

THE BATTLE FOR ELECTRONIC HEALTH RECORD FINANCING: THE NEXT EPOCH IN THE STORY OF THE AMERICAN HEALTH CARE SYSTEM

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The ever-changing American health care system is moving in the direction of more coordinated care models in efforts to increase the quality and efficiency of and access to care. Wider adoption of electronic health records systems can help achieve these goals. However, significant legal barriers stand in the way of optimal adoption rates. Fraud and abuse laws, specifically the Stark Law and the Anti-Kickback Statute serve as some of the greatest barriers to wider electronic health records adoption, as they inhibit the creation of beneficial economic incentives to adoption. While commentators often express concern that antitrust law functions as a barrier to adoption, these concerns are largely unfounded. In order to enhance the rate of electronic health records adoption regulators should focus on alleviating the burdens created by the Stark Law and Anti-Kickback Statute.

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INTRODUCTION

The American health care system is constantly working to improve the quality and efficiency of care it provides. One of the most recent changes towards that end has been propelled by the technological innovations enabling the development of electronic health records (EHR). EHRs and similar health information technology (HIT) are making the provision of care more accurate and efficient, and are generating improved results for patients. EHRs have the potential to more efficiently store and organize health information, prevent human error, and provide broader and quicker analyses, among other capabilities, and have already begun to do so in the settings where they have been implemented.

As the technologies utilized in EHRs continue to improve, and EHRs continue to contribute with greater significance to positive health outcomes, EHRs will become more desirable to providers and patients alike. With the current health care legislation and policy objectives, they will continue to be adopted at increasing rates. However, at this time, the rate of adoption is still relatively low, and significant barriers—particularly legal barriers—remain to prevent wider adoption. These barriers must be reconciled with policy goals in order for the technology and, accordingly, the American health care system to reach its full potential.

This note posits that the most critical legal barriers to adoption

of EHRs in the United States arise principally from the Physician Anti-Referral Law, or Stark Law, and the Anti-Kickback Statute. It addresses the exceptions and safe harbors available for EHRs under current legal and regulatory regimes, as well as the shortcomings of these protections. Next, the note addresses the current misconceptions around the role of antitrust enforcement in the health care setting as applied to the adoption of EHRs. Finally, this note suggests potential solutions that can enable providers to work more effectively within the current framework, and mold that framework to be more supportive of the goal of wider EHR adoption.

I. ELECTRONIC HEALTH RECORDS' POTENTIAL TO IMPROVE HEALTHCARE

Health information technology has great potential to improve the current American health care system. There are many different types of HIT, however; different technologies provide different benefits and have different scopes of applicability. While the language is often used interchangeably, electronic health records are different from electronic medical records (EMR).¹ EMRs record information involved in the administration of care within one organization.² EHRs, on the other hand, are longitudinal compilations of a patient's medical information, which include EMRs from different providers a patient has visited.³ Policy discussions surrounding the improvement of current HIT focus on the implementation of EHRs.⁴ Specifically, the goal of policy makers is to build into the current health care system interoperable EHRs—that is, EHRs that are capable of communicating and sharing information with the EHRs of other providers.⁵

Interoperability is the ability of two or more HIT systems to both exchange information and use the information that is exchanged in a “meaningful” way.⁶ Interoperability is different than health information exchange, which is the exchange of a patient's

1. DAVE GARETS & MIKE DAVIS, ELECTRONIC PATIENT RECORDS 1 (2005), http://www.providersedge.com/ehdocs/ehr_articles/Electronic_Patient_Records-EMRs_and_EHRs.pdf [<https://perma.cc/8YAP-89NC>].

2. *Id.* at 2.

3. *Id.*

4. See *HITECH Act Enforcement Interim Final Rule*, HHS, <https://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/> [<https://perma.cc/L89B-XSNR>] (last visited Oct. 25, 2016).

5. See THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., CONNECTING HEALTH AND CARE FOR THE NATION: A SHARED NATIONWIDE INTEROPERABILITY ROADMAP, <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf> [<https://perma.cc/A5KQ-REUS>].

6. Doug Fridsma, *Interoperability vs Health Information Exchange: Setting the Record Straight*, HEALTH IT BUZZ (Jan. 9, 2013, 9:45 AM), <https://www.healthit.gov/buzz-blog/meaningful-use/interoperability-health-information-exchange-setting-record-straight/> [<https://perma.cc/Y298-VDQZ>].

health information among providers, or between providers and other parties.⁷ When an information exchange occurs, one provider transfers a patient's information to another. If the information is stored in a digital format that is incompatible with the electronic system of the receiving provider, the receiving provider may not be able to integrate the information into its electronic system, and thus may not be able to make use of the patient's information in a "meaningful" way.⁸

Patient health information exchange is a necessary component of, but is not alone enough to accomplish interoperability. Systems exchanging information must be able to use the information that is exchanged to improve the provision of health care in order to achieve interoperability.⁹ Because different EMR and EHR systems currently use different technologies, exchanging the information between providers does not guarantee that both providers will be able to translate and use the exchanged information.¹⁰

Notwithstanding the problem of interoperability among providers, EHRs in the current state of the art already are capable of improving health outcomes. EHRs can reduce medical errors by providing more accurate information, tools for diagnosis and prescription, and error prevention alerts.¹¹ High-function EHRs allow for greater patient participation and education through enhanced patient trust in the system and access to interactive patient portals.¹²

Implementation of EHRs leads to greater provider efficiencies and cost savings in addition to improving health outcomes.¹³ EHR

7. See *What is HIE?*, HEALTH IT, <https://www.healthit.gov/providers-professionals/health-information-exchange/what-hie> [<https://perma.cc/8VQW-NQDX>] (last visited Oct. 25, 2016), (Health information exchange is quite literally the exchange of information related to one's health.).

8. Note that the term "meaningful" is inherently objective. In addition to each provider having its own needs and goals, and thus having a different idea of what constitutes "meaningful" use of the technology, the Department of Health and Human Services has defined the term and established strict standards that providers must achieve to meet the definition. See *infra* Section III (Efforts to Promote Adoption).

9. See *id.*

10. *Id.*

11. See *Medical Practice Efficiencies & Cost Savings*, HEALTH IT, <https://www.healthit.gov/providers-professionals/medical-practice-efficiencies-cost-savings> [<https://perma.cc/7UPK-KUYN>] (last visited Nov. 15, 2016); Nir Menachemi & Taleah Collum, *Benefits and Drawbacks of Electronic Health Record Systems*, 4 RISK MGMT. & HEALTHCARE POL. 47 (2011).

12. See *Health Care Quality & Convenience*, HEALTH IT, <https://www.healthit.gov/providers-professionals/health-care-quality-convenience> [<https://perma.cc/A8HP-VQTQ>] (last visited Oct. 25, 2016); *Patient Participation*, HEALTH IT, <https://www.healthit.gov/providers-professionals/patient-participation> [<https://perma.cc/T6NE-WT26>] (last visited Oct. 25, 2016).

13. See *Medical Practice Efficiencies & Cost Savings*, HEALTH IT, <https://www.healthit.gov/providers-professionals/medical-practice-efficiencies-cost-savings> [<https://perma.cc/U5UM-4TRK>] (last visited Oct. 25, 2016); Menachemi & Collum, *supra* note 11, at 50–51.

capabilities can reduce transcription, chart pull, storage, and re-filing costs.¹⁴ They can allow for more accurate reimbursement through accurate coding and improved documentation.¹⁵ EHRs will also facilitate better accounting practices by keeping more accurate records. The keeping of more accurate records in turn may result in improved fraud detection, and decreased medical malpractice liability by decreasing adverse results and providing tools to more efficiently and effectively defend against medical malpractice claims.¹⁶ Further, EHRs can improve research by making recorded information organized and accessible, which will lead to the development of new treatments and cures.¹⁷

II. EFFORTS TO PROMOTE ADOPTION

Despite all of the advantages of utilizing EHRs, there are presently significant barriers to wider adoption. Social barriers include physician resistance,¹⁸ lack of sufficient knowledge of applicable HIT among health care professionals,¹⁹ and privacy concerns.²⁰ Additionally, from a technological stand point, the technology is still advancing and working out kinks in the provision of these new services.²¹ What has continuously been cited as the largest barrier to widespread EHR adoption is the large cost of implementation, coupled with a lack of economic incentives to invest in the systems.²²

As the government, providers, and vendors work together to address these challenges, they also face an onslaught of legal barriers to wider adoption. Anti-kickback laws, anti-referral laws, antitrust laws, a lack of a comprehensive network of privacy regulations, and a convoluted Health Insurance Portability and Accountability Act of 1996 (HIPAA) framework are among the greatest legal concerns. Other legal barriers associated with implementation of EHRs include fraud and abuse laws, the threat of increased medical malpractice liability, state regulation of

14. HEALTH IT, *supra* note 13.

15. *Id.*

16. Menachemi & Collum, *supra* note 11, at 50–51.

17. *Id.* at 49–50.

18. James Anderson, *Social, Ethical and Legal Barriers to E-Health*, 76 INT'L J. OF MED. INFORMATICS 480, 481–483 (2007).

19. Ashish Jha, et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. OF MED. 1628, 1634–35 (2009).

20. Anderson, *supra* note 18, at 481.

21. See Ed Burns, *System-Wide EHR Integration Limits Flexibility in Care*, TECH TARGET (Sept. 2012), <http://searchhealthit.techtarget.com/feature/System-wide-EHR-integration-limits-flexibility-in-care> [<https://perma.cc/68WQ-5V4U>]; Anderson, *supra* note 18, at 481.

22. See Akanksha Jayanthi, *15 Thoughts on Interoperability From Healthcare Leaders*, BECKER'S HEALTH IT & CIO REVIEW (Aug. 6, 2015), <http://www.beckershospitalreview.com/healthcare-information-technology/15-thoughts-on-interoperability-from-healthcare-leaders.html> [<https://perma.cc/VWL9-HCF4>]; Anderson, *supra* note 18, at 481–82; Jha, *supra* note 19, at 1632.

medical records (based on paper record models), federal income tax laws, intellectual property laws, and state licensing requirements.²³

Notwithstanding these issues, commentators believe that the public could benefit greatly from the implementation of EHRs by health care providers, and the United States government agrees.²⁴ Congress has played an active role in promoting the adoption of EHRs by enacting laws and empowering health-focused administrative agencies.²⁵ This has resulted in the creation of incentive programs and the promulgation of exceptions and safe harbor provisions to protect the implementation and sharing of EHRs from prosecution under the anti-referral law²⁶ and anti-kickback law.²⁷ However, as discussed in this note, these incentives are not currently sufficient to promote adoption of EHR technology at the desired rate.

In 2009, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) was enacted as a part of the American Recovery and Reinvestment Act.²⁸ The goal of the HITECH Act was to promote the adoption of HIT, including EHRs.²⁹ The Act legislatively mandated the creation of the Office of the National Coordinator for Health Information Technology (ONC), an agency originally created by Executive Order in 2004, to encourage providers to adopt EHRs, and to help them achieve interoperability among systems.³⁰ The HITECH Act also empowered the Department of Health and Human Services and its various subdivisions to promulgate rules to facilitate these goals.³¹

To promote the adoption of EHRs, The Centers for Medicare and Medicaid Services (CMS) has implemented a Medicare and Medicaid-based incentive program that awards health care providers who adopt and exercise “meaningful use” of EHR systems.³² CMS describe “meaningful use” as the use of certified

23. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-991R, HHS'S EFFORTS TO PROMOTE HEALTH INFORMATION TECHNOLOGY AND LEGAL BARRIERS TO ITS ADOPTION 44–52 (2004).

24. Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79202, 79206 (Dec. 27, 2013) (“Continued use and further adoption of electronic health records technology remains an important goal of the Department [of Health and Human Services].”).

25. *E.g.*, Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 300jj-11 – 300jj-51 (2012).

26. *See* 42 C.F.R. §§ 411.355 – 411.357 (2016).

27. *See* 42 C.F.R. § 1001.952 (2016).

28. Clinical Health Act, 42 U.S.C. §§ 300jj-11– 300jj-51 (2012).

29. HIPAA Administrative Simplification: Enforcement, 74 Fed. Reg. 56123 (Oct. 30, 2009); *See* HHS, *supra* note 4.

30. *About ONC, HEALTH IT*, <https://www.healthit.gov/newsroom/about-onc> [<https://perma.cc/82TW-6T7E>] (last visited Oct. 21, 2016).

31. 42 U.S.C. §§ 300jj-11 – 300jj-51 (2012).

32. 42 C.F.R. §§ 495.4, 495.6, 495.8 (2016); *see Electronic Health Records (EHR) EHR Incentive Programs*, CENTERS FOR MEDICARE & MEDICAID SERVICES <https://www.cms.gov/Regulations-and->

EHRs to “[i]mprove quality, safety, efficiency, and reduce health disparities[,] [e]ngage patients and family[,] [i]mprove care coordination, and population and public health [and] [m]aintain privacy and security of patient health information.”³³ The Department of Health and Human Services (HHS) has created requirements for participation in the meaningful use program, with three different stages of participation.³⁴

While the program does provide economic incentives for EHR adoption, it has many limitations. In order to participate in either the Medicare or Medicaid incentive program, an individual or hospital must be an “eligible provider”.³⁵ Non-physician practitioners such as physician assistants and nurse practitioners are not eligible for the Medicare program.³⁶ Physicians who are eligible must choose either the Medicare or the Medicaid incentive program, but may not participate in both.³⁷ Further, these incentives are tied to Medicare and Medicaid payments and do not provide incentives to providers who do not participate in those programs. Even if HHS and CMS find a way to eliminate these specific barriers to adoption, an extensive list of legal barriers to wider adoption still exists, the most troublesome of barriers being those that prevent economic incentives to adoption—namely the anti-referral, anti-kickback, and antitrust laws—the application of which extend beyond the meaningful use program.

III. THE EPIC MODEL

One company that sells interoperable EHR technology that meets the ONC standards is Epic Systems (Epic). Epic is a private, employee-owned software company based in Verona, Wisconsin with a work model and product that serve as an example of the promise of providing and adopting interoperable EHRs.³⁸ The company develops its own software to provide EHR systems tailored to providers’ needs.³⁹ These EHRs are used by health care

Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/ [https://perma.cc/9WUN-ULV3] (last visited Oct. 21, 2016).

33. *Meaningful Use Definition & Objectives*, HEALTH IT, <https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives> [https://perma.cc/HB46-MUBL] (last visited Oct. 21, 2016).

34. *Electronic Health Records (EHR) Incentive Programs*, *supra* note 33.

35. *Eligibility*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html> [https://perma.cc/Z4TH-CPS3] (last visited Oct. 21, 2016).

36. *Id.*

37. Mark Faccenda & Lara Parkin, *Meaningful Use – What Does It Mean to You?*, 23 HEALTH LAW 10 (2011).

38. *In A Nutshell*, EPIC, <http://www.epic.com/about> [https://perma.cc/B64C-MFXJ] (last visited Oct. 21, 2016).

39. *See Software Page*, EPIC, <http://www.epic.com/Software#CareAtADistance> [https://perma.cc/9YMJ-FYJ2] (last visited Oct. 21, 2016).

providers such as medical groups and hospitals, and are designed such that both health care professionals and patients can use them in some capacity.⁴⁰ Epic is one of the country's largest and most successful EHR vendors, serving over 50% of patients in the United States.⁴¹

As described by Epic, Epic's Care Everywhere system provides a framework of interoperability between Epic and non-Epic EMR systems.⁴² This allows health care providers to meet one of the goals of the meaningful use program that EHRs be interoperable.⁴³ However, greater functionality occurs among providers where they all utilize technology created by the same vendor, and incentivizes networks of providers to contract with a single vendor. This may help explain the fact that nearly, if not more than, half of U.S. patients are served by Epic.⁴⁴ This may also be an indication of the direction in which the American health care system is moving: toward more coordinated and cooperative care models. Large providers must be careful, however, when implementing new technology systems, not to violate anti-referral, anti-kickback, and antitrust laws. These legal barriers serve as deterrents to what would otherwise be economically successful and beneficial relationships that have potential to improve health outcomes.

IV. LEGAL BARRIERS

Like all businesses, providers and vendors consider the risk of

40. *In A Nutshell*, *supra* note 39.

41. Judy Newman, *Epic Systems Shows Off Its New Deep Space Auditorium as Customers Gather for Annual Meeting*, MADISON.COM (Sept. 18, 2013), http://host.madison.com/business/epic-shows-off-its-new-deep-space-auditorium-as-customers/article_2e9e8e01-02cc-53c5-9e5c-bb2a9e05a6a4.html [<https://perma.cc/EVA3-DU6R>] ("We've just gone over the 51 percent mark. You take care of a little over half of the patients in this country.") (quoting Judy Faulkner, CEO, Epic).

42. *See Organizations on the Care Everywhere Network*, EPIC <http://www.epic.com/CareEverywhere/> [<https://perma.cc/KCH5-86Q2>] (last visited Oct. 21, 2016). *But see* Darius Tahir, *Epic Systems Feeling Heat Over Interoperability*, MODERN HEALTHCARE (Oct. 1, 2014), <http://www.modernhealthcare.com/article/20141001/NEWS/310019945> [<https://perma.cc/Q8TS-JHCX>] (discussing political pressure Epic is experiencing related to perceived lack of interoperability with other EHR systems).

43. The Meaningful Use Program does not have exact interoperability requirements, but all explicit requirements are intended to promote interoperability. Medicaid and Medicare Programs; Electronic Health Record Incentive Program- Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62761, 62761 (Oct. 16, 2015).

44. Helen Gregg, *10 Things to Know About Epic*, BECKER'S HOSP. REV. (Apr. 17, 2014), <http://www.beckershospitalreview.com/lists/10-things-to-know-about-epic.html> [<https://perma.cc/W9AZ-P54B>]; Jeff Glaze, *Epic Systems Draws on Literature Greats for Its Next Expansion*, MADISON.COM (Jan. 6, 2015), http://host.madison.com/news/local/govt-and-politics/epic-systems-draws-on-literature-greats-for-its-next-expansion/article_4d1cf67c-2abf-5cfd-8ce1-2da60ed84194.html [<https://perma.cc/2Y9Z-97R6>].

legal liability before making business decisions. Laws like the Stark Anti-Referral Law (Stark) and the Medicare and Medicaid Anti-Kickback Statute (AKS) limit the types of relationships that businesses in the health care industry may legally enter into. Stark and AKS have exceptions as well as safe harbor provisions that protect the creation of certain relationships that would otherwise violate the laws, including certain relationships related to the implementation of EHRs. However, other laws that affect the American health care system, such as the antitrust laws, offer no such protection.

The terms “exceptions” and “safe harbors” hold a particular meaning for the purposes of analysis in this note. “Exceptions” are instances defined as not being in violation of the law. Stark is a strict liability statute, which means if all elements are satisfied, a violation has occurred. Exceptions to Stark are by definition instances where Stark has not been violated. AKS, on the other hand, requires a specific level of intent in addition to its other elements in order for a violation to occur. As certain terms within the statute are not defined, analysis occurs on a case by case basis, and there is no clear line between an arrangement that does or does not violate the law. “Safe harbors” are well-delineated instances that are guaranteed to be safe from prosecution under the law. Thus, the analogy to boats docked in a safe harbor.

Where protections do exist in relation to EHRs, their requirements are often difficult to satisfy. This is the case for the Stark exceptions and AKS safe harbors. Generally, arrangements that do not fall squarely within a safe harbor are not automatically in violation of a statute.⁴⁵ However, arrangements implicated by these laws but not falling within an AKS safe harbor are at risk of being found in violation. This threat of liability serves as a powerful deterrent to entering into what would otherwise be beneficial relationships that could improve adoption of beneficial HIT, including and especially EHRs.

A. *The Stark Law*

Stark prohibits a physician from making a referral to an entity for designated health services, in the context of Medicare claims,⁴⁶ where there is a financial relationship between the physician (or an

45. As Stark is a strict liability statute, if the elements of Stark are satisfied, and an arrangement does not fall squarely within a safe harbor, it is automatically in violation of the statute. *A Roadmap for New Physicians Fraud & Abuse Laws*, OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf [<https://perma.cc/8UL8-FE4N>] (last visited Oct. 10, 2016).

46. Medicaid has also been incorporated through state versions of the Stark law. *See, e.g.*, Tex. Occ. Code Ann. § 102.001(a) (West 2012).

immediate family member of the physician) and the entity.⁴⁷ The law also prohibits presenting or causing to be presented a claim for payment for the prohibited services.⁴⁸ Generally, “financial relationship” means that the physician has an ownership or investment interest in the entity, or that there is a “compensation arrangement” between the physician and the entity.⁴⁹ A compensation arrangement is an arrangement to provide remuneration⁵⁰ in return for referrals between a physician and an entity, unless an exception applies.⁵¹

There are exceptions to the Stark prohibitions which establish that certain provider relationships do not constitute compensation arrangements, although they might technically qualify as such without the protection. CMS promulgated these exceptions and exempted from Stark liability “financial relationships that do not pose a no risk of program or patient abuse.”⁵² The exceptions were amended in 2006 to add to the list of protected relationships certain transactions involving “electronic health records items and services.”⁵³

One main focus of CMS when creating the new exception was “to limit the risk of data and referral lock-in.”⁵⁴ CMS did not want to allow the donation of EHR items and services to and from providers in a manner that would incentivize referrals, or the safeguarding rather than sharing of patient information that could be used to improve health outcomes. As a result of this concern, financial relationships must satisfy many requirements in order to qualify for protection under the exception.⁵⁵

1. Stark EHR Exception

To begin with, the donation of EHR *hardware* from one player in the health care industry to another is not protected by the EHR exception.⁵⁶ Recipients of remuneration in the form of EHR technology donations must take on the costs of acquiring the

47. 42 U.S.C. § 1395nn(a)(1)(A) (2012).

48. *Id.* § 1395nn(a)(1)(B).

49. *Id.* § 1395nn(a)(2).

50. Remuneration is defined as “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind . . .” 42 C.F.R. § 411.351 (2015).

51. 42 U.S.C. § 1395nn(h)(1)(A) (2012).

52. Medicare Program; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements, 78 Fed. Reg. 78751, 78752 (Dec. 27, 2013).

53. 42 C.F.R. § 411.357(w) (2015).

54. Medicare Program; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements, 78 Fed. Reg. 78751, 78752 (Dec. 27, 2013).

55. 42 C.F.R. § 411.357(w)(1)–(13) (2015).

56. *Id.* § 411.357(v) (“Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary . . . to create, maintain, transmit, or receive electronic health records . . .”).

appropriate hardware themselves. In addition to covering significant implementation costs, providers are limited by Stark in the organizations from whom they may legally accept donations of approved items and services. Laboratory companies, for example, are completely excluded from making donations of any items or services related to EHRs.⁵⁷

Between eligible recipients and donors, the receiving physician must pay 15% of the donor's cost of providing the items or services, and that payment cannot be financed by the donor.⁵⁸ The donor may not take action to limit or restrict the "use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems,"⁵⁹ or to limit or restrict use to certain patients.⁶⁰ The arrangement must be set forth in writing and signed by the parties.⁶¹

Where parties enter into an arrangement for one to provide EHR software to another, that software must be interoperable. Specifically, the technology must be certified as interoperable by the ONC.⁶² The donor also cannot have actual knowledge, act in reckless disregard of, or act in deliberate ignorance of the fact that the recipient obtains or possesses items or services equivalent to those provided by the donor.⁶³ Moreover, if a donor provides items and services that are not considered equivalent to any the recipient already owns, the donor may not provide staffing to operate the technology.⁶⁴

One of the requirements that most directly mirrors CMS's concern that donations will induce referrals is the requirement that receipt of the items and services not be conditioned on the recipient doing business with the donor.⁶⁵ Furthermore, eligibility to receive items and services cannot be determined considering "the volume or value of referrals or other business generated between the parties"⁶⁶ This greatly increases the investment risk for donors, who will have a more difficult time predicting returns on

57. 42 C.F.R. § 411.357(w)(1) (2015).

58. *Id.* § 411.357(w)(4).

59. *Id.* § 411.357(w)(3).

60. *Id.* § 411.357(w)(9).

61. *Id.* § 411.357(w)(7)(i).

62. *Id.* § 411.357(w)(2).

63. *Id.* § 411.357(w)(8).

64. *Id.* § 411.357(w)(10).

65. *Id.* § 411.357(w)(5).

66. *Id.* § 411.357(w)(6); Determination is deemed not have been based on the volume or value of referrals or other business where determination is based on: 1.) the number of prescriptions written by a receiving physician; 2.) the size of the physician's practice; 3.) the total number of hours the physician practices medicine; 4.) the physician's use of automated technology in the physician's office; 5.) whether the physician is a member of the donor's medical staff; 6.) the level of uncompensated care provided by the physician; or 7.) any other "reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business. . . ." *Id.* §§ 411.357(w)(i)-(vii).

their investment.

While recipients might be able to make necessary investments over time with the help of other providers through relationships that fall within the exception, all exception conditions must be satisfied by the end of 2021.⁶⁷ In preparation for adopting the final version of the Stark regulations, HHS accepted comments on proposed changes.⁶⁸ Commenters urged HHS to make the EHR exception permanent instead of including a date by which all protected software and service donations must be completed.⁶⁹ CMS's response to the comments was that eliminating the 2021 requirement would lessen the incentive to complete adoption in the "near term."⁷⁰

An additional fear that CMS expressed during discussions of the permanency of the exception is that doing so may "exacerbate [the risk of data and referral lock-in] over the longer term without significantly improving adoption rates."⁷¹ CMS continued:

[Stark exceptions are] only one of a number of ways that physicians are incited to adopt electronic health records technology, including the incentives offered by the EHR Incentive Programs and the movement in the health care industry toward the electronic exchange of patient health information as a means to improve patient care quality and outcomes.⁷²

2. Limitations to Successful Adoption Created by the Stark EHR Exception

The requirements of the Stark EHR exception have created significant limitations to providers' ability to adopt EHR systems, and other parties' ability to aid in this adoption. First, the requirement that *hardware* not be donated leaves the burden of substantial implementation costs with the provider. HHS, the department that houses CMS, suggests that "potential hardware costs may include database servers, desktop computers,

67. *Id.* § 411.357(w)(13). The original date of implementation was 2013, but CMS pushed back the deadline, perhaps realizing that the health care system would benefit from allowing providers more time to adapt. *See* Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements, 78 Fed. Reg. 249, 78751-78769 (Dec. 27, 2013) (extending the deadline for adoption to 2021).

68. The Final Rule was a set of rules promulgated by HHS under the statutory authority granted it under section 1877 of the Social Security Act that interpreted the Stark Law and included the Stark Safe Harbors. *See* 78 Fed. Reg. 78751, 78751-78768 (Dec. 27, 2013).

69. 78 Fed. Reg. at 78755 (Dec. 27, 2013).

70. *Id.* at 78756.

71. *Id.*

72. *Id.*

tablets/laptops, printers, and scanners.”⁷³

HHS has estimated that the average cost of EHR implementation in a practice over a five-year period is \$48,000, with an initial investment of \$33,000 in the first year.⁷⁴ Estimates from other sources range as high as \$162,000 total with an additional input of \$85,500 to cover maintenance expenses in the first year.⁷⁵ One-time hardware costs alone can exceed \$25,000 per practice.⁷⁶

To implement EHR systems, providers who do not currently use electronic medical records must invest in this equipment without financial support from other providers who might be in a position and have an incentive to help (e.g. heightened interoperability and effectiveness among providers using the same systems). Providers who already have desktops and servers might still need to invest in updated equipment, mobile devices, and additional servers to house all of the information collected and the software used in interoperable systems. Not only are donors unable to provide recipients with hardware and other critical EHR components, organizations like laboratory companies, that might be among the most willing and able to provide donations, are excluded completely from the donor pool.

Potential donors who consider donating allowable software, items, or services may not do so if the recipient already possesses similar technology. This is particularly troubling because it effectively prohibits donors from aiding recipients in expanding their practices. Where recipients seek to expand their current operations to serve a greater portion of the population, interested donors could help with this expansion, but for the recipient’s possession of similar items or services, regardless of whether those items or services are insufficient to serve a growing patient base. While goals expressed by federal agencies related to improving the American health care system focus on promoting greater quality and efficiency of care, this provision limits the ability of providers to increase efficiency by utilizing more HIT and serving a greater number of patients.

Even when donors are in a position to donate software, they may not provide staff to operate, or train others to operate, the technology. This alone might be enough to deter many software donations because it limits the chances that the recipient will be

73. *How Much Is This Going To Cost Me?*, HEALTH IT (last updated Nov. 12, 2014), <https://www.healthit.gov/providers-professionals/faqs/how-much-going-cost-me> [<https://perma.cc/E8EL-ECRF>].

74. *Id.*

75. *Study Identifies Costs of Implementing Electronic Health Records in Network of Physician Practices: Research Activities No. 374*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (Oct. 2011), <http://archive.ahrq.gov/news/newsletters/research-activities/oct11/1011RA15.html> [<https://perma.cc/Z6TS-Z7MP>] (estimated for a primary care practice of five physicians).

76. *Id.*

able to make effective use of the technology. If a provider cannot afford to hire additional staff to work with the hardware and donated software, or to train existing staff to operate the technology, the provider may still have a hard time successfully implementing an EHR system, meeting meaningful use requirements, or both. The lack of understanding of how to operate new EHR systems has been cited as a barrier to EHR adoption.⁷⁷

Perhaps the greatest deterrent to donors is the requirement that the donation of EHR items and services not be determined based on the volume or value of referrals to the donor by the recipient. If donors may not connect their donations in any way to referrals or other business they anticipate as a return on their investment, there is little incentive for them to make donations at all. This is especially so in the current competitive environment where if they do not provide donations they will likely be in a better position to compete for the recipients' patients, possessing the hardware, staff, and other resources necessary to meaningfully use EHRs, which recipients cannot afford. The requirement stems from the desire to prevent "data and referral lock-in."⁷⁸ However, CMS has already classified the relationships that fall within the Stark exception as relationships that do not pose that risk.⁷⁹

Furthermore, CMS makes a somewhat false distinction between relationships that violate Stark and those that qualify for the EHR exception. The definition of "compensation arrangement" as prohibited by Stark already excludes remuneration in the form of a payment made to a physician where "the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals."⁸⁰ The limiting instruction thus makes the exception superfluous because an arrangement will not fall within the exception unless the arrangement complies with Stark law itself.

Another provision that creates a limitation to adoption, and which has received much push-back from commenters in the field, is the requirement that all conditions of the exception be satisfied by 2021. Providers are forced to make substantial investments in the next five years or they will face the full cost of implementation on their own, or risk liability under Stark for accepting donations of EHR items and services. Making the exception permanent, proponents argue, would allow for greater predictability and

77. Anderson, *supra* note 18, at 481.

78. 78 Fed. Reg. 78751, 78752 (Dec. 27, 2013).

79. *Id.* (describing safe harbor exceptions as "financial relationships that do not pose a risk of program or patient abuse").

80. 42 U.S.C. § 1395nn(h)(1)(C)(iii)(III) (2012).

adoption by physicians newly entering the market or struggling to meet the costs of implementation.⁸¹ Making the provision permanent would also facilitate implementation of EHRs at a more reasonable rate, and would not exclude otherwise potential participants who cannot meet the capital requirements by 2021, but who could do so over a longer period of time.

The ultimate goal of HHS, to promote the switch to interoperable EHR systems by as many providers as possible, would be better served by allowing every provider who has the potential to make the switch to do so, rather than making the exception incentive available only for the providers who are capable of doing so by 2021. Additionally, if “the need for a safe harbor for donations of electronic health records technology [will] diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice,”⁸² there seems to be little risk in eliminating incentives in the near term. Many providers who are capable of adopting EHRs in the near term will do so regardless of deadlines in order to keep up with the standard medical practice in the current market.

CMS points to incentive programs such as the meaningful use program that will enable providers to achieve meaningful adoption of EHRs in the next five years. The EHR Incentive Program options are limited to eligible professionals, however, who participate in Medicare or Medicaid, and that those professionals are further limited depending on criteria such as practice area.⁸³ Moreover, the idea that movement of the health care industry toward EHR utilization will naturally incentivize providers to implement EHRs discounts the argument that adoption will not continue at a desirable rate should the exception become a permanent aid to adoption.

Providers will still be motivated to work toward adoption after 2021 by the need to provide the market standard of quality and efficiency of care.⁸⁴ New providers will still be entering the market and providers will still face economic and other barriers to implementation after 2021. Continuing to provide as many incentives as possible to EHR adoption will not, therefore, slow the rate of adoption, but will aid in the widest possible adoption rates of EHRs overall.

B. The Anti-Kickback Statute

AKS can be distinguished from Stark initially by the fact that

81. 78 Fed. Reg. 78751, 78755 (Dec. 27, 2013).

82. 71 Fed. Reg. 45110, 45162 (Aug. 8, 2006).

83. *See supra* Section II (Efforts to Promote Adoption).

84. HEISEY-GROVE & PATEL, PHYSICIAN MOTIVATIONS FOR ADOPTION OF ELECTRONIC HEALTH RECORDS, ONC DATA BRIEF NO. 21 3-4 (Dec. 2014).

it reaches a broader range of providers and relationships. Whereas Stark is limited to instances of physicians making referrals to certain entities, AKS applies to the exchange of any remuneration in return for any referrals that implicate payment by a federal healthcare program.⁸⁵ AKS prohibits knowingly and willfully soliciting or receiving “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a [provider]” for an item or service for which payment is made by a federal health care program.⁸⁶

The law further prohibits knowingly and willfully “mak[ing] or caus[ing] to be made any false statement or representation of a material fact” in an application for payment of a benefit under a Federal health care program.⁸⁷ For purposes of the Act, a Federal health care program is “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government.”⁸⁸ Interestingly, one final requirement of the Stark exception for EHRs is that any financial relationship not violate AKS.⁸⁹ In order for a financial relationship to fall within the Stark exception then, it must meet all of the other requirements of the exception, as well as all of the requirements of the broader AKS law, or one of the AKS safe harbors provisions.

In response to concern expressed by commenters that the statute covered “some relatively innocuous commercial arrangements,” the Office of Inspector General (OIG) published the “Final Rule”⁹⁰ that promulgated the finalized safe harbor exceptions for AKS, including a safe harbor for electronic health records.⁹¹ These provisions specify certain business arrangements and practices that do not constitute a violation under the statute, “even though they may potentially be capable of inducing referrals of business under the Federal health care programs.”⁹²

3. AKS EHR Safe Harbor

The AKS safe harbor provisions for EHRs establish all of the same conditions as the Stark EHR exception with the addition that providers not shift the cost of EHR items and services to the federal

85. 42 U.S.C. § 1320a-7b(b) (2012).

86. *Id.*

87. *Id.* § 1320a-7b(a)(1).

88. *Id.* § 1320a-7b(f)(1).

89. 42 C.F.R. § 411.357(w)(12) (2016).

90. 78 Fed. Reg. 79202, 79202–79220 (Dec. 27, 2013). Note that the Final Rule is where the Stark exceptions were promulgated as well.

91. *Id.* at 79203.

92. *Id.* at 79202.

health care program they are billing.⁹³ Thus, the same considerations and concerns are implicated in the AKS EHR safe harbor analysis, with the addition of an important requirement, contradictory though it may be.

The additional requirement makes a distinction in the division of responsibility for assuming costs of implementation. The agencies administering federal health care programs are pushing wider adoption of EHRs and expect that the technology will be used to provide better services to patients by 2021. They will not, however, take on the costs of implementation. There appears to be a disconnect between the agencies' goals, and their willingness to help achieve those goals.

Supplementing the considerations mentioned above, the application of AKS case law has clarified the requirement that arrangements not be determined based on the value of referrals or other business.⁹⁴ Even where an agreement is not conditioned upon referrals or other business, it may constitute a violation of AKS if *one* purpose of the relationship is to obtain referrals.⁹⁵ A provider may be at risk of being found to have violated AKS, and not to fall within the protections of a safe harbor, where a transaction can be perceived in any way as anticipating certain referrals or the generation of certain business in return for remuneration, such as donating EHR software.

A provider that is considering donating to another provider EHR items or services of any kind must take care not to violate either Stark or AKS. The only way to be sure that a relationship is not in violation of either law is to ensure that it falls within the exceptions or safe harbors of both. A Stark and AKS analysis for EHRs would run generally as follows:

- 1) *Does the relationship or business transaction implicate Stark?*
 - a) Is there a financial relationship between a physician and another provider entity?
 - i) Does the physician or a family member of the physician have a financial interest in or compensation arrangement with the entity?
 - b) Are the providers in question participants in Medicare or Medicaid?
 - c) Are the services in question designated health services?
- 2) *If the maneuver falls under Stark, does the relationship fall under a Stark exception?*
- 3) *If the relationship falls under a Stark exception, does the transaction implicate AKS?*

93. 42 C.F.R. § 1001.952(y)(13) (2016); *See* 42 C.F.R. § 1001.952(y) (2016); 42 C.F.R. § 411.357(w) (2016).

94. 42 C.F.R. § 1001.952(y)(5) (2016).

95. *U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000).

- a) Is any remuneration provided?
 - b) Is the remuneration provided in return for referrals or the generation of other business?
 - c) Is the referral for an item or service paid for under a Federal health care program?
 - 4) *If the transaction falls under AKS, does the remuneration fall under an AKS Safe Harbor?*
4. Limitations to Successful Adoption Created by the AKS EHR Safe Harbor

Not only do the requirements of the AKS EHR safe harbor that are identical to those of the Stark EHR exception raise the same concerns,⁹⁶ but the additional requirement that the cost of implementation not be passed on to federal payers creates additional limitations and concerns. This refusal to take on some of the costs of donating items and services to recipient providers is justified, at least in part, by the reasoning that incentive programs are available for providers who achieve “meaningful use.” However, as discussed above, the meaningful use requirements are difficult to satisfy and the benefits are available only to certain Medicare and Medicaid participants.⁹⁷

When considering potentially prohibited arrangements under AKS, the OIG has expressed concern regarding “increased risk of overutilization, increased program costs, patient freedom of choice, and unfair competition.”⁹⁸ One effect of Stark and AKS has been to drive physicians and hospitals to compete, instead of working together to provide care to patients.⁹⁹ Where providers cannot develop relationships that are beneficial to both parties without being at risk of violating Stark, AKS or both, providers choose not to share information, items, and services in order to preserve a competitive advantage. Physicians who own their own practices, for example, have begun purchasing their own equipment so that they will receive the insurance reimbursement for services provided with that instrument, instead of referring the patient in need of that

96. 42 U.S.C. § 1395nn(b) (2016).

97. *Eligibility*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html> [https://perma.cc/5ELP-PQSN] (last updated May 17, 2012); *Overview of Eligible Professional (EP) and Eligible Hospital (EH) Types*, MEDICARE & MEDICAID EHR INCENTIVE PROGRAM REGISTRATION AND ATTESTATION SYSTEM, <https://ehrincentives.cms.gov/hitech/loginCredentials.action> [https://perma.cc/6CTR-ECTG] (last visited Oct. 25, 2016).

98. ADVISORY OPINION 98-3, OFF. OF INSPECTOR GEN (Apr. 6, 1998), https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_3.pdf [https://perma.cc/3XPH-XR3U].

99. Robin Lock Nagele, *Hospital-Physician Relationships After National Health Reform: Moving From Competition to Collaboration*, 82 PA. BAR ASS'N Q. 1, 4 (Jan. 2011).

service to a hospital that already owns the technology.¹⁰⁰ This and similar behavior leads to overutilization and increasing charges for services.¹⁰¹ This environment also cultivates an increased risk of fraud and abuse by providers, who may feel pressure to increase referrals in order to make back the cost of these improvements to their practice.

The federal government takes the position that competition in the health care market will lead to the best outcomes.¹⁰² However, forced competition is causing exactly what the Government seeks to prevent: overutilization and increased costs. Many critics of the current health care environment and health care professionals argue that increased cooperation, rather than increased competition, will increase the quality and efficiency of care.¹⁰³

C. Antitrust Laws

Another concern related to cooperation among health care providers is the potential for anticompetitive behavior that could increase health care costs.¹⁰⁴ In 1890, Congress passed the Sherman Antitrust Act (Sherman Act) as a “comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.”¹⁰⁵ Generally, courts determine whether relationships are illegal based on each fact scenario.¹⁰⁶ The overall objective of antitrust laws is to “protect the process of competition for the benefit of consumers, making sure there are strong incentives for businesses to operate efficiently, keep prices down, and keep quality up.”¹⁰⁷

The Sherman Act’s Section I prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations.”¹⁰⁸ The Federal Trade Commission Act (FTC Act) created the Federal Trade Commission (FTC) and empowered the FTC to enforce the Sherman Act and prevent what it deems anticompetitive market activity.¹⁰⁹ Amendments, further delineating potentially unfair competitive behavior,¹¹⁰ came to the

100. See CTR. FOR HEALTHCARE RES. & TRANSFORMATION, PHYSICIAN OWNERSHIP IN HOSPITALS AND OUTPATIENT FACILITIES 2 (July 2013).

101. *Id.*

102. See *infra* Section V.3 (Antitrust Laws).

103. See Nagele, *supra* note 99.

104. *Id.* This behavior could include, for example, prohibited joint contracting or price fixing.

105. *N. Pac. Ry. Co. v. U.S.*, 356 U.S. 1, 4 (1958).

106. *The Antitrust Laws*, FTC, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> [<https://perma.cc/NA74-XSPY>] (last visited Nov. 27, 2015).

107. *Id.*

108. 15 U.S.C. §1 (2016).

109. *Id.* at §§ 41, 45.

110. See *id.* at §§ 13–14.

Sherman Act in 1914 in the form of the Clayton Antitrust Act (Clayton Act).¹¹¹

5. Perception of Antitrust Laws as Applied to EHR Adoption and EHR Safety Zones

An executive summary published by the FTC and Department of Justice (DOJ) (hereinafter collectively referred to as the Agencies) in 2003 expressed the Agencies' position that competition is integral to the success of the American health care system.¹¹² The Agencies stated that “[p]rice competition generally results in lower prices and, thus, broader access to health care products and services. . . new and improved drugs, cheaper generic alternatives to branded drugs, treatments with less pain and fewer side effects and treatments offered in a manner and location consumers desire.”¹¹³ According to the executive summary, “[c]ompetition cannot provide its full benefits to consumers without good information and properly aligned incentives.”

Critics of the current health care system argue that the market incentivizes competition between hospitals and physicians. This has led to increased costs and poorer health outcomes, according to Dr. Atul Gawande, a professor at Harvard School of Public Health and Harvard Medical School.¹¹⁴ Robin Nagele of the Pennsylvania Bar agrees: “Among other things, physician ownership of advance technologies, diagnostics and surgery centers has led to overutilization, higher complication rates, and escalating charges.”¹¹⁵

Overutilization and increased costs, however, are not necessarily caused by antitrust enforcement. The FTC has consistently executed its power under the FTC Act to bring cases against what it believes to be illegal anticompetitive behavior.¹¹⁶ The FTC does not pursue relationships in the industry that it believes will create benefits for consumers. In fact, the FTC has identified many health care relationships as the type that deserve

111. *Id.* at § 12.

112. EXECUTIVE SUMMARY, ANTITRUST DIVISION OF THE DOJ (2003), <http://www.justice.gov/atr/executive-summary> [https://perma.cc/5C96-S6DB].

113. *Id.*

114. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER (June 1, 2009), <http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum> [https://perma.cc/REM5-LVWG].

115. Nagele, *supra* note 99, at 4.

116. See ROXANE BUSEY, THOMAS GREANEY & DOUGLAS ROSS, AMERICAN HEALTH LAWYERS ASSOCIATION, ABA SECTIONS OF ANTITRUST AND HEALTH LAW, SELECTED ANTITRUST DEVELOPMENTS IN HEALTH CARE (2014), https://www.healthlawyers.org/Events/Programs/Materials/Documents/AT14/busey_greaney_ross.pdf [https://perma.cc/WZL2-YS2B].

protection under what the Agencies refer to as “safety zones.”¹¹⁷

While antitrust concerns continue to be one of the most often cited legal barriers to wider adoption of EHRs,¹¹⁸ these concerns are often voiced by competitors in the market, rather than by consumers or by the Agencies. Take for example a recent contract entered into by Epic to install interoperable EHRs across the Partners system.¹¹⁹ The \$1.2 billion project has the potential to increase the quality and efficiency of care across 10 hospitals and 6,000 physicians in the ways previously described.¹²⁰ Despite, or perhaps because of, the potential for the Partners-Epic relationship to be very successful, Partners’ competitors were quick to voice antitrust concerns.¹²¹

However, critics of the relationship did not provide tangible examples of how the relationship would negatively impact the market and consumers. Moreover, no antitrust claims have yet been brought against Partners or Epic. That large organizations like Partners are continuing to enter into these and similar relationships indicates that one successful way to improve the quality and efficiency of care may be to create a more unified, cooperative system; that these and similar relationships do not violate antitrust laws; and thus, that antitrust laws do not function as a significant barrier to wider adoption of EHRs.

If relationships like the one between Partners and Epic were legally prohibited, each provider in a system like Partners would be forced to face all of the considerations and costs associated with implementing an EHR system alone. Each provider might end up with a different system, a system that is not as efficient as others, a system that is not interoperable with the others, or with no system at all, if they cannot come up with the implementation costs. That is why the FTC has identified relationships like the Partners-Epic relationship as the type that will increase efficiency and lower costs within the healthcare market, and that therefore deserve protection within the antitrust safety zones.¹²²

117. DOJ & FTC, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE 2 (1996). Similar to the concept of a safe harbor, a safe zone is a category of relationships that the FTC believes do not pose a sufficiently large risk of violating antitrust laws and that it will not prosecute under the antitrust laws; *see id.*

118. Letter from Janet Heinrich, Director, Health Care- Public Health Issues, to Judd Gregg, Chairman, U.S. Senate Committee on Health, Education, Labor, and Pensions (Aug. 13, 2004), <http://www.gao.gov/assets/100/92869.pdf> [<https://perma.cc/TUD8-72VB>].

119. Akanksha Jayanthi, *Paul Levy: Partners HealthCare, Epic Relationship Fringes on Antitrust Violations*, BECKER'S HEALTH IT & CIO REVIEW (Sept. 1, 2015), <http://www.beckershospitalreview.com/healthcare-information-technology/paul-levy-partners-healthcare-epic-relationship-fringes-on-antitrust-violations.html> [<https://perma.cc/ZB7L-8USD>].

120. *Id.*

121. *Id.*

122. *See generally* DOJ & FTC, *supra* note 117.

Not only do providers and the Agencies believe that increased cooperation can benefit the American health care system, the most recently passed Federal legislation addressing the issue is structured to move the system in the direction of more coordinated care.¹²³ The Patient Protection and Affordable Care Act (ACA) was designed to improve access to, affordability of, and quality of health care in the United States through health insurance reform.¹²⁴ The ACA promotes increased cooperation among providers by promoting the creation of accountable care organizations and community health centers and systems.¹²⁵

State legislators and citizens have also begun endorsing more cooperative care models. In 2011, Green Mountain Care was established in the state of Vermont as a single-payer health care system.¹²⁶ Although the program has encountered setbacks to its original timeline,¹²⁷ supporters of the unified health care movement in Vermont will not be discouraged. The New York State Assembly passed the New York Health Act in May 2015, and it has moved on to the Senate.¹²⁸ Coloradans voted on the opportunity to implement a single-payer system called Colorado Care in 2016.¹²⁹ Oregon citizens have rallied in the capitol to call on state legislators to create a single-payer system in their state.¹³⁰

Unified systems of care within the states will not necessarily eliminate competition. In the models presented thus far, individuals will have a right to choose among providers.¹³¹

123. Nagele, *supra* note 99, at 3.

124. *Key Features of the Affordable Care Act*, HHS, <http://www.hhs.gov/healthcare/facts-and-features/key-features-of-aca/> [<https://perma.cc/YN2L-EEGK>] (updated on Nov. 18, 2014); Nagele, *supra* note 99, at 3.

125. See Leighton KU, PETER SHIN, MARSHA REGENSTEIN & HOLLY MEAD, PROMOTING THE INTEGRATION AND COORDINATION OF SAFETY-NET HEALTH CARE PROVIDERS UNDER HEALTH REFORM: KEY ISSUES (2011), http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2011/Oct/1552_Ku_promoting_integration_safetynet_providers_under_reform_ib_v2.pdf [<https://perma.cc/5E7G-EA4K>].

126. H.202, Gen. Assemb., Reg. Sess. (Vt. 2011–2012).

127. *Gov. Shumlin Details Health Care Financing Report to Business and Consumer Advisory Councils*, VERMONT.GOV (Oct. 24, 2014), <http://governor.vermont.gov/press-release/gov-shumlin-details-health-care-financing-report-business-and-consumer-advisory> [<https://perma.cc/N7BY-VZRJ>].

128. S.3525, State Assemb., (N.Y. 2015–2016).

129. See *ColoradoCare Yes*, COLORADOCAREYES.CO, <http://coloradocareyes.co/> [<https://perma.cc/3GB8-8EQ3>] (last visited Nov. 16, 2016) (proposing a 69th amendment to the Colorado Constitution). Voters ultimately voted down the measure. Bruce Japsen, *Colorado Rejects Single-Payer Healthcare Insurance*, FORBES: PHARMA & HEALTHCARE (Nov. 9, 2016, 12:57 AM), <http://www.forbes.com/sites/brucejapsen/2016/11/09/colorado-rejects-single-payer-healthcare-insurance/#7a88640f6296> [<https://perma.cc/Z6KM-829L>].

130. *Health Care for All Rally Brings Hundreds to Salem*, NWLABORPRESS.ORG (February 20, 2015), <https://nwlaborpress.org/2015/02/health-care-rally-brings-hundreds-salem/> [<https://perma.cc/V4M7-P8ZS>].

131. See, e.g., S.B. 400, Gen. Assemb., Reg. Sess. (Pa. 2013–2014); S.3525, State Assemb., (N.Y. 2015–2016); *ColoradoCare Yes*, COLORADOCAREYES.CO,

Providers will still compete against one another and experience incentives to provide the best care at the best cost. However, it is clear that improving the quality of care through competition can be accomplished only where competition functions effectively in the market.

The Agencies have cited asymmetry of information between providers and consumers and underutilization of information technology as problems that limit the effectiveness of competition.¹³² Information disparity is particularly relevant in the health care setting where patient consumers are more reliant on providers and have less bargaining power due to their limited medical knowledge and vulnerable health conditions.¹³³ Underutilization of applicable technology is also particularly relevant in the health care setting where the technology is available, and yet is not utilized at an optimal rate due to various barriers, including those herein discussed.

Interestingly, EHRs could actually improve consumer access to information,¹³⁴ but for the barriers to wider adoption of the technology. As the FTC is committed to encouraging relationships that will improve access to and utilization of EHRs,¹³⁵ antitrust enforcement will continue to be a tool to enhance, rather than a barrier to, adoption of the technology. The Agencies, HHS, and other agencies involved in regulating the American healthcare system should, therefore, focus on addressing legal structures that do currently function as barriers to wider adoption, such as Stark and AKS.

Information disparity in the market can pressure providers to turn to prohibited referrals, implicating Stark and AKS. Trust in, and reliance on, medical professionals by patients naturally translates to an increased reliance on referrals. While some providers are struggling to find the capital to adopt or update EHRs, the pressure of the current competitive market environment might drive those providers to turn to prohibited referral arrangements. This could in turn lead to greater overutilization. It could also increase waste in the system as more federal resources are spent prosecuting Stark, AKS, and other potential fraud and abuse violations.

<http://coloradocareyes.co/> [<https://perma.cc/XQZ9-AKDJ>] (last visited Nov. 16, 2016) (proposing a 69th amendment to the Colorado Constitution).

132. EXECUTIVE SUMMARY, ANTITRUST DIVISION OF THE DOJ (2003), <http://www.justice.gov/atr/executive-summary> [<https://perma.cc/K6ND-MQEK>].

133. See John Roberts, *Primary Care: Core Values, Primary Care in an Imperfect Market*, *BMJ* 317, 186–189 (July 18, 1998).

134. JAMOON, ET AL., NCHS DATA BRIEF NO. 98: PHYSICIAN ADOPTION OF ELECTRONIC HEALTH RECORD SYSTEMS: UNITED STATES, 2011 (Revised Jan. 11, 2013).

135. See DOJ & FTC, *supra* note 117.

V. POTENTIAL SOLUTIONS

In the spirit of cooperation among physicians and hospitals in place of competition, employment is one solution that could be realized in the near-term. Employment, subject to certain requirements, is already one of the qualified exceptions and safe harbors under Stark and AKS respectively. Where hospitals and physicians already work closely and have integrated payment structures, hospitals could employ physicians for the same work and provide the hospital's hardware, software, services, and staff because physicians will be members of the hospital system, rather than competitors or recipients of donations. In addition to alleviating anti-referral and kickback concerns, this method would promote cooperation.

One permanent and necessary solution to the current legal barriers to EHR adoption presented by Stark and AKS is to eliminate the 2021 termination date of the exception and safe harbor, and make them a permanent part of the legal framework. CMS and OIG have expressed resistance to this approach for the concern that eliminating the deadline would eliminate the incentive for providers to adopt EHRs in the short term.¹³⁶ An alternative solution to the current all-or-nothing approach is to extend the deadline for a finite period of time, and provide other incentives to adopt EHRs in a timely manner (by 2021). Incentives might be adjusted into the existing EHR Incentive Programs, or new incentives could be created.

Another option would be for CMS and OIG to review the success of implementation at the end of 2021, then delineate another timeline during which another round of providers would be able to come within the exception and safe harbor (similar to the meaningful use stages). The benefit of allowing for another time period in the future is that it will give providers who cannot meet the requirements by 2021 another opportunity to receive support to achieve what may otherwise be an unobtainable goal. In addition to providers who are not able to meet the requirements by 2021, new providers will enter the market place after that date for whom no aid will be available if the timeline is not extended.

It seems appropriate that CMS and OIG should continue to adjust these provisions over time, rather than promulgating one Final Rule that will govern forevermore in a market that is ever changing. Congress has expressed that “[i]n giving HHS the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business

136. 78 Fed. Reg. 78751, 78756 (Dec. 27, 2013).

practices and technologies in the health care industry.”¹³⁷ If that is the vision of Congress, HHS should utilize its power to make regulations in a manner consistent with that vision.

Another issue that must be addressed in order to allow the Stark exception and AKS safe harbors to function more effectively is the overlap in restrictive language between Stark and its exception, which effectively invalidates the protection provided under the exception. HHS should consider eliminating the provision from the Stark exception that prohibits donations that are based on the volume or value of referrals or other business, or at least consider limiting the scope of the restriction. If HHS is unwilling to eliminate the provision completely, it should consider editing the language to provide some flexibility for donors to be able to predict some sort of return on their investment. Otherwise, there will be no incentive for providers to donate when they could use the resources to outcompete recipients.

There is one type of relationship that might be possible without affecting any change to the current Stark or AKS framework as applied to the implementation and sharing of EHR technology. Data analysis companies might provide donations to providers in return for the right to run analytics on information that providers collect through the use of the donated technology. Although, parties anticipating such a relationship must be sure to confirm that the data analytics company in question does not qualify as an entity covered by Stark or AKS, and address the privacy concerns implicated in sharing what is potentially HIPAA-protected health information.

Such a relationship would satisfy the requirement that donations not be based on the volume or value of referrals, because providers would not refer anyone to the data analytics company. However, privacy concerns would still act as a large deterrent to that kind of relationship. Further, for the same reasons that the government does not want providers to make decisions based on economic considerations instead of considering what will be best for patients, it would likely not want providers to be beholden to data analytics companies who could have the same effect of causing overutilization by requesting increased usage of certain services in order to obtain more data from those services. In any case, creative relationships like these might provide alternative sources of revenue to providers seeking to implement EHRs.

CONCLUSION

The American health care system has already benefitted from and will continue to benefit from the efficiencies and more intricate

137. *Id.* at 79203.

services provided by EHRs. In order for EHRs to reach their full potential, they must be interoperable among different provider systems, and most if not all providers must adopt such a system. Significant barriers to wider adoption of EHRs remain, the most troublesome of which are the capital requirements of implementation and the legal barriers preventing the creation of economic relationships to alleviate those burdens.

This note has presented several solutions that have the potential to promote greater adoption of EHRs by addressing the problems presented by the Stark Law, Anti-Kickback Statute, their exception and safe harbor provisions for EHRs, and the perceived problems created by antitrust laws as applied to the health care industry. The solutions mentioned above would serve to temporarily address these legal barriers, but cannot alone enable adoption of EHRs at the desired rate. Congress, regulators, providers, vendors, and patients must work together to develop a more comprehensive strategy to implementation. To improve the current framework, dissonances between the laws as applied to the health care system and the overall goals of that system must be reconciled.

In order to facilitate wider adoption of EHRs that will improve patient outcomes and health system efficiencies, new legislation must be created that is consistent with health care goals, or the current legislation must be adjusted to promote rather than prevent wider EHR adoption. Such a large scale change in the current system will take the support and activism of government agencies, providers like Partners, vendors like Epic, and patients.

With activism from individuals like those rallying in Vermont and Oregon and further steps by agencies such as HHS, OIG, DOJ, and FTC to promote beneficial relationships that will promote wider adoption of EHRs, the American health care system is moving toward a system that provides higher quality care to a greater number of Americans. The support of a legal system that is adjusted to work in cooperation with health care goals will help move the system in that direction by facilitating wider adoption of EHRs and other beneficial HIT as it is developed. Adjusting the legal framework will take hard work, creativity, and compromise on the part of legislators, and reevaluation of goals and policies on the part of government agencies. The results, a more efficient health care system, higher quality of care, and better health outcomes, will be well worth it, and will serve as a fantastic transition into the next epoch in the saga of the American health care system.