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## **Electronic Health Record Offers: What's a Doctor to Do?**

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# Electronic Health Record Offers: What's a Doctor to Do?

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A hospital or pharmaceutical company offers to provide a physician with an electronic health record (EHR) software system for free. Can the physician accept this offer? If the physician refers patients to the donor hospital or pharmaceutical company, would this “donation” violate the federal Stark Law or Anti-Kickback Law or, in the case of New York-based doctors, the state’s Health Care Practitioner Referrals Act?

This question is being faced by many physicians today as they receive offers of donated EHR systems or electronic prescribing (EP) technology services. There is a growing trend in the healthcare industry to implement EHR systems

and electronic prescribing capabilities in the hope of making patient health information clearer and more easily shared among practitioners and hospitals or other healthcare providers, leading to fewer errors, less duplication of healthcare services, and ultimately, lower costs.

Federal government leaders also believe that EP and EHR systems will promote improved quality measures in patient care and the exchange of information between patients and public health agencies. To encourage adoption and use of EP and EHR technology, the federal government will be providing increased payments to physicians who use electronic prescribing for

Medicare patients and incentive payments of up to \$44,000 per eligible professional over a period of five years if the professional is a “meaningful” EHR user.<sup>1</sup> (See “Incentive Payments for EP.”)

If the physician refers patients to the donor hospital or pharmaceutical company, would this “donation” violate the federal Stark Law or Anti-Kickback Law?

Despite these financial incentives, however, many physicians have been slow to implement EHR and EP systems. Moreover, because of existing anti-kickback and anti-referral laws, it has been impossible for third-party health service providers to intervene and donate EP or EHR components to physicians because such donations might be viewed as inducements to refer patients to providers. However, the federal government has solved this problem and provided further incentives to adopt EP and EHR systems by adding two new exceptions to the Stark Law and the Anti-Kickback Law (AKL). Under certain conditions, these exceptions allow donations of EHR and EP items and services to physicians by hospitals and other entities. Although the federal government acknowledges that there is a risk in allowing healthcare entities to provide free or almost free items and services to a physician or other

healthcare provider (i.e., it could be a vehicle to disguise an unlawful payment for the referral of business or a financial inducement for referrals that would otherwise violate the Stark Law and the AKL), the two exceptions are expected to strike a fair and appropriate balance between the potential for fraud and abuse and the development of health information technology.

This article provides guidance to physicians about the two exceptions and “safe harbors” under the federal Stark Law and AKL that would permit third party entities to donate EHR and EP systems to physicians.

### **Under What Circumstances Is It Permissible to Accept Donations of EHR Under the Stark Law?**

The Stark Law, in general, prohibits a physician<sup>2</sup> from referring Medicare or Medicaid patients for certain designated health services to a person or entity with whom the physician (or his immediate family member) has a financial relationship, unless an exception applies. The financial relationship could be either an ownership or investment interest or a compensation arrangement involving any form of remuneration. Thus, a physician could not legally refer a patient to a hospital or a laboratory if he had a compensation arrangement with, or received any form of remuneration from, that hospital or laboratory, absent an exception.

The new EHR exception under the Stark Law expressly excludes from the definition of *remuneration* in a compensation relationship any *non-monetary* remuneration, consisting of items and services in the form of software (but not hardware) or information technology and training services, which are *necessary* and *used predominantly* to create, maintain, transmit or receive electronic health records, if certain conditions are met. Note that the donor cannot give the recipient money for the EHR system. Key conditions of the EHR exception are:

- The EHR items and services must be provided by an entity<sup>3</sup> to a physician.
- The software must be interoperable, i.e., able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and the meaning of the data are preserved and unaltered. Software will be deemed “interoperable” if it is certified by the Secretary of Health and Human Services within 12 months prior to the date it is donated.
- Neither the eligibility of the recipient nor the amount or nature of the EHR items or services provided by the donor can be determined in a manner that directly takes into account the value or volume of referrals between the parties. The exception lists several permissible criteria that the donor may rely upon to select eligible recipients.
- The donor cannot limit or restrict the use, compatibility, or interoperability of the EHR system with other systems.
- For items and services of the type that can be used for any patient regardless of payer status, the donor cannot restrict or take any action to limit the use of the items for any patient.
- The recipient cannot make receipt of the EHR a condition of doing business with the donor, (i.e., the physician cannot say that he will only do business with that vendor or refer to that provider if it donates the EHR).
- The arrangement must be set forth in a written agreement between the donor and recipient, which must satisfy certain requirements.
- The EHR software must contain electronic prescribing capability that meets required standards under the Medicare Part D (prescription drug) program.
- The EHR items and services cannot include staffing for the recipient’s office, and cannot be used primarily to conduct business that is personal or unrelated to the recipient’s clinical practice.
- Before receipt of the EHR items and services, the recipient must pay 15 percent of the donor’s cost and the donor cannot finance this payment or provide a loan. There is no cap on the cost of the items and services donated.
- The donor cannot shift the cost of the EHR to any federal healthcare program.
- The donor cannot have actual knowledge or act in reckless disregard or deliberate ignorance of the fact that the recipient already possesses equivalent EHR items or services. (What appears to concern CMS is that there may be instances where a donor gives a practitioner an EHR system or services when he already had such equivalent items or services. Therefore, CMS makes the EHR exception available only where a donor does not have actual knowledge that the recipient already has the items and services and did not act in some deliberate fashion to avoid ascertaining whether the recipient already had the items or services, i.e., the donor could have or should have known, but made no reasonable effort to determine whether the recipient already had an EHR system.)
- There is a sunset provision applicable to the EHR exception: the transfer of EHR items and services must be completed and all requirements of the exceptions must be satisfied by December 31, 2013.
- The arrangement cannot violate the AKL or any federal or state law governing billing.

### **Under What Circumstances Is It Permissible to Accept an EP System under the Stark Law?**

The Stark Law also includes a new exception for donating and receiving an EP system. Like the EHR exception, the EP exception specifically permits a physician to receive *non-monetary* remuneration in the form of items and services such as hardware, software, information technology, and training services that are *necessary* and *used solely* to receive and transmit electronic prescription information, if certain conditions are satisfied. These conditions are similar, but not identical, to the conditions under the EHR exception.

Key among the requirements to satisfy the EP exception under the Stark Law are the following:

- The EP items and services must be provided by a hospital to a physician who is a member of its medical staff, by a group practice to a member of the group who is a prescribing healthcare professional, or by a Prescription Drug Plan (PDP) sponsor or Medicare Advantage (MA) organization to a prescribing physician.
- The EP items and services must be part of, or used to access, an electronic prescription drug program that meets the standards under the Medicare Part D program.
- The donor of the EP system cannot limit or restrict the use or compatibility of the donated system with other EP systems or EHR systems.
- The donor cannot take any action to restrict use of items and services that can be used for any patient regardless of payor status to certain patients.
- The recipient cannot make the receipt of the EP system a condition of doing business with the donor.
- The arrangement must be set forth in a written agreement between the donor and recipient,

which must satisfy certain requirements.

- The eligibility of the recipient and the amount and nature of the donated items and services cannot be determined in a manner that takes into account the volume or value of referrals between the parties.
- The donor cannot have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the recipient already possesses equivalent EP items or services.

### **Key Differences between the EHR and EP Exceptions**

A physician who wishes to take advantage of the EHR exception must do so by the end of calendar year 2013. The EP exception has no sunset provision. The EP items and services that are donated must be used *solely* to receive and transmit electronic prescription information and cannot be used to conduct other office or personal business functions. The EHR items and services, on the other hand, must be used *pre-dominantly* for creating, maintaining, transmitting, or receiving electronic health records, but can include other software “bundles,” such as patient administration, billing, and scheduling, which directly relate to care and treatment of patients, although the core functionality of the software must be for EHR purposes. The EP exception includes the donation of hardware, e.g., a computer; the EHR exception excludes hardware and storage devices. The EP exception does not require a contribution by the recipient. The EHR exception limits the donor’s contribution to 85 percent of the value of the items and services and requires the recipient to contribute 15 percent of the donor’s cost for the items and services.

### **The Stark Law Exceptions vs. the AKL Safe Harbors**

In general, the AKL prohibits the giving or receipt of any form of remuneration, in cash or in kind, for

the referral or inducement of business paid for by a federal healthcare program. There are, however, several “safe harbors” enumerated under the AKL; these identify certain forms of conduct or financial relationships considered permissible by the federal government, such that a person would be immune from prosecution if specific requirements of the safe harbor were satisfied. The safe harbors for EP and EHR under the AKL are essentially the same as the exceptions described above under the Stark Law. However, strict compliance with the Stark Law is mandatory—any failure to satisfy every requirement under a Stark Law exception may mean that the physician is in violation of the Stark Law. Failure to satisfy every aspect of a safe harbor under the AKL, however, does not mean that the physician is automatically in violation of the AKL. Such a determination will depend upon the facts and circumstances of the case and the intent of the parties.

### **What Is New York’s Position?**

New York’s Health Care Practitioner Referrals Act is similar in many ways to the federal Stark Law. New York has not, however, enacted any new exceptions for EHR or EP in its law. Without such explicit exceptions, it is not certain that New York will follow the federal government in permitting donations of EHR and EP to physicians by a hospital or other entity. However, New York historically has followed the federal Stark Law, with only certain differences. It is likely, therefore, that New York’s Department of Health will continue to follow the federal government’s lead and not object to donations of EHR or EP systems if they satisfy the Stark Law/AKL exception requirements—unless the donation is made by a clinical laboratory. That is where a different approach can be expected because New York has a specific regulation<sup>4</sup> prohibiting the donation of a computer system, software,

or related equipment and supplies (collectively, “computer system”) by a laboratory to a healthcare provider except in specific, limited circumstances. The computer system can only be donated by a laboratory to a health services provider if it is used solely and exclusively to enable the provider to send specimens to the laboratory, receive test results, transmit relevant patient data to the laboratory, and transfer laboratory data to the its medical record system. In addition, the laboratory must ensure that the computer system is limited to the foregoing uses, monitor the use of the computer system by the purveyor, continue to own the computer system (it cannot be transferred to the provider), be responsible for repair and maintenance of the computer system, and maintain documentation about the provider’s use of the computer system.

New York’s regulation expressly states that the regulation and the related statutory provision<sup>5</sup> should not be deemed to prohibit a general hospital from providing a computer system to a health services provider to facilitate the delivery of health services and laboratory services to patients of the hospital, as long as the provider is a staff member or has professional privileges at the hospital.

### Incentive Payments for EP

2009	2%
2010	2%
2011	1%
2012	1%
2013	0.5%

### Conclusion

Physicians should be pleased to know that if a hospital or other entity offers to donate an EHR or EP system (including licenses, intellectual property, upgrades, training or support services, and maintenance services) the physician will be permitted to accept such donation if it meets the conditions discussed in this article. A broad definition seems to have been intended in order to encourage adoption and to encompass constantly evolving health information technology. The federal government is intent on promoting the public policy of “open, interconnected, and interoperable” electronic health information systems and for now, at least, appears to be letting down the guardrail of the anti-referral laws in a measured fashion.

### References

1. The Medicaid program will also provide incentive payments to eligible professionals of up to \$63,750 per professional over a period of six years. To further promote the use of EHR systems, the federal government will begin to penalize any physician who fails to implement a meaningful EHR system by 2015 by reducing the physician’s fee-for-service payments by 3 percent.
2. The definition of *physician* in the Stark Law includes doctors of medicine, osteopathy, dental medicine, dental surgery, podiatry, optometry and chiropractic.
3. *Entity* under the Stark Law means a physician’s sole practice, or a practice of multiple physicians, or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation or incorporated association that furnishes designated health services (as such term is defined in the Stark Law), or a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility. An entity does not include the referring physician himself/herself, but does include his/her medical practice.
4. 10 New York Codes, Rules and Regulations Section 34 - 2.9. (10 NYCRR 34 - 2.9.)
5. Public Health Law §587. Public Health Law Section 587 is part of the Public Health Law, Title 6 entitled “Laboratory Business Practices.” Section 587 specifically covers “Prohibited Practices.”

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