



BY BRUCE D. ARMON

E-Possibilities

An electronic health record system may have just come within your reach. The federal government has issued guidelines and safe harbors for donating and receiving these systems.

THE E-REVOLUTION IS upon us. It affects us in our personal lives and our professional ventures. Physicians and medical practices constantly look for ways to stay up-to-date and e-connected. One of the most significant ways to enhance technology in practice management is by implementing an electronic health record (EHR) system.

Every physician has heard the praises of EHRs, but most smaller practices cannot afford the kind of capital expenditure it takes to purchase and implement an EHR system. Hospitals or health plans may have wanted to assist physician practices in this conversion

by 'donating' EHR software to the practice that would work with their own records. This would make the donor organizations' record-keeping more efficient and potentially help eliminate errors.

Unfortunately, such a gift risked violating the Stark and federal anti-kickback statutes.

In order to encourage the general use of EHRs, the federal government has recently finalized two new sets of regulations relating to e-prescribing and EHR arrangements. These regulations provide opportunities for physicians and medical practices to ride the e-wave and modernize their offices.

Trends and developments

As though practices needed another reason to make the conversion to EHR, the Medical Group Management Association recently released a study (*MGMA Performance and Practices of Successful Medical Groups: 2006 Report*) that included an interesting statistic regarding the staff cost per full-time-equivalent physician for multi-specialty groups with EHR versus paper medical records. Those groups that had fully integrated EHR systems spent approximately \$4,700 per FTE physician on medical records. Groups that relied on paper medical records—charts filed in cabinets—had a staff cost of over \$6,800 per FTE physician. Of course, there

are up-front costs accompanying these conversions, but long-term cost savings can be significant.

Federal and state governments have recognized the importance of EHRs. Last August, President Bush signed an executive order entitled, "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs." Beginning January 1, 2007, federal agencies that administer or sponsor a federal health-care program were directed to utilize, where available, health information technology systems that meet so-called interoperability standards, and to mandate agreements with health-care providers and health plans that acquire or up-

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grade health information technology systems to do so in a manner that meets recognized interoperability standards.

Safe harbors and Stark exceptions

In the same month as the President's order, the Department of Health and Human Services Office of Inspector General and the Centers for Medicare and Medicaid Services published final regulations relating to e-prescribing and EHR arrangements under the federal anti-kickback statute and the federal Stark statute. These new regulations took effect on October 10, 2006 and should guide hospitals that wish to donate EHR or e-prescribing software components and the physician practices which may receive those donations.

The federal anti-kickback statute mandates criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the federal health-care programs. The Stark statute prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies. These basic premises still apply when it comes to EHR software, but the new rules will help physicians and hospitals understand what is acceptable. The regulations use the term "electronic health record" or EHR, rather than "electronic medical record," even though many individuals use the terms interchangeably. The regulations specifically define an EHR 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."

The rules address five broad categories with respect to EHR: covered technology, standards with which the donated technology must comply, donors and recipients, selection of recipients, and value of protected technology.

Covered Technology. The regulations permit the donation of software necessary and used predominantly for EHR purposes. This includes creating, maintaining, and sending and receiving EHRs. The software must include an e-prescribing component. Training, maintenance and help-desk services are permitted. Hardware and storage devices are not included as covered technology.

Standards for Donated Technology.

EHR technology must be interoperable. Essentially, the EHR will not tie the recipient solely to the donor. According to the Stark regulations, interoperability means that at the time of the donation, the software is able to (1) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and (2) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

The notion of interoperability is an evolving one, and for software to qualify, it should be as interoperable as the prevailing state of technology permits. The Certification Commission for Healthcare

Information Technology (CCHIT) is a voluntary, private sector organization that certifies health information technology products. CCHIT has certified certain EHR products based on their functionality, interoperability, and security.

Donor and Recipients. Protected donors are individuals and entities that provide covered services and submit claims or requests for payment, either directly or through reassignment, to any federal health-care program or health plan. Protected recipients are individuals and entities engaged in the delivery of health care. Under the Stark exception, the only protected recipients are physicians because the statute focuses solely on physicians.

Selection of Recipients. A donor may not select recipients using any method that directly takes into account the volume or value of referrals from the recipient or other business generated between the parties. The regulations state that a determination will be deemed not to directly take into account the volume or value of referrals if any of the following conditions is met: The determination is based on the total number of prescriptions written by the recipient; the determination is based on the size of the recipient's medical practice; the determination is based on the total number of hours that the recipient practices medicine; or, the determination is based on the recipient's overall use of automated technology in her medical practice.

Value of Protected Technology.

Recipients must pay 15 percent of the donor's cost for the donated technolo-

gy before receipt of the items and services. In addition, the donor must not finance the recipient's payment directly, or loan funds to the recipient for payment of the technology. The cost-sharing requirements also apply to related services (in addition to the software) such as training, help-desk, and EHR maintenance.

The preamble to the Stark exception suggests that CMS will scrutinize the methods of cost allocation to be certain that no shifting of costs occurs that would provide an impermissible benefit to a physician.

The anti-kickback statute safe harbor and the Stark regulatory exception will sunset on December 31, 2013. The sunset date is consistent with President Bush's goal of widespread EHR adoption by 2014.

For physician recipients to consider

Everyone likes to get something for nothing, or in these instances, 15 percent of its cost. Physicians must be sure that they do not consider the receipt of the EHR software and related services as a condition of doing business with the donor.

Also, the regulations require that the technology the recipient receives from the donor not be duplicative of what the recipient already possesses.

CMS estimates that 10 percent of the approximately 609,000 physicians who provide Part B services to Medicare beneficiaries will adopt electronic prescribing and EHR technology each year until 2013.

Like most anti-kickback statute safe harbors and regulatory exceptions, the parties must memorialize the arrangement in writing. The agreement must be signed by the donor and recipient; specify the items and services being provided, the donor's

cost of those items and services, and the amount of the recipient's contribution; and cover all of the EHR items and services to be provided by the donor. Physician-recipients and their counsel should carefully review these "donation agreements" to ensure they conform to the regulatory requirements.

Federal and state governments and the private sector continue to rapidly move into new areas of e-technology. These two new sets of regulations should help physicians and their practices move forward in those efforts without having to shoulder the entire cost. If it has not yet occurred, your local hospital(s) are likely implementing new EHR initiatives. Keep looking for new EHR opportunities and be aware of the rules and regulations that govern them, to ensure your arrangement is in compliance. ■

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