



Health Information Technology

Practice Management Services

Stark Law Exemptions and Electronic Health Records

"What we obtain too cheaply, we esteem too lightly; 'Tis dearness only that gives everything its value." — Thomas Paine

As physicians of modern medicine are all too aware, the availability of high tech devices and services can weave a very tangled web. The use of health information technology (HIT) is becoming more common as physicians continually focus on quality care for their patients and the demands of maintaining good business practices. On one hand, this technology has provided physicians ways to increase efficiency and accuracy; control expenses; access information; and establish safer, more patient-friendly services. On the other hand, the initial expense and yearly cost of the technological devices and services can be very intimidating.

Formally known as Section 1877 of the Social Security Act, the "Stark law" prohibits physicians from referring Medicare or Medicaid patients for certain designated health services to an entity with which the physician has a financial relationship, unless an exception applies. Additionally, in 1972, Congress passed the antikickback statute that made it illegal for providers, including physicians, to knowingly and willfully accept any remuneration in return for generating Medicare, Medicaid, or other federal health care program business. Likewise, a physician cannot offer anything of value to induce federal health care program business or the utilization of benefits.

Both the Stark and the antikickback laws have specific exceptions and safe harbors. In August 2006, the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services' Office of the Inspector General announced expanded exceptions to the Stark regulations and additional safe harbors in the antikickback laws that are expected to encourage the adoption of electronic prescribing and electronic health record (EHR) technology. These new provisions were borne of President George W. Bush's April 2004 call for the majority of Americans to have interoperable electronic medical records (EMRs) within 10 years.

The new regulations permit hospitals to offer computer health information systems (or access thereto) to ambulatory medical practices, potentially at a significantly greater discount than the practices could obtain if they pursued the systems individually. While this option may be a key to faster adoption — and faster and improved interoperability — faster may not be better. Although the inevitable attraction of an inexpensive EHR offering through a local hospital may

hold promise in the short term, in the long term the risk exists that physicians may lose control in the practice of medicine and provision of patient care, interoperability notwithstanding.

A recent survey* indicated that 72 percent of physicians not currently using an EMR are willing to accept help from their hospital. It is important that physicians be informed and well-prepared prior to embarking along the path of health information technology. Before accepting a technology donation from a health services organization, one should consider the implications of the gift.

According to Joseph Perkinson, MD, a family practice physician in Victoria, TX, and a member of TMA's Ad Hoc Committee on Health Information Technology, physicians need to be wary of rushing into an offer that seems too good to be true. He states, "Having been an early adopter in the ambulatory HIT arena, I wonder about the wisdom, in terms of practice independence, of tying practice and hospital so intimately in this fashion. It seems clear to me that the more established hospital systems with broader resources are going to use their buying power to coax practices to their HIT system, building that subtle, but no less pervasive, dependency on them. Will this be good for privately practicing physicians in five to 10 years? And, what if the hospital switches their HIT system? What does the practice do then for maintenance and data management and/or transfer? Renegotiate to some ridiculously expensive arrangement? I do not think, under the Stark relaxation, that physicians will realize the cost of the investment, and therefore they will not value it as much."

It is important that physicians understand both the reach and limitations of these new regulations. To meet requirements, any donated system must be "necessary and used predominately" to create, maintain, transmit, or receive electronic health records. Although not necessarily disadvantages, the following are some key considerations and exceptions to the regulations that physicians need to address prior to accepting a donated system. (Note: These bullets address only the electronic health records regulations and *not* the electronic prescribing provisions.)

Inclusions

- Software packages may include practice management functionality (e.g., scheduling, billing, and reporting) only if the functions already are integrated with the donated EMR system.
- The donated system must be interoperable, which means the software must have the ability to communicate and exchange data accurately, effectively, securely, and consistently with different technology systems. Certification by the Certification Commission for Health Information Technology assures interoperability.
- The EMR license is included in the donation.
- Training on the software, software maintenance, and helpdesk services are included.
- Connectivity and interfaces *may* be included (but are not required).
- Software *must* include an e-prescribing component.
- The software and training services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

*Harris Interactive, a Rochester, N.Y.-based polling firm, conducted the survey, commissioned by McKesson Corp., San Francisco

Exclusions

- Hardware costs are excluded.
- The donation of staff and staff time for office operations, scanning, abstraction, or transfer of paper records to electronic format is not permitted.

Considerations

- Most EMRs are available in one of two ways — as a unified, community patient record or as a brokered architecture within the individual practices. Both forms come with their own implications. The primary distinction between the two models is the storage location of patient and practice information. When considering a donated system, one should deliberate on who actually may own the records entered into a unified system.
- What assurance does the practice have that the services the donor hospital provides will at least equal services the vendor would provide?
- Does the physician admit patients to more than one health system? The physician practice may have to pay for interfaces with other organizations that compete with the donor hospital.
- Neither the physician nor anyone else in the practice may accept donated items or services as a condition of doing business with the donor hospital.
- The exceptions have a limited time frame. The transfer of the items and services must occur on or before the regulation's sunset date of Dec. 31, 2013.

Costs

- The physician practice must pay at least 15 percent of the cost of the technology.
- The donor hospital may not finance the physician's payment or the loan funds the physician uses to pay for the items and services.

Benefits

- The package must include the e-prescribing component or be able to interface with it.
- The donated technology must be certified by the Certification Commission for Health Information Technology. This process will become more comprehensive for vendors as requirements for certification become more stringent.
- The donated technology must be interoperable as proven by the certification process.
- The donor hospital would not have the ability to turn off the interoperability component.
- The donor must provide the physician the items or services in a manner that does not take into account the physician's practice volume or value of referrals to the donor.
- The donor may not take any action to limit or restrict the items' or services' use or compatibility with other electronic prescribing or electronic health records systems.
- For items or services designed for use with any patient without regard to payer status, the donor can not restrict the physician's right or ability to use the items or services for any patient.

Questions and issues to consider — General

- If the donor hospital doesn't employ a third party to offer the donated services, what assurance does the practice have that the services the donor hospital provides will at least equal services the EMR vendor would provide?
- Does the physician admit patients to more than one health system? The physician practice may have to pay for interfaces with other organizations that compete with the donor hospital.
- If a practice already has an EMR system, can it receive a donation? This depends on what the donor is offering. The Stark exception and the antikickback safe harbor do not allow for the donation of equivalent software or services to a practice. However, this does not prevent the donation of upgrades or services that either enhance functionality or result in standardization among donors and physicians. The rules do not prevent the donation of outpatient EMR software to physicians who already have access to an inpatient-focused system so long as it is not equivalent technology.

Questions and issues to consider — Product

- What if the practice wants richer features or a more flexible software environment than the donor provides (one that it can configure uniquely to its particular needs)? For example, hospitals may be slow to take upgrades that provide enhancements because of budget or manpower constraints.
- Is the donor system more suited for a large practice or for inpatient settings? Does the system have application in the solo practice?

Questions and issues to consider — Support and Service

- Will implementation support by the vendor and/or donor hospital be tailored to your practice? Implementation assistance will vary.
- The software and training services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records.
- What specific track record does the donor have in providing information technology services to physician practices?
- The donation of training and help-desk services is permitted.

Questions and issues to consider — Contracts

- The donor hospital and the physician recipient must sign a written agreement.
- The agreement should cover interfaces, testing, and provisions of upgrades.
- The agreement should include a fallback plan in the event relationship ends.
- The agreement should address response time guarantees, downtimes, and similar issues.
- The agreement should address data ownership issues. If the relationship is terminated, will the practice have access to its own data? How is data ownership defined in a shared EMR?
- The agreement should specify what is included with the donation and the costs for additional services such as interfaces, help-desk time, and training.
- If the relationship is terminated, will the practice have access to its own data? How is data ownership defined in a shared EMR?
- The agreement should address security and privacy issues.

Questions and issues to consider — Interfaces

- The donor *may* pay for the cost of developing interfaces but is not required to. Consider that the system's ambulatory component likely will make it *very easy* to order labs or x-rays at the associated hospital and probably not as easily at other facilities.

Questions and issues to consider — Data

- How will data be converted to/from the donated system?
- What if the hospital loses the practice's critical data?
- If the EMR is the unified, or shared, type, can practice management systems and accounts receivable data be kept separate?

Consider the following examples.

- **The physician practicing in a moderate-sized urban area dominated by two competing health systems.** A health system would not necessarily include an interface with the competing health system. A physician wishing a complete continuum of care for all patients in both health systems likely would have to pay for the development of an interface to the second hospital system or convince the other system to pay for such an interface.
- **The practice that has accepted a donated system but for whatever reason has to terminate the contract.** What are the costs of converting the data to a new EMR system? As indicated earlier, one may want to consider who has ownership of the data in the system and if the contract addresses that.
- **The practice that uses a particular practice management system (PMS) but is unwilling or unable to change to the PMS integrated with the donated EMR system.** To continue to use its old practice management system, the practice may have to pay for the development of an interface with that PMS. Does the license for the donated system allow for the use of customized interfaces?

In summary, be advised that while a technology donation may be ideal and highly beneficial for the recipient physician in some cases, any physician considering whether to accept a donation from a health system must be aware of all the implications and costs of doing so. Physicians are encouraged to enter into such agreements fully informed and only after weighing the advantages and disadvantages for their particular practice.

Resources:

- [CMS press release on physician self referral and antikickback statutes](#)
- [Letter from the Office of Inspector General](#) — Position on physician self-referral and the anti-kickback statutes
- [TMA Practice E-Tips on Legal Topics](#)
- [Technology readiness assessment](#) offered by TMA Practice Consulting
- [Technology information](#) and resources from the TMA Department of Health Information Technology
- [American Academy of Family Physicians' Stark FAQs](#)