ELECTRONIC MEDICAL RECORDS

ELECTRONIC HEALTH RECORDS IMPLEMENTATION: WHAT HOSPITALS AND PHYSICIANS NEED TO KNOW TO COMPLY WITH RECENT HEALTH LAW REQUIREMENTS

*By Neville M. Bilimoria**

Introduction

Hospitals and physician groups have been clamoring this year over the various electronic medical record (EMR) or electronic health record (EHR) vendors vying to capture the healthcare market in the race to rollout electronic medical records. Technology for EHR has spiked, with more vendors offering EHR solutions for hospitals and physician groups than ever before. The question now for hospitals and physicians is how to implement the EHRs efficiently and how to comply with the ever-increasing government pronouncements concerning EHRs.

Make no mistake about it, an effective EHR implementation has a number of advantages, not the least of which is substantial cost savings for healthcare providers generally. But with EHRs come certain risks, risks involving healthcare fraud and abuse under the Stark law,[1] the federal anti-kickback statute,[2] and even privacy issues regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule[3] and Security Rule,[4] not to mention the potential adverse effect on nonprofit tax-exempt status for hospitals.[5] While the government does not want to stand in the way of healthcare progress and technology, it is important for hospitals and physicians to understand the various laws regarding EHRs that have recently been enacted or promulgated by the federal government. This article will attempt to wade through the regulations and present a bright picture for the use of EHRs in the future.

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1. 42 U.S.C. § 1395nn; regulations codified at 42 C.F.R. § 411.353.
2. 42 U.S.C. § 1320a-7b; regulations codified at 42 C.F.R. § 1001.952.
3. 45 C.F.R. Part 160 and 45 C.F.R. Part 164, subparts "A" and "E."
4. 45 C.F.R. Part 160 and 45 C.F.R. Part 164, subparts "A" and "C.".
5. 26 U.S.C. § 501(c)(3).

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Technology has often been seen as the cornerstone to effective, quality healthcare in the United States.[6] New technological advances in medicines, new medical devices and telemedicine, for example, have all improved medicine in terms of quality, efficiency and even access to healthcare. EHRs are the latest use of new and innovative technologies in healthcare today.

It's no wonder. EHRs have a number of advantages, whether for a solo physician practice or a large hospital system. These enhancements include reduced costs for storage and copying of records, increased efficiency, better documentation, efficiency in the handling of records and quicker access to records. With EHR enhancements, healthcare providers can also increase efficiency and boost productivity, given the increased access and ease of access of medical records. Other enhancements include better warnings for physicians at the point of treatment for allergy reminders and patient prescription refill reminders. In all, EHRs have the unique potential not only to increase efficiency, but also to foster an increase in the quality of care for patients, all the while increasing revenue for healthcare providers by eliminating waste through easier access to patient information.

Recent federal government activity suggests that the government, like most providers, is also keen on advancing the latest EHR technology for the good of healthcare. In 2004, the Bush Administration set a goal of having an electronic health record for every American within 10 years.[7] In 2005, the Wired for Healthcare Quality Act (S. 1418)[8] was introduced and is currently pending as S. 1693[9] in Congress. The Act, if passed, would provide financial assistance to providers that develop compliant EHR systems that improve interoperability and privacy.

But the disadvantages to EHRs often serve to discourage wary healthcare providers from implementing new EHR technology. For example, seventy percent of all information technology (IT) projects fail, according to various surveys and studies.[10] For years, the IT industry has cited this seventy percent failure rate on implementation of IT systems, and

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6. Professor Gerald M. Hoffman, *Information Technology and the Future of Health Care*, SCHOOL OF COMMUNICATION AT NORTHWESTERN, PROFESSOR'S CORNER, April 2005, http://www.communication.northwestern.edu/mscstrategy/profcorner/InfoTech/.

7. Judith Lamont, *Electronic Medical Records: A Promising Prognosis*, KMWORLD, September 2005.

8. Wired for Health Care Quality Act , S. 1418, 109th Cong. (2005), *available at* http://www.govtrack.us/congress/bill.xpd?bill=S109-1418 (last visited Sept. 11, 2007).

9. Wired for Health Care Quality Act. S. 1693, 110th Cong. (2007), *available at* http://www.govtrack.us/congress/bill.xpd?bill=S110-1693 (last visited Sept. 11, 2007).

10. Alex Gheorghiu, *Why IT Projects Fail?*, PROJECT'S ANATOMY, January 14, 2006, http://www.projectsanatomy.com/?p=6; Sharon Gaudin, *Study: Many Major IT Projects Still Fail*, DATAMATION, June 16, 2003, http://itmanagement.earthweb.com/it_res/article.php/2222391.

while IT specialists claim the failure rate is improving or not that high,[11] most agree that failure of new IT systems is often inevitable and can lead to litigation.[12] Couple failure rates with the growing public concern about privacy and breaches of security in healthcare,[13] many providers spend sleepless nights wondering how a new EHR system can maintain privacy and security for patients. Earlier this year, for example, some patients of a Pittsburgh, Pennsylvania, hospital had their personal information, social security numbers and even x-rays posted on the web without their permission.[14] Indeed, one report described a new EHR system for Kaiser Foundation Health Plan/Hospitals as "nothing short of an IT project gone awry," with multiple system failures and hundreds of technical problems with the system, some of which affected patient care.[15] Lastly, some physicians have resisted change to EHRs from paper records, often resulting in disruptive behavior over the frustration with implementing an EHR system in the workplace.[16]

The disadvantages and horror stories aside, the race for better technology and improved patient care still has providers asking for advice regarding a hospital's ability to provide financial assistance to physicians with respect to EHRs and the applicable regulatory restrictions on hospital/physician IT arrangements. Hospital/physician EHR arrangements are generally governed by the federal Stark law and regulations and the federal anti-kickback fraud and abuse laws and regulations, as well as HIPAA privacy and security, and federal tax-exemption provisions. This article provides a legal and regulatory overview of the federal provisions governing hospital/physician relationships and specific requirements of federal law relating to hospital/physician technology arrangements for implementing an effective EHR system.

Fraud and Abuse Legal and Regulatory Considerations

On August 8, 2006, the Centers for Medicare & Medicaid Services (CMS) promulgated two new exceptions to the Stark law prohibitions on physician self-referrals to create "a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technol-

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11. Robert L. Glass, The *Standish Report: Does it really describe a software crisis?* Communications of the ACM, August 2006.

12. Michael J. Silverman, *Where Did We Go Wrong? Litigating A Failed Systems Development Contract, Duane Morris LLP*, 2002, http://www.duanemorris.com/site/static/silvermansys devproj.pdf.

13. Cinda Becker, Technical Difficulties; *Recent Health IT Security Breaches Are Unlikely to Improve the Ppublic Perception about the Safety of Personal Data*, Modern Healthcare, February 20, 2006.

14. Steve Twedt, *UPMC Patients' Personal Data Left on Web*, Pittsburgh Post-Gazette, April 12, 2007.

15. Linda Rosencrance, *Problems Abound for Kaiser E-health Records Management System*, Computerworld, November 13, 2006.

16. *Reporter's Notebook, EHRs put some docs on edge*, Modern Healthcare, May 16, 2007.

ogy and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records."[17] While CMS promulgated these new exceptions to the Stark law to facilitate healthcare's adoption of technology for interoperable medical records and prescribing transactions,[18] simultaneously, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued two new similar safe harbors under the anti-kickback statute for the similar purpose of creating "a separate new safe harbor for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records."[19]

What many physicians fail to realize is that the Stark exceptions and anti-kickback safe harbors offer a distinct opportunity for physicians to have their EHRs subsidized by hospitals. Indeed, hospitals, too, fail to realize that the exceptions created by CMS and the OIG also allow hospitals to better implement EHR in their communities through physician office use. Therefore, physicians weary of the costs of implementing EHRs now have specific laws through these regulations to allow hospitals to subsidize EHR rollouts. This is a win-win for the American healthcare consumer: fostering the coordination and implementation of EHRs. The problem is, because these regulations are so new and somewhat complicated, hospitals and physicians have not availed themselves of these EHR-promoting regulations. An overview is provided below.

Stark Law and Exceptions

Stark is a Medicare billing and payment rule. Under Stark, a physician is prohibited from making a referral to an entity for the furnishing of designated health services (DHS) payable by Medicare if the physician or an immediate family member of the physician has a financial relationship with the entity, unless a regulatory exception to Stark applies to the financial relationship.[20] The new Stark exceptions for hospital/physician information technology arrangements permit DHS entities such as hospitals to furnish physicians with items or services of information technology.[21] The second Stark physician information technology exception applies to electronic prescribing standards.[22] The electronic prescription exception has many common elements to the electronic health records exception, which are discussed below.

17. 71 Fed. Reg. 45140 (August 8, 2006) (New Stark Law exceptions).
18. 71 Fed. Reg. 45140 (August 8, 2006).
19. 71 Fed. Reg. 45110 (August 8, 2006) (New anti-kickback safe harbors).
20. 42 U.S.C. §1395nn(a)(1); 42 C.F.R. §411.353(a).
21. 42 C.F.R. § 411.357(w).
22. 42 C.F.R. § 411.357(v).

Anti-Kickback Statute and Safe Harbors

OIG promulgated safe harbors under the anti-kickback statute that are similar to the Stark exceptions created by CMS.[23] The Stark exceptions are narrower than the anti-kickback safe harbors because the Stark exceptions apply only to physicians and the protections are only for transactions between a physician and a provider of designated health services (DHS). Furthermore, it is important to note that all elements of the Stark exceptions must be met in order to gain protection from the Stark law. This is in contrast to the anti-kickback statute safe harbors, which are a voluntary, though not an exclusive, protection from violations of the statute.

The anti-kickback statute prohibits illegal remuneration paid to induce a patient referral. The law prohibits offering, paying, soliciting, or receiving kickbacks, bribes or rebates, in cash or in kind, directly or indirectly: 1) for referring patients covered by a federal healthcare program to providers in return for an item or service; or 2) buying, leasing, or ordering any item, service, or facility covered by a federal healthcare program.

The fear of providers is that if a hospital offers EHR to its physicians or select physician groups, this may be tantamount to a payment in exchange for physician referrals to the hospital prohibited by the anti-kickback statute. Indeed, the OIG has warned about the provision of free technology, such as computers or even fax machines, as implicating the anti-kickback prohibition.

The ban, however, on illegal remuneration does not apply when an arrangement meets the conditions of a fraud and abuse safe harbor. Each safe harbor has numerous conditions that must be met to come within the protection of the safe harbor. While failure to strictly comply with the conditions of a safe harbor does not mean that an arrangement is illegal, compliance with a safe harbor provides a comfort level for the parties. Two new safe harbors, like the two Stark exceptions, exist with respect to hospital/physician information technology arrangements that permit hospitals to provide physicians with information technology under certain conditions.[24] Stark's exceptions for electronic prescribing and health record systems are almost identical to the anti-kickback safe harbors. Under the anti-kickback safe harbors, an entity may donate items and services to physicians and non-physicians, while Stark exceptions apply only to physicians.

The New EHR Regulations

The OIG's anti-kickback statute safe harbor regulations and CMS' Stark exceptions regulations for EHR (collectively, HHS EHR Regulations) must be examined in detail when reviewing hospital/physician IT

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23. 71 Fed. Reg. 45110 (August 8, 2006) (New anti-kickback safe harbors).
24. 42 C.F.R. § 1001.952(x); 42 C.F.R. § 1001.952(y).

arrangements. The Stark regulatory EHR exception defines EHRs as: "A repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."[25] The EHRs exception is not restricted to technology only; instead, the standard for the technology is that it must be "necessary and used predominantly" to create, maintain and transmit or receive EHRs. The Stark exception does not extend to computer hardware.

"Necessary" is defined to mean that the physician does not already have the equivalent software or services. However, it does not preclude upgrades of items or services that enhance the functionality of the physician's existing technology, including upgrades that make software more user friendly or current, nor would it preclude items and services that result in standardization of systems among hospitals and physicians, provided that the standardization enhances the functionality of the EHRs system (and any donated software is interoperable).

The following are permissible examples of "software, information technology and training services necessary and used predominantly" for EHRs:

- Interface and translation software;
- Rights, licenses and intellectual property related to EHRs software;
- Connectivity services, including broadband and wireless Internet services;
- Clinical support and information services related to patient care (but not separate research or marketing support services);
- Maintenance services;
- Secure messaging (for example, permitting physicians to communicate with patients through electronic messaging); and
- Training and support services (such as access to help desk services).[26]

Software that meets the EHRs standard and that is also used for patient administration, scheduling functions, billing and clinical support will also qualify for the exception as long as it has an e-prescribing component or the ability to interface with the physician's existing e-prescribing system that meets the exception's interoperability requirements at the time of the donation. Other types of technology that would qualify for the Stark exception include:

- An EHR operating within an "Application Service Provider" model (a business model that provides computer-based services over the Internet); and

25. 71 Fed. Reg. 45110, 45169; 42 C.F.R. § 411.351.
26. 71 Fed. Reg. 45140, 45151-45152 (August 8, 2006).

- A patient portal software that enables patients to maintain online personal medical records, including scheduling functions.

However, CMS has indicated that the EHRs exception does not extend to the following:

- Hardware (and operating software that makes the hardware function);
- Storage devices;
- Software with core functionality other than EHRs (for example, human resources or payroll software);
- Items or services used by a physician primarily to conduct personal business or business unrelated to the physician's practice;
- Systems comprised solely or primarily of technology that is incidental to electronic prescribing and EHRs; and
- The provision of staff to physicians or their offices.

The Stark EHR exception also requires the software to be interoperable at the time of donation. Software will be deemed to be interoperable if a certifying body recognized by the Secretary of HHS has certified the software no more than twelve months prior to the date it is provided to the physician. Software must contain electronic prescribing capability (either in an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system) that complies with the applicable standards under Medicare Part D at the time the items and services are donated.

Once a hospital selects its software, how does it roll it out to the physicians on its medical staff? For purposes of the Stark EHR exception, hospitals may select physicians for receipt of EHRs technology using criteria that do not directly take into account the volume or value of referrals from the physician or other business generated between the parties. The final rule sets forth seven criteria that hospitals or other eligible entities may use to select physicians for receipt of EHRs technology. The seven criteria are as follows:

1. Total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program).
2. The size of the physician's medical practice (for example, total patients, total patient encounters or total relative value units).
3. Total number of hours that the physician practices medicine.
4. Physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor).
5. Whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff.
6. Level of uncompensated care provided by the physician.

7. The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.[27]

Physicians and physician groups may be surprised to learn that there is no cap on the value of the donation of EHR software from a hospital. Physicians, however, must pay fifteen percent of the hospital's costs before receipt of the donated technology. The hospital (or any party related to the hospital) may not fund any portion of this contribution. This includes any upgrades and training services. The donor or hospital cannot shift the cost of the donated systems to Medicare. Finally, and importantly, the Stark EHR exception requires a written agreement between the parties, including the hospital's cost and the amount of the physician's cost sharing, which must be paid before the items or services can qualify for the exception.

Finally, it is important to note that the two Stark exceptions (for electronic prescribing and for EHRs technology and training services) have a number of common elements:

- Donors may not condition their donations on doing business with the donee and may not take into account the volume or value of referrals or other business generated by the physician.
- Physicians must be able to use the technology for any patient, not just those associated with the entity making the donation.
- The agreement to donate must be in writing, signed by both parties, describe all the items and services the physician (or family members) will receive from the donor and document the donor's cost. This comprehensive description may be accomplished by a cross-reference to a master list of agreements between the donor and donee.
- The donor must not have actual knowledge of and must not act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.
- Both exceptions require the technology to be interoperable with specified standards in effect at the time of the donation.
- The donor (or any agent of the donor) must not take steps to disable the interoperability of any technology or otherwise impose barriers to the compatibility of the donated technology with other technology.[28]

These same common elements in the Stark EHR exceptions apply equally to the corresponding anti-kickback safe harbors.[29]

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27. 42 C.F.R. § 411.357(w)(6); 42 C.F.R. § 1001.952(y)(5).

28. A *Guide To Complying With Stark Physician Self-Referral Rules*, (Atlantic Information Services, Inc.), June 2007.

29. 42 C.F.R. § 1001.952(x); 42 C.F.R. § 1001.952(y).

IRS Considerations for Tax-Exempt Entities

In addition to complying with the HHS EHR Regulations, providers increasingly must be wary of the effect of EHR rollouts on the tax-exempt status of nonprofit healthcare entities. For instance, in order to qualify for exemption from federal income tax as an organization described under Internal Revenue Code § 501(c)(3), no part of the organization's net earnings may inure to the benefit of private individuals, often referred to as "insiders" (also called the prohibition against "Private Inurement"), and the exempt organization must be operated for public benefit rather than for the benefit of any private interest. Hospitals, therefore, may fear that providing EHRs to physicians, even though compliant with the new Stark and anti-kickback rules, nonetheless may jeopardize tax-exempt status due to the ban against private inurement.

But on May 11, 2007, the Internal Revenue Service (IRS) offered much-needed guidance in a field memorandum (Memorandum) specific to IT arrangements between hospitals and physicians.[30] The Memorandum quelled the fears of hospital executives, stating that the implementation of IT financial assistance to physicians would not be viewed by the IRS as private benefit or private inurement in violation of § 501(c)(3). However, in providing this needed exception, the IRS imposes additional requirements for hospitals seeking to avoid private benefit or private inurement penalties:

- Hospitals must enter into health IT subsidy agreements with physicians receiving IT items and services;
- Hospitals and physicians must comply with rules promulgated by HHS;
- The health IT subsidy agreements provide that, to the extent permitted by law, the hospital may access all of the electronic medical records created by a physician using the health IT items and services subsidized by the hospital;
- The hospital ensures that the health IT items and services are available to all of its medical staff physicians; and
- The hospital provides the same level of subsidy to all of its medical staff physicians or varies the level of subsidy by applying criteria related to meeting the healthcare needs of the community.[31]

Many physicians do not understand hospital tax-exemption compliance issues in the detail provided here. Hospitals will have to be diligent in making sure that EHRs are made available to all medical staff physicians, but do not necessarily have to provide the same subsidies to each physician on their medical staff. For example, a hospital can justify a larger subsidy or early rollout of its EHR system to a particular physician

30. *IRS to allow NFPs to give financial aid for EHRs*, Modern Healthcare, May 11, 2007.

31. Lois Lerner, Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records, IRS Memorandum, May 11, 2007, http://www.irs.gov/pub/irs-tege/ehrdirective.pdf.

group if it can justify a greater benefit to the community pursuant to the § 501(c)(3) community-benefit standard. Other physicians may have the ability to partake in a hospital EHR rollout, but may be required by the hospital to pay fair market value for the EHR implementation.[32]

HIPAA Concerns

Indeed, one cannot talk about EHRs without speaking of concomitant concerns with the HIPAA Privacy and Security Rules. While both hospitals and physicians are covered entities subject to the privacy and security regulations under HIPAA, careful attention must be paid to making sure EHR software vendors install adequate safeguards to protect the privacy and security of information.[33] Furthermore, additional policies and procedures for maintaining privacy and security are certainly in order, given the ease of access to protected health information (PHI) fostered by EHR technology. Just because EHRs foster wide-open access between providers does not mean that every instance of a PHI disclosure through EHRs is allowable under the HIPAA Privacy and Security Rules. The unfettered access that is such an advantage with EHR systems may also prove to extend substantial liability to unwary providers under HIPAA.

Other Liability Concerns

While a novel idea, questions have arisen as to whether eventual increased use of EHRs by providers will affect the standard of care if a physician on a hospital's medical staff does not avail himself or herself of the many advantages of an EHR system, or if a physician does not adopt an EHR system in her/his practice. Some believe that EHR systems will not affect the standard of care because physicians currently do not have a widespread obligation to check a patient's prior medical records.[34] However, providers should understand that it is not an outlandish argument for a plaintiff's attorney to point out, in a medical malpractice case, the ease with which a physician could access a patient's record through EHR to better diagnose a particular patient. Will EHRs then impose upon physicians the added burden of checking prior medical records of patients because of the ease of use? Only time will tell.

Conclusion

In all, the new safe harbors and HHS exceptions outlined above, combined with the new IRS pronouncements, are aimed at protecting

32. *Some cautious of additions to IRS health IT ruling*, MODERN HEALTHCARE, May 17, 2007.

33. Michael Silverman, *Privacy Challenges*, Inside the Minds: Privacy Matters, (Aspatore, Inc., 2002), http://www.duanemorris.com/articles/static/SilvermanBookExcerpt.pdf.

34. Edward F. Shay, *Legal Barriers to Electronic Health Records*, PHYSICIAN'S NEWS DIGEST, May 2005.

arrangements in which hospitals, group practices and prescription drug plans (collectively known as donors) give items at steeply discounted prices to providers in order to facilitate healthcare's adoption of technology for interoperative medical records and prescribing transactions. Hospitals entering into IT arrangements with physicians can work collaboratively with physicians to assure that patients, hospitals and physicians receive the benefits of EHRs without the fear of violating Stark or the anti-kickback laws as long as the IT arrangements comply with the specific requirements of the Stark exception and the intent of the safe harbors. The IRS and HIPAA issues will continue to evolve. Once an arrangement is structured, after all the headaches, there is one more: Do not forget to focus on the actual EHR contract with the IT software vendor![35]

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35. Michael J. Silverman & Sandra A. Jeskie, *Key Elements of an E-Commerce Integration Project Contract*, *Duane Morris LLP*, 2001, http://www.duanemorris.com/site/static/silvermancontractlit.pdf.