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CHARTING A NEW COURSE: PRACTICAL CONSIDERATIONS FOR IMPLEMENTING AN ELECTRONIC HEALTH RECORDS SYSTEM

Roy H. Wyman & Amanda L. Kutz***

To a startling extent, physicians today document their work in much the same way that physicians did in the nineteenth century.¹ Often, those unfamiliar with the United States's healthcare system and physician practices will assume that all physicians and hospitals have electronic health record ("EHR") systems that seamlessly share data as in other industries. The healthcare industry, however, spends a meager amount on information technology ("IT") compared to other industries. For example, the industry, as a whole, spends approximately two percent of gross revenues on IT compared with other industries that spend upwards of ten percent.²

The current environment for health information technology ("HIT"), however, is changing rapidly, and the current methods of creating and maintaining health records will not continue.³ The space

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1. Cf. BRIAN RAYMOND & CYNTHIA DOLD, KAISER PERMANENTE INST. FOR HEALTH POLICY, CLINICAL INFORMATION SYSTEMS: ACHIEVING THE VISION 1 (2002), available at http://www.kpihp.org/publications/docs/clinical_information.pdf.

2. *Id.* at 13.

3. See *id.* at 1.

and expense of storing physical records are two obvious concerns, but more importantly the lack of convenience and medical errors associated with handling paper will ultimately require a new way of doing business.⁴ Common sense, if nothing else, suggests that the current process of hand writing records and prescriptions, transcribing, copying, and sending facsimiles cannot and should not survive the IT age. Most estimates place the potential cost savings from the current HIT environment at between seventy-eight and eighty billion dollars *each year*.⁵ Unfortunately, at present there are numerous barriers to the implementation of EHR systems. The most basic is that many systems do not function properly—up to thirty percent of EHR installations fail.⁶

What is true for many aspects of life is also true for HIT—timing is everything. When a practice is ready to move forward with an EHR system, the potential benefits are numerous, from capturing potential clinical and billing mistakes to lessening the need for additional personnel and the prompt sharing of information with other providers.⁷ Attempting to install an EHR system before a practice, or any provider, is ready, however, can lead to disaster, as was discovered at Cedars-Sinai Medical Center when it was forced to shelve its three-month-old, thirty-four million dollar computer system.⁸ This Article explores the legal issues and practical considerations that a practice should be aware of before making the leap to an EHR system.

II. THE STARK LAW AND THE ANTI-KICKBACK STATUTE

The Bush Administration called for the national implementation of EHR systems by 2014.⁹ In response, the United States Department of Health and Human Services (“HHS”) has published an exception to the federal physician self-referral law, commonly known as the Stark Law,¹⁰

4. *See id.*

5. FEDERICO GIROSI ET AL., EXTRAPOLATING EVIDENCE OF HEALTH INFORMATION TECHNOLOGY SAVINGS AND COSTS xii, 65 (2005); Jon Walker et al., *The Value of Health Care Information Exchange and Interoperability*, HEALTH AFFAIRS, Jan. 19, 2005, at 16.

6. Ceci Connolly, *Cedars-Sinai Doctors Cling to Pen and Paper*, WASH. POST, Mar. 21, 2005, at A1 (quoting Interview with David J. Brailer, Nat’l Coordinator for Health Info. Tech., Dep’t of Health & Human Servs.).

7. *Id.*

8. *Id.*

9. Exec. Order No. 13,335, 69 Fed. Reg. 24054 (Apr. 27, 2004); DEP’T OF HEALTH & HUMAN SERVS., THE ONC-COORDINATED FEDERAL HEALTH IT STRATEGIC PLAN: 2008–2012 iii, 1 (2008).

10. Pub. L. No. 101-239, 103 Stat. 2106 (codified as amended at 42 U.S.C. § 1395nn (2000 & Supp. V

and a safe harbor provision under the Anti-Kickback Statute¹¹ to allow certain entities to provide non-monetary assistance to physician groups in order to promote the adoption of EHR systems.¹²

The EHR exception under the Stark Law and safe harbor provision under the Anti-Kickback Statute are nearly identical.¹³ In an effort to foster the implementation of electronic medical records by 2014, only the safe harbor statute has an expiration date.¹⁴ For practices considering the adoption of an EHR system donated by another health care entity in the next couple of years, it is important to ensure the system meets the requirements under both the exception and safe harbor provision to limit liability under the Stark Law and the Anti-Kickback Statute.

Physician groups should be aware of the basic prohibitions under the Stark Law and the Anti-Kickback Statute in order to fully understand the exception and safe harbor for EHR systems. The Stark Law prohibits a physician from referring a patient to an entity for certain designated health services payable by Medicare or Medicaid if the physician, or his or her immediate family member, has a financial relationship with the entity, unless an exception applies.¹⁵ The Stark Law is a civil statute with strict liability, meaning that no intent to violate the law is required.¹⁶ In order to protect common business relationships, the statute and federal regulations provide exceptions to the Stark Law.¹⁷ Practices must be careful to meet each requirement in an exception in order to avoid a Stark Law violation.

The Anti-Kickback Statute prohibits entities from knowingly and willingly offering, paying, soliciting, or receiving remuneration in order to induce or reward the referral of business reimbursable by a federal health care program.¹⁸ The Anti-Kickback Statute is a criminal statute and requires an intent to violate the law.¹⁹ Like the Stark Law, statutory and regulatory safe harbor provisions protect common business

2006)).

11. Pub. L. No. 92-603, 86 Stat. 1329 (codified as amended at 42 U.S.C. § 1320a-7b(b) (2000)).

12. 42 C.F.R. §§ 411.351, 1001.952(y) (2007).

13. Compare 42 C.F.R. § 411.351, with § 1001.952(y).

14. 42 C.F.R. § 1001.952(y)(13). The safe harbor provision expires on December 13, 2013. *Id.*

15. 42 U.S.C. § 1395nn(a) (2000).

16. *Id.* § 1395nn(g)(3)-(4).

17. *Id.* § 1395nn(b)-(e) (2000 & Supp. V 2006); 42 C.F.R. § 411.353(e)-(f).

18. 42 U.S.C. § 1320a-7b (2000).

19. *Id.*; see also *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

relationships.²⁰ However, complying with a safe harbor provision is not mandatory.²¹ An arrangement that is not in compliance with a safe harbor provision may not necessarily violate the Anti-Kickback Statute and is subject to a case-by-case review.²²

Under both the Stark exception and Anti-Kickback Statute safe harbor provision, EHRs are defined broadly to include any patient information in a computer processable form that is used for clinical diagnosis and treatment.²³ Federal regulations permit donations of software, IT, and training services that are necessary and used predominantly to create, maintain, transmit, or receive EHRs.²⁴ Donated software must be interoperable, meaning that data can be communicated and exchanged accurately, effectively, and securely with different IT systems in a way that preserves the clinical and operational meaning of the data.²⁵ Software will be considered interoperable if it has been certified by a body recognized by the Secretary of HHS no more than twelve months prior to a practice's receipt of the donated software.²⁶ Recognized by HHS, the Certification Commission for Health Information Technology ("CCHIT") is a voluntary, private-sector organization established to develop certification standards.²⁷

Once the EHR software is received, a practice cannot take any actions to limit or restrict the use, compatibility, or interoperability of the system with other EHR systems.²⁸ The practice also cannot require the receipt of a donated EHR system as a condition of doing business with the donor.²⁹ In addition, a practice cannot receive donated items or services that it already has available in its office.³⁰ The exception also requires the practice to pay fifteen percent of the donor's cost for

20. 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952 (2007).

21. OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS (1999), available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>.

22. *Id.*

23. 42 C.F.R. §§ 411.351, 1001.952(y).

24. *Id.* §§ 411.351, 1001.952(y) (The Stark exception and Anti-Kickback Statute safe harbor provision do not prohibit the use of donated software, IT, and training services for other uses. They only require the predominate uses to be for the transmission, maintenance, and creation of EHRs.).

25. *Id.* § 411.351.

26. *Id.* §§ 411.351, 1001.952(y).

27. CCHIT: Certification Commission for Healthcare Information Technology, About, <http://www.cchit.org/about/index.asp> (last visited Dec. 27, 2008). The role of CCHIT may change under the economic stimulus signed into law by President Obama on February 17, 2009. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

28. 42 C.F.R. §§ 411.357(w), 1001.952(y).

29. *Id.* §§ 411.357(w), 1001.952(y).

30. *Id.* §§ 411.357(w), 1001.952(y).

the donated items and services.³¹ The donation must be documented in a written agreement and signed by the parties, describing all donated items and services the practice is to receive from the donor.³²

If the cost of implementing an EHR system is a barrier for the practice, a system donated from a hospital or other health care entity may make the transition more feasible. Meeting the Stark exception and Anti-Kickback Statute safe harbor provision, however, is paramount and should be carefully reviewed by legal counsel before a practice enters into an agreement for a donated EHR system. In addition, the practice should balance its cost considerations with the other practical considerations explored below. There is no such thing as a “free lunch,” and while a donated EHR system may be more economically feasible, the practice may lose out on important features that give the system significant practical value.

III. PRACTICAL CONSIDERATIONS

Determining whether a practice is ready and making the right decisions for implementing an EHR system can be the difference between helping a practice grow and wasting money on a boondoggle. On the positive side, providing better care with less waste and fewer errors is an unadulterated good. On the negative side, paying more than a practice can afford for a system that does not work, or does not fit within the practice itself, is nothing more than a waste. A significant barrier to the implementation of EHR systems is that much of the benefit of the system—fewer medical errors and easier handling of claims—accrues to insurance companies rather than to physician practices. For the most part, however, practices have not benefited from EHRs in the form of higher reimbursement or reduced costs of malpractice coverage.³³ Before leaping into the purchase of an EHR system, physicians therefore should consider whether their practices are ready. They should also consider how best to reduce the risk of a system that does not work properly and understand their options in the event of the worst-case scenario—large amounts of money spent and no functional system.

Installation of an EHR system can be successful. Making the system

31. *Id.* §§ 411.357(w), 1001.952(y).

32. *Id.* §§ 411.357(w), 1001.952(y).

33. Pamela Lewis Dolan, *Insurer Finds EMRs Won't Pay Off for Its Doctors*, AM. MED. NEWS, Mar. 10, 2008, at 1.

work for a practice, however, requires a great deal of thinking and planning ahead. The following are suggestions for what a practice should do and the questions a practice should ask before making the leap.

Leadership is everything during major changes. In order to have a successful integration of an EHR system, a practice must obtain not just the consent but the enthusiasm of physicians and staff. Leaders within a practice will often decide what they want, when they want it, and how they want it before bringing others into the process. Early buy-in, however, is crucial to making a system work. As such, leadership should start a dialogue at the very beginning of the process to talk to other physicians and staff about how their jobs could be made better and how efficiencies could be obtained. Knowing what personnel want and expect, as well as shaping those desires and expectations, is a crucial part of leadership, particularly with regard to the adoption of IT changes.

Of course, the yes-or-no issue of whether to bring in EHR is more straightforward than determining which system to obtain. Approximately 270 EHR vendors offer their products, and no one vendor appears dominant across all specialties. The suitability of a particular type of system often depends on the specialty of the practice.³⁴ As such, speaking with various vendors and finding out the options may not actually be the best approach. Instead, practices should ask what applications best fit the particular practice. For example, how important is e-prescribing? If it is important, what systems do the local pharmacies use, and which systems can communicate with them? How important is it that other systems be integrated into the clinical systems? This list of various applications can help determine the most suitable EHR system.

Once a practice has decided that implementing an EHR system makes sense and has determined which applications are the most important, it also should consider what hardware is most likely to be used. Are the physicians in the practice most comfortable with personal computers, personal digital assistants (“PDAs”), or tablet displays? Is there hardware that will be most usable and comfortable for all of the physicians? If there are a minority of physicians who feel strongly, and differently, about hardware—or who are doubtful about the whole concept—is it possible to get them involved early and allow them to feel that they are a part of the decision-making process, thus encouraging them to be involved in the solution adopted?

34. Ken Terry, *Exclusive Survey: Doctors and EHRs*, MED. ECON., Jan. 21, 2005, at 72.

Once a practice has done some of the above preliminary work, it is time to begin looking at particular offerings in the market. In all likelihood, a practice will not find the perfect system, designed specifically with that practice in mind, which provides end-to-end integration from new patient registration through clinical records, e-prescribing, and billing for all services provided. How close the practice can come to that ultimate system, however, very much depends on the particulars of a system and the budget. Many of the questions that should be posed to vendors will be brought to light by the above steps. Examples of these questions include what type of hardware is compatible and what applications the software will provide.

Making sure that the system is solid, with robust privacy and security protections as well as interoperability, is tantamount. Even if the physician group does not want to accept a donated EHR system, any system worthy of significant consideration should be CCHIT certified.³⁵ This certification assures that the program has been reviewed and meets certain criteria, including the ability to send and refill prescriptions electronically, to receive laboratory results in a standard format, to ensure appropriate drug interaction checking, to perform thorough patient reporting and clinical management, and to provide strong security protections for patient data.³⁶

In addition to ensuring that the EHR system will work and work well, physicians also should ask some fairly sensitive questions and conduct background checks on the financial viability and reliability of the vendor. The best system in the world will quickly be of no use if the service provider is stuck in bankruptcy, dissolved, or does not feel obligated to answer questions or fix bugs. Decision makers also should visit other practices within the same subspecialty that installed the software in order to see how it works.

Of course, finding the right system is only half of the equation. Cost is the other half, and while we all may want that Lamborghini, some practices will have to stay within a Hyundai budget. Determining the total cost of a system, however, may not be as simple as the software and hardware prices. Two other considerations may lower the actual costs of an EHR system. First, certain systems may save money in other areas, particularly personnel costs relating to file handling. While some have believed that the reduction of errors would pay for the

35. 42 C.F.R. § 1001.952(y) (2007).

36. *See id.*

system, overall cost savings are slow to accumulate.³⁷ It is generally estimated that it takes five to six years for an EHR system to recoup its cost in an office-based practice.³⁸ Nonetheless, certain systems may save more money than others, particularly where they allow for less labor-intensive chart handling and/or transcribing.³⁹ A second potential savings is found in attempts to obtain reimbursement from another entity. As discussed above, relatively recent changes in regulations dealing with the Anti-Kickback Statute, Stark Law, and tax exemption allow certain entities, such as hospitals, to pay for at least a portion of the cost for a physician practice to purchase an EHR system.⁴⁰ Additional assistance may also arrive under the auspices of the economic stimulus package which President Obama signed into law on February 17, 2009.⁴¹

IV. CONCLUSION

An EHR system can help a practice save time, function more efficiently, and improve patient safety. As the world becomes more electronically integrated, deciding to implement an EHR system may be a no-brainer. Determining which EHR system to implement can be more daunting. Physician practices should first evaluate the expectations of the group from an EHR system and how the group expects to use the system in the future. If a practice wants to take advantage of the Stark exception and Anti-Kickback safe harbor provision for EHR systems, legal counsel should be consulted to ensure each requirement of the exception is met. No practice wants to pay for an EHR system—whether it is fifteen or one hundred percent of the total cost—that ends up not being successful. By evaluating expectations and legal constraints beforehand, a practice should be able to implement an EHR system that will save time and money, as well as improve patient safety, for years to come.

37. Dolan, *supra* note 33.

38. *Id.*

39. Terry, *supra* note 34.

40. 42 C.F.R. § 1001.952(y) (2007).

41. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.