDARDIZATION, PRIVACY PROTECTION AND SECURITY (2015).

<sup>&</sup>lt;sup>5</sup> The University of Scranton, *EMR: The Progress to 100% Electronic Medical Records*, http://elearning.scranton.edu/resource/health-human-services/emr\_the-progress-to-100-percent-electronic-medical-records (last visited Mar. 31, 2017).

<sup>&</sup>lt;sup>6</sup> *Id*.

Reinvestment Act of 2009, HITECH was enacted to promote the adoption of health information technology. The Act encouraged the adoption of EHRs, and after 2015 began penalizing healthcare providers who failed to demonstrate meaningful use. Meaningful use has three stages. Each stage must be complete before moving onto the next stage. A stage is complete after a provider demonstrates his or her ability to meet specific requirements set out by the Centers for Medicare and Medicaid (CMS). Such requirements could include things such as the provider using a computerized physician order-entry system. With the threat of financial penalties, the implementation of EHR systems grew significantly.

This article argues that the current EHR system is inadequate to address the current needs of patients. Part II provides an overview to current EHR system. Part III discusses pertinent legislation related to the adoption and implementation of EHRs. Part IV addresses any applicable Stark law considerations and implications. Part V evaluates and recommends an option for a universal electronic health records system for the state of Illinois.

## II. Regulating Electronic Health Records

Although there are provisions that serve to promote the adoption of EHRs, there are also several provisions in place to ensure the protection of those records.

A. Health Insurance Portability and Accountability Act of 1996

<sup>&</sup>lt;sup>7</sup> HHS, *HITECH Act Enforcement Interim Final Rule*, U.S. Department of Health and Human Services, https://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html?language=es, (last visited Mar. 31, 2017).

<sup>&</sup>lt;sup>8</sup> Margaret Rouse, *HITECH Act*, TechTarget,

http://searchhealthit.techtarget.com/definition/HITECH-Act, (last visited Mar. 31, 2017).

<sup>&</sup>lt;sup>9</sup> *Id*.

<sup>&</sup>lt;sup>10</sup> *Id*.

<sup>&</sup>lt;sup>11</sup> *Id*.

<sup>&</sup>lt;sup>12</sup> *Id*.

Signed into law by President Bill Clinton, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") seeks to protect patient privacy by implementing provisions to safeguard medical information.<sup>13</sup> The goal of HIPAA is "to improve portability and continuity of health insurance coverage...to combat waste, fraud, and abuse in health insurance and health care delivery...and to simplify the administration of health insurance." <sup>14</sup> To accomplish this goal, HIPAA established an "Administrative Simplification" provision. <sup>15</sup> This provision aims to increase the development and use of electronic health information systems by establishing standards and requirements for the electronic transmission of health information. <sup>16</sup> Under this provision is the creation of "Unique Health Identifiers." These identifiers belong to individuals, providers, health plans, etc., to separately classify each patient's health information. <sup>18</sup>

All covered entities<sup>19</sup> who "create, receive, maintain, or transmit" medical information electronically are subject to the regulations and standards of HIPAA.<sup>20</sup> Covered entities must protect the confidentiality of patient medical information that is stored electronically against "reasonably anticipated threats."<sup>21</sup> However, HIPAA does not give a definition as to what is meant

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<sup>&</sup>lt;sup>13</sup> Margaret Rouse, *HIPAA (Health Insurance Portability and Accountability Act)*, TechTarget, http://searchdatamanagement.techtarget.com/definition/HIPAA, (last visited Mar. 31, 2017).

<sup>&</sup>lt;sup>14</sup> 110 Stat. at 1936. <sup>15</sup> *Id.* at 2021.

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>&</sup>lt;sup>17</sup> Id. at 2025.

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> A covered entity is defined as: "(1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction referred to 1173(a)(1)." 110 Stat. at 2023.

<sup>&</sup>lt;sup>20</sup> 45 C.F.R. 164.314(a)(2)(i)(B).

<sup>&</sup>lt;sup>21</sup> 45 C.F.R. 164.306(a)(2).

by a "reasonably anticipated threat."<sup>22</sup> To determine the precise security measures that need to be taken for a particular entity, HIPAA suggests that these entities should consider the following:

- (i) The size, complexity, and capabilities of the covered entity....
- (ii) The covered entity's...technical infrastructure, hardware, and software security capabilities.
- (iii) The costs of security measures.
- (iv) The probability and criticality of potential risks to electronic protected health information.<sup>23</sup>

To ensure compliance and security of protected health information when information could potentially be shared with third parties, covered entities must have business associate agreements with third parties before sharing information.<sup>24</sup>

When a specification is meant to be a mandatory implementation, HIPAA makes clear with either "required" or "addressable" at the end of the specification.<sup>25</sup> When an implementation is "addressable," the entity must decide for itself whether the specification is reasonable and appropriate for implementation in their specific environment. <sup>26</sup> These "addressable" specifications must only be implemented if doing so would be "reasonable and appropriate." However, again, HIPAA does not provide a definition for "reasonable and appropriate." <sup>28</sup>

<sup>&</sup>lt;sup>22</sup> *Id*.

<sup>&</sup>lt;sup>23</sup> 45 C.F.R. 164.306(b)(2)(i-iv).

<sup>&</sup>lt;sup>24</sup> 45 C.F.R. 164.314(a)(2)(i).

<sup>&</sup>lt;sup>25</sup> 45 C.F.R. 164.306(d)(1).

<sup>&</sup>lt;sup>26</sup> 45 C.F.R. 164.306(d)(3)(i).

<sup>&</sup>lt;sup>27</sup> *Id*.

<sup>&</sup>lt;sup>28</sup> *Id*.

Examples of required implementation specifications are: risk analysis, risk management, sanction policy, and information system activity review.<sup>29</sup>

Additionally, HIPAA attempts to regulate the amount of protected information that is shared with the minimum necessary standard.<sup>30</sup> This standard holds that a covered entity must make "reasonable efforts" to limit the amount of protected health information to that which is minimally necessary to meet the requested purpose.<sup>31</sup> However, there are several circumstances where the minimum necessary requirement does not apply.<sup>32</sup> These exceptions include requests by healthcare providers for treatment, disclosures made in accordance with an authorization, or disclosures made in accordance with the law.<sup>33</sup>

Title II of HIPAA gives the U.S. Department of Health and Human Services ("HHS") the ability to create and enforce regulations pertaining to electronic health information.<sup>34</sup> In response to the HITECH Act, HHS implemented the HIPAA Omnibus Rule in 2013.<sup>35</sup> Part of this rule increased the penalty a provider could face to a maximum of \$1.5 million per incident.<sup>36</sup> The HIPAA Omnibus Rule enacted a Breach Notification Rule requiring providers to notify their patients when a data breach has occurred.<sup>37</sup> After a breach has been confirmed, providers could face civil and criminal sanctions.<sup>38</sup>

B. Health Information Technology for Economic and Clinical Health Act

<sup>&</sup>lt;sup>29</sup> 45 C.F.R. 164.308(a)(1)(ii)(A-D).

<sup>&</sup>lt;sup>30</sup> 45 C.F.R. 164.502(b).

<sup>&</sup>lt;sup>31</sup> *Id*.

<sup>&</sup>lt;sup>32</sup> 45 C.F.R. 164.502(b)(2).

<sup>&</sup>lt;sup>33</sup> 45 C.F.R. 164.502(b)(2)(i-ii).

<sup>&</sup>lt;sup>34</sup> Supra, note 14.

<sup>&</sup>lt;sup>35</sup> *Id*.

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>37</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> *Id*.

Enacted as part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") was meant to provide updates to and strengthen HIPAA.<sup>39</sup> These two acts work together to ensure the privacy and confidentiality of consumer health information.<sup>40</sup> While the overall cost of implementing and maintaining a system of compliance and protection for this information is high, it is hard to quantifiably compare cost versus impact, due to the subjective nature of monetizing an individuals' privacy and dignity.<sup>41</sup>

The HITECH Act was established to "promote the widespread adoption and interoperability of health information technology." In order to increase technology in health care, the Act first had to ensure patients' privacy would not be put at an unnecessary risk. Some of the provisions introduced to HIPAA by HITECH are: the introduction of business associations for third parties handling confidential information; the notification of breaches to all affected parties; a limitation on the use of health information for marketing; a prohibition of the sale of any confidential and protected information; the modification of a covered entity's notice of privacy practices; and an expansion of individuals' rights to access their information, while restricting their health plan's access to that same information. Since its enactment, several steps have been taken to implement HITECH's enhanced privacy and security measures. Additionally, as a mechanism

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<sup>&</sup>lt;sup>39</sup> 78 Fed. Reg. 5566.

<sup>&</sup>lt;sup>40</sup> *Id*.

<sup>&</sup>lt;sup>41</sup> *Id.* at 5567.

<sup>&</sup>lt;sup>42</sup> *Id.* at 5568.

<sup>&</sup>lt;sup>43</sup> *Id*.

<sup>&</sup>lt;sup>44</sup> *Id*.

<sup>&</sup>lt;sup>45</sup> Id. For example, the Federal Trade Commission has issued regulations on breach notification requirements for personal health record vendors and any of their business associates.

for enforcement, HITECH increased the civil monetary penalty structure, which became effective in November 2009.<sup>46</sup>

The HITECH Act has four tiers of increasing culpability for information mismanagement. The lowest tier of violations occurs when a covered entity, or their business associates, is unknown, and, with reasonable diligence would not have known, of the violation. The second tier of violations occurs where the violation is due to reasonable cause, yet no willful neglect is present. The third tier includes willful neglect on behalf of the organization, but where the entity has attempted to correct the violation. Finally, the fourth tier consists of willful neglect on behalf of the organization where no attempt for reconciliation has been made. Each tier brings an increase in the dollar amount per violation. Tier one has a minimum fine of \$100 per violation, where tier four has a minimum fine of \$50,000 per violation.

## C. The Antitrust Laws

The Antitrust Laws are a series of laws enacted by Congress to promote competition and prevent monopolies.<sup>52</sup> The first antitrust law, the Sherman Act, was enacted in 1890.<sup>53</sup> Providing some modifications to antitrust law, the Federal Trade Commission Act, which created the Federal Trade Commission ("FTC"), and the Clayton Act were both enacted in 1914.<sup>54</sup> These three Acts

<sup>&</sup>lt;sup>46</sup> *Id*.

<sup>&</sup>lt;sup>47</sup> *Id.* at 5580.

<sup>&</sup>lt;sup>48</sup> *Id*.

<sup>&</sup>lt;sup>49</sup> *Id*.

<sup>&</sup>lt;sup>50</sup> HIPAA Journal, *What are the Penalties for HIPAA Violations?*, HIPAA Journal, (Jun. 24, 2015), http://www.hipaajournal.com/what-are-the-penalties-for-hipaa-violations-7096/.

<sup>&</sup>lt;sup>51</sup> Id.

<sup>&</sup>lt;sup>52</sup> Federal Trade Commission, *The Antitrust Laws*, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws, (last visited Mar. 31, 2017).

<sup>&</sup>lt;sup>53</sup> *Id*.

<sup>&</sup>lt;sup>54</sup> *Id*.

are what are known today as "The Antitrust Laws." This section will look at each Act and the implications of that Act on the EHR system.

## 1. The Sherman Act

The Sherman Act was designed to prevent conspiracies in trade, as well as any attempt to monopolize a good or service.<sup>56</sup> However, the Supreme Court has held that the Sherman Act does not restrict every form of trade, only that which is unreasonable.<sup>57</sup> While this term must be interpreted by courts to determine what is reasonable and what is not, there are some trade agreements that are considered so harmful that they are almost always illegal.<sup>58</sup> These violations are considered "per se" violations of the Sherman Act and no defense to the agreement is allowed.<sup>59</sup>

Penalties for violating the Sherman Act range from civil monetary penalties to possible criminal convictions prosecuted by the Department of Justice.<sup>60</sup> However, criminal prosecutions are typically limited to intentional violations and violations that so clearly create an undisputed advantage for corporations.<sup>61</sup> Criminal prosecutions can result in monetary penalties of up to \$100 million for corporations and \$1 million for individuals.<sup>62</sup> In addition, those found guilty could face up to 10 years in prison.<sup>63</sup>

<sup>&</sup>lt;sup>55</sup> *Id*.

<sup>&</sup>lt;sup>56</sup> *Id*.

<sup>&</sup>lt;sup>57</sup> *Id.* Some instances of mergers and trade are so unreasonable that it unreasonably limits competition. However, other instances of trade are not illegal, like when two individuals enter into an agreement. While this merger may limit competition, it does not do so unreasonably and is therefore lawful.

<sup>&</sup>lt;sup>58</sup> *Supra*, note 53. These acts consist of agreements between competitors that "fix prices, divide markets, or rig bids."

<sup>&</sup>lt;sup>59</sup> *Id*.

<sup>&</sup>lt;sup>60</sup> *Id*.

<sup>&</sup>lt;sup>61</sup> *Id*.

<sup>&</sup>lt;sup>62</sup> *Id*.

<sup>&</sup>lt;sup>63</sup> *Id*.

## 2. The Federal Trade Commission Act

The FTC Act is very similar to the Sherman Act.<sup>64</sup> The FTC Act "bans unfair methods of competition and unfair or deceptive acts or practices."<sup>65</sup> Throughout its enactment, the Supreme Court has determined that any violation of the Sherman Act is also a violation of the FTC Act.<sup>66</sup> Therefore, although the FTC cannot enforce the Sherman Act, lawsuits concerning violations which would normally be brought under the Sherman Act can be brought under the FTC Act by the FTC.<sup>67</sup> This is a mechanism by which the FTC essentially enforces antitrust violations.<sup>68</sup>

## 3. The Clayton Act

The Clayton Act is a modification to the Sherman Act to include things that the original Act did not address. <sup>69</sup> Specifically, the Clayton Act covers mergers and "interlocking directorates." <sup>70</sup> Section 7 of the Clayton Act is the portion of the act that addresses and prohibits mergers that would "substantially…lessen competition, or…tend to create a monopoly." <sup>71</sup> In 1976, the Clayton Act was amended to require government notification of large mergers or acquisitions in advance. <sup>72</sup> Damages that companies could face if found to have violated the Clayton Act are triple that of which the victim lost. <sup>73</sup>

## III. The Current Electronic Health Record System

<sup>&</sup>lt;sup>64</sup> *Id*.

<sup>&</sup>lt;sup>65</sup> *Id*.

<sup>&</sup>lt;sup>66</sup> *Id*.

<sup>&</sup>lt;sup>67</sup> *Id*.

<sup>68</sup> *Id*.

<sup>69</sup> Id

<sup>&</sup>lt;sup>70</sup> *Id.* An "interlocking directorate" violation occurs when one person makes business decisions for competing corporations.

<sup>&</sup>lt;sup>71</sup> *Id*.

<sup>&</sup>lt;sup>72</sup> *Id*.

<sup>&</sup>lt;sup>73</sup> *Id*.

## A. What is an Electronic Health Record?

An Electronic Health Record (EHR) is an electronic version of a patient's medical record.<sup>74</sup> A patient's EHR contains any clinical data that is relevant to that individual's care.<sup>75</sup> A patient's EHR can be accessed by various providers who care for the patient. Having a patient's information stored electronically mitigates the need to have a physical copy of the patient's chart. The electronic storage of medical records allows immediate access for providers. This immediate access can be essential in many ways, such as:

- During emergency situations when a provider is unable to communicate with the patient, a
  provider can learn a patient's medical history that may prove essential to the treatment of
  that individual.
- Medical errors can be reduced by an improvement in the accuracy of medical records.
- When health information is readily available to providers, patients receive better care and have better relationships with their doctors through informed decision making.
- Increased access to information leads to a decrease of duplicate testing and an increase in quality care.

Currently, providers who have an EHR system have the ability to share patient information with other providers who also have some form of EHR system.<sup>76</sup> However, this sharing comes at a cost.<sup>77</sup> Providers using the system "Epic" were charged \$0.20 for each outgoing message and

<sup>&</sup>lt;sup>74</sup> Centers for Medicare & Medicaid Services, *Electronic Health Records*, U.S. Centers for Medicare & Medicaid Services, (Mar. 26, 2012), https://www.cms.gov/Medicare/E-Health/EHealthRecords/index.html?redirect=/ehealthrecords.

 $<sup>^{75}</sup>$  Id.

<sup>&</sup>lt;sup>76</sup> Joseph Conn, *Epic, other EHR vendors agree to waive record-sharing fees*, Modern Healthcare, (April 15, 2015),

http://www.modernhealthcare.com/article/20150415/NEWS/150419944.

<sup>&</sup>lt;sup>77</sup> *Id*.

\$2.35 for each incoming message from non-"Epic" users. 78 In April 2015, the Office of Health and Human Services' (HHS) Office of the National Coordinator the Health IT questioned this type of charging system and labeled it as potential "information blocking." In response, many EHR developers announced that they would waive these costs. 80 However, so far these promises were set to expire at the end of 2017 for Aetna's "CommonWell" and 2020 for Epic's "Care Everywhere."81

Benefits of implementing an electronic health record system include: reducing in the rate of medical errors; improving the accuracy and clarity of medical records; making health information readily available to patients; reducing duplicate testing; reducing or potentially mitigating delays in treatments; and having a more informed patient.<sup>82</sup>

#### IV. A New Type of Electronic Records System

A lot of problems arise when assessing the current state of the electronic health records system. In 2012, there were over one thousand EHR technologies for ambulatory care and over five hundred for inpatient care. 83 Ultimately, the variety of EHR systems harm the health system, regardless of the provider using them, because each has a different way of measuring, storing, and accessing patient data, which leads to incompatibility and inability to share patient information. Each system offers different features and capabilities that may not be compatible with each other.

<sup>&</sup>lt;sup>78</sup> *Id*.

<sup>&</sup>lt;sup>79</sup> Darius Tahir, ONC outlines plans to curb EHR 'blocking', Modern Healthcare, (April 11, 2015), http://www.modernhealthcare.com/article/20150411/MAGAZINE/304119974.

<sup>&</sup>lt;sup>80</sup> *Supra*, note 76.

<sup>&</sup>lt;sup>81</sup> *Id*.

<sup>&</sup>lt;sup>82</sup> *Supra*, note 74.

<sup>&</sup>lt;sup>83</sup> Margalit Gur-Arie, Arguments for a Universal Health Record, On Health Care Technology, (Jan. 22, 2012), http://onhealthtech.blogspot.com/2012/01/arguments-for-universal-healthrecord.html.

Even different versions offered by the same manufacturer are often incompatible with one another.<sup>84</sup> While the ultimate solution for this problem would be a universal electronic records system nationwide, a more obtainable goal would be to start on the state level and have uniformity there before moving to a national level. Overall, a statewide universal EHR system would save money while providing greater safety, quality, and efficiency in the medical care that is provided to patients. A universal EHR system has the potential to create better patient outcomes, ultimately saving their lives.

## A. The Goal of a Universal Electronic Health Records System

In the twenty-first century, people are more mobile than ever. We are constantly going new places and experiencing new things. However, sometimes those experiences can get us into trouble and lead us to an unplanned visit to the emergency room. But what happens when you are one hundred miles away from home and you need to go to the hospital? Typically, depending on the severity of your injury, you will simply go to the nearest hospital you can find. When you get there, you will most likely have to regurgitate your entire medical history, including any prescriptions you take, any surgeries you have had, your allergies and their reactions, and any previous complications that you have experienced, before you are given any type of treatment. Once you finish, hopefully you have brought your health insurance card with you, or you could be paying for this visit out of pocket.

It is not hard to see the benefits of a universal health records system. If one were in place, you would be able to go to that hospital, even one hundred miles from home, and the doctor would have all of your health information at their fingertips. The main goal of a universal system is

<sup>&</sup>lt;sup>84</sup> *Id*.

patient access. It gives patients the autonomy and ability to be portable, yet still receive the same basic level of care wherever they go.

## 1. Benefits of a Universal Health Records System

As discussed above, the ultimate goal and biggest benefit of a universal EHR system is patient access. A universal system gives the patient freedom to move freely without worrying about always having their medical information accessible. This type of benefit makes a difference for people who have chronic health conditions that are not visible or easily identifiable. In an emergency, where a patient is unconscious, how are the medical staff supposed to know that the patient is a hemophiliac? In an emergency situation, surgery may be necessary to save a person's life. However, without knowing of a patient's condition of this magnitude, even the smallest surgery may be lethal. Having a universal system would minimize the chance of these types of errors from occurring.

Another significant benefit is the amount of cost savings that will result from a universal system for both the patients and the insurance companies. After the initial cost of implementation of the system, cost savings would be easily obtainable. When multiple providers are able to see what other providers have done and what tests they have ordered, there will be less wasteful medical tests performed. This often happens when a primary care physician performs a test and then refers their patient to a specialist who then performs the same test simply because it takes too long to get these records from the primary care physician's office. This is a test that would be unnecessarily and needlessly performed twice, and therefore paid for twice. By having access to the primary care physician's records, a specialist can see test results without having to perform it again. This would save the insurer, and ultimately the patient, a significant amount of money.

Doctors and hospitals pay thousands of dollars to have employees extract and send medical records to other providers. Another benefit of a universal system is the streamlined administrative systems. This means that doctors and hospitals will save money by not having to employ someone for the sole purpose of medical record retrieval, because they are readily available to the secondary provider through the electronic records system. When the hospital saves money, their administrative costs decrease, which could save money for patients in the end.

A final significant benefit is the promotion of better patient outcomes. When various parts of a patient's medical records are stored in a variety of locations in several different formats, medical errors and overutilization can easily occur. There is no way to know if a part of a patient's medical record is missing, which can clean lead to negative outcomes if the available set of records is blindly relied on. Having all of the necessary information on a patient is an obvious way to have a positive outcome. Access to the entire patient record can also prevent drug seeking. <sup>85</sup> This could decrease the amount of inadvertent hospital assisted drug overdoses overall and lead to a higher quality of care for these people.

## 2. Drawbacks and Barriers of a Universal Health Records System

One of the biggest drawbacks that stop the adoption of a universal system is the notion that this type of internet-based data system is a "scary database in the sky." This brings privacy and data security concerns. While this is a valid consideration, it is important to note that the risks would not be significantly greater than they are now. Currently, if a patient has Medicare or Medicaid, the government already has access to this information. Because the government has

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<sup>&</sup>lt;sup>85</sup> Jenny James, *Dealing with drug-seeking behaviour*, National Center for Biotechnology Information, (June 1, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919169/. <sup>86</sup> *Supra*, note 83.

<sup>&</sup>lt;sup>87</sup> *Id*.

access to this information, it is susceptible to those same security threats. Along the same line, many people believe that even though security risks exist, that privacy is best managed when the at-risk data is close to its origin. 88 The only way for a universal system to work is for every patient to have a unique identification code. These codes could be changed often in order to ensure that any data is not misused after a specified time. Overall, the same security risks regarding the privacy of patient records exist whether you have an isolated EHR system or a universal one.

Another major concern for most people is the idea that the free market would suffer as a result of a universal system. However, universal is not necessarily synonymous with "one." As long as each system interfaces seamlessly, it can be considered a part of the universal system. As discussed above, potential antitrust violations are a major consideration when combining technology to create a common EHR system. The Sherman Act was enacted to relieve monopolization of goods. 89 This type of situation would occur when all but one EHR system was eliminated. This would have negative implications associated with it, such as: driving the cost of the system up, there would be little incentive for new development that would ultimately make the EHR system better, and security risks would increase because there would only be one system for hackers to infiltrate. However, if the universal system could be one that was comprised of multiple EHRs, the fear of monopolization would be minimized, costs would remain reasonable, and competition would flourish.

When assessing why a universal system is slow to be developed and implemented, it is beneficial to look at what barriers exist for the adoption of practice-wide EHR systems. These include factors such as: high cost with little return; the inability or refusal to redesign current

<sup>&</sup>lt;sup>88</sup> *Id*.

<sup>&</sup>lt;sup>89</sup> Supra note 53

processes to adapt to the new technology; fear that ever-advancing technology will outdate the adopted system; inadequate and incompatible technology to support an EHR system; belief that the advanced technology would not benefit the practitioner's patient population; and concerns of negative impacts of the technology. These same concerns transfer over into the reasoning behind why industry leaders are hesitant to spend time and money developing a universal system.

## B. How to Develop and Implement a Universal Electronic Records System

A type of system of this magnitude would have to start in the statue legislature. The state would have to be the entity to implement the necessary law to structure a system of this magnitude. The government would have to partner with a variety of representatives from the pharmaceutical industry, as well as various technology developers to ensure that the EHR system accommodates all types of providers. Funding for this type of project would most likely have to come from the federal government. Congress is the only governmental body that can incentivize these industries to create a cost-effective alternative to the current EHR system through taxes and advertising constraints.<sup>91</sup>

The most efficient way to ensure the universal adoption of an EHR system is to make it as simple and adaptable as possible. The majority of healthcare professionals do not have time to learn how to use a new system. However, if a system was designed to replicate the steps they already take and format it in a quick "click through" design, there would be less hesitation in using the new system.<sup>92</sup> Because not every healthcare institution has the same resources, funding from

 $^{92} Id.$ 

<sup>&</sup>lt;sup>90</sup> Agency for Healthcare Research and Quality, *Electronic Medical Records Systems*, U.S. Department of Health & Human Services, https://healthit.ahrq.gov/key-topics/electronic-medical-record-systems, (last visited Mar. 29, 2017).

<sup>&</sup>lt;sup>91</sup> Charles A. Sninsky, *Developing Universal Electornic Medical Records*, National Center for Biotechnology Information, (Mar. 4, 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088297/.

the state and federal government is crucial in implementing a universal EHR system. Some parts of rural Illinois may not be able to afford such a luxurious technology, which becomes problematic when the ultimate goal is to provide seamless care for patients. By combining funding from the state and federal government, these rural institutions will have the same access to the EHR system as their urban counterparts.

## 1. What Could Be Included?

Information that is created, gathered, and stored by patients is called patient-generated health data "PGHD." People already share all types of data through various cell phone applications, health watches, or online portals with their electronic health record. With the implementation of quality metrics beginning with the adoption of the Affordable Care Act, doctors are more concerned than ever with what their patients are doing outside of the doctor's office to ensure their own health. Since doctors cannot monitor all of their patients on a daily basis, these applications and online tools for storing information have become a popular option for monitoring patient data. Having a more complete picture of their patient's health status can prevent extra office visits and possibly reduce or eliminate emergency room visits.<sup>94</sup>

These types of PGHD are considered different forms of telehealth or telemedicine. Telemedicine refers to "traditional clinical diagnosis and monitoring that is delivered by technology." Telemedicine offers many benefits including a significant cost savings, as well as

<sup>&</sup>lt;sup>93</sup> RegRoom, *Empower Individuals through Health IT to Improve Health and Health Care*, Planning Room, http://planningroom.org/healthit/issue-posts/pghd/ (last visited Mar. 29, 2017). <sup>94</sup> *Id* 

<sup>&</sup>lt;sup>95</sup> Center for Connected Health Policy, *What is Telehealth?*, The National Telehealth Policy Resource Center, http://www.cchpca.org/what-is-telehealth, (last visited Mar. 31, 2017).

offering convenience to both the patient and provider. <sup>96</sup> By constantly monitoring a patient's activities, various forms of telemedicine can remotely relay patient information to their provider without the need of an office visit. Telemedicine is also cost efficient for both patients and insurers. Patients will have fewer unnecessary emergency room visits, they will have less frequent physician office visits, and they will spend less time traveling from home to the various offices.

However, to best serve their patients in this respect, providers must build in time to evaluate this patient data for it to be useful. <sup>97</sup> Additionally, there are various factors that play into how accurate and useful PGHD is to providers, such as: education, health literacy <sup>98</sup>, age, socioeconomic status, and access to the technology. These factors could prohibit those who would get the most benefit out of the technology from using it. There is also the initial cost of developing and implementing an EHR system that can "talk" to this technology. Because this information is collected 24/7, the provider must have an adequate system in place to collect and store that information.

## 2. Provider Liability

The growing field of telemedicine brings with it a set of unique challenges when it comes to medical provider liability. One of the biggest liability issues for telemedicine is licensure. Licensure is administered and regulated by the states, and each state has their own standards and regulations. While providers can be licensed in multiple states, there is currently no multi-state license. Physicians cannot practice in states in which they are not licensed. However, telemedicine is designed to be portable and accessible at the patient's convenience. While this would not be an

<sup>&</sup>lt;sup>96</sup> Jessica Harper, *Pros and Cons of Telemedicine for Today's Workers*, U.S. News, (July 24, 2012), http://health.usnews.com/health-news/articles/2012/07/24/pros-and-cons-of-telemedicine-for-todays-workers.

<sup>&</sup>lt;sup>97</sup> *Supra*, note 93.

<sup>&</sup>lt;sup>98</sup> *Id*.

issue for a statewide universal EHR system, if a national EHR system was ever created, this would be of greater concern.

In the context of a statewide EHR system in Illinois, providers will face an increased liability when having to rely on another practitioner's interpretations and care. For example, when a patient presents with a chronic disease, such as heart failure, the current provider must rely on the maintenance and record documentation of the patient's previous providers to determine the best course of action. If information is inputted wrong or if the patient is misdiagnosed, the provider may be prompted to initiate a plan of care that is not in the patient's best interest or is contraindicated to the patient's condition. This type of contraindication could lead to negative outcomes, which leads to malpractice claims against that provider. With the increased liability, providers are likely to be hesitant in adopting this type of universal system. Although there is initially a greater increase in liability, it is likely that over time, this will be minimized and patients will see better overall outcomes.

## 3. Security Concerns with A Universal Electronic Healthcare System

One of the biggest questions that would eventually need to be answered is in a state with a universal EHR system, who owns the information and who is liable for any privacy breaches? To address this question, the state would have to evaluate who is providing funding for the system. Ideally, a universal EHR system would be run by the state since the state has such a big interest in the wellbeing of its citizens. It would make sense that the state would have to allocate at least some money to this project to motivate manufacturers to produce, providers to adopt, and patients to utilize the system. To promote the usage of a universal EHR system, the state may need to step in and establish policies to address liability and responsibility issues. In the beginning, for the sake of simplicity, it may be in the best interest for the success of the universal system for the state

to absorb this liability. Eventually, the state will need to create and implement policies that designate an official who is liable for controlling the patient data.

## C. Potential Legal Implications of a Universal EHR System

The Antitrust Laws are a series of laws enacted by Congress to promote competition and prevent monopolies. This will be one of the biggest legal concerns of a universal EHR system. When one thinks about a universal system, they typically think that there will only be one system being operated. While this can be the case, this type of system poses anti-trust implications. When only one system for EHRs exist, this limits competition and drives out all other manufacturers. This creates unilateral effects. Unilateral effects occur in a merger or acquisition when the new entity eliminates competitors. This type of competition elimination is feared by the government, because one or more of the following may occur: increase in prices, reduction of quality, and less choice.

However, as noted above, universal does not have to mean that only one EHR system exists. So long as the various EHR manufacturers have the same basic communication mechanisms and have a way to seamlessly communicate with one another, this could satisfy the goals of having a universal EHR system. While this may still have some lingering anti-trust effects due to trade restraint, they are not as obvious and are not likely to be as easily contested.

<sup>99</sup> *Supra*, footnote 53.

<sup>&</sup>lt;sup>100</sup> Westlaw Practical Law, *Healthcare Competition: Providers and Insurers*, Thomson Reuters Practical Law,

https://l.next.westlaw.com/Document/I538a987c0ec711e598db8b09b4f043e0/View/FullText.ht ml?navigationPath=Search%2Fv3%2Fsearch%2Fresults%2Fnavigation%2Fi0ad6ad3e0000015b 26f6535797cb69fa%3FNav%3DKNOWHOW%26fragmentIdentifier%3DI538a987c0ec711e598 db8b09b4f043e0%26startIndex%3D1%26contextData%3D%2528sc.Search%2529%26transition Type%3DSearchItem&listSource=Search&listPageSource=afe7629179e3aec97cd089e1530217f 4&list=KNOWHOW&rank=1&sessionScopeId=2e45348396ba3fbf2fcced0aeffd854a7bda6539f fe7c04dd6464856b1e3ba4b&originationContext=Search%20Result&transitionType=SearchItem &contextData=%28sc.Search%29 (last visited Mar. 30, 2017).

## V. Conclusion

A universal EHR system would benefit consumers by allowing any provider they see throughout their continuum of care to have access to their entire medical history without extra fees or time. A universal system could aid in fraud prevention and "doctor shopping" by providing transparent medical records to all types of providers. Emergency situations could be eased by having the patient's entire history in the doctor's hands. Patients who have to see multiple providers would not have to pay fees for copies of their records or have to worry about whether or not each of their providers had an adequate EHR system for transferring their records. When doctors have more access to a patient's medical history, they are able to better treat the patient, which leads to positive patient outcomes and decreases overall liability for providers. Each of these ultimately lead to benefitting the patients who utilize the system. While logistical and possible legal implications may stand in the way of a universal EHR implementation at this point, these challenges may have simple solutions. If the state initiates the system and controls the information, for the time being, and current manufacturers made their systems more transparent, these challenges may begin to disappear. Overall, a universal system would help accomplish many quality improvements and patient safety goals.