

# White Paper

## **Safe Harbor: A Physicians Guide to EHR Donations as Exceptions to the Physician Self-Referral Laws And Anti-Kickback Statute (Stark Laws)**

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# Foreword

This paper is designed to help physicians and administrators better understand the opportunities now available to finance the transition from paper-based records to more effective computerized systems of clinical management.

Safe Harbor exceptions to the Physician Self-Referral Law and the Anti-Kickback Statute, which now govern donations of electronic health record (EHR) systems from hospitals, health plans, and other entities to physicians and medical practices, are especially important to community-based physicians of all specialties. These rulings are generally considered to have the potential to free up substantial resources from hospitals, large provider groups, and health plans willing to help pay for the transformation to interoperable EHRs in surrounding medical practices. Physicians know it is only fair for the costs of these systems to be shared among the healthcare delivery stakeholders in any given locale, given that the quality and cost savings benefits of EHRs often extend well beyond their own practices.

Physician leaders and their administrative partners in these communities are more likely to achieve success under the new Safe Harbor rules if they have a comprehensive understanding of the specifics determining the “who, what, when, and how” of donors, donations, and recipients.

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## 1.0 The Importance of Electronic Health Records

If your medical practice is like many others, you're interested in an electronic health record software system, or EHR. Only about 15% of American physicians use EHRs in daily medical practice near the beginning of 2007. However, polls and surveys indicate that well over 50% of physicians representing all the major specialties of medicine and surgery are seriously interested in transforming to an EHR within the next two years.

EHRs are becoming more desirable, because their value is proven. Computerized office systems can take some of the most routine, repetitive, and costly aspects of paper-based workflows and automate them in a manner that saves time and money. EHRs make clinical information accessible from any location with an internet connection, un-tethering the physician from the paper chart on a shelf in the office. EHRs also reduce the hassles of refilling prescription medications through e-prescribing, creating a win-win situation for patient and doctor alike.

Properly chosen and implemented EHRs, even in small practices with 1-5 physicians or clinicians, can significantly increase revenues and patient satisfaction above pre-EHR levels.

### **EHR Case Study**

#### **ROI realized utilizing NextGen® suite of ambulatory solutions:**

- Reduced medical staff costs by \$450,000 annually
- Increased revenue by \$3.00 per visit, due to more accurate coding
- Point of care documentation eliminated transcription costs by 95%, or \$96,000
- Increased health maintenance visit revenue by \$72,000
- Employee training was reduced from 4 days to 1.5 per employee, resulting in a shorter learning curve for new hires and an associated increase in their productivity
- Staff have become more efficient and productive due to the time savings for a number of key roles in the clinic — including laboratory staff, receptionists, coding staff, and medical assistants
- After two months, about half of the practice's physicians report that the EMR saves them about a half-hour each day
- With secure access to the EMR system from their homes, on-call physicians can now access patients' histories and manage care remotely; a number of emergency department visits have been avoided in this way

However, barriers to EHR adoption still exist. Among them is the high upfront cost of purchase and implementation. As William Jessee, MD, CEO, of the Medical Group Management Association, has stated: "Finding the money to implement the technology in the first place is no easy task for physicians in small practices, and many are still uncertain about the return on investment."

In fact, in many interviews with physicians who desire to implement EHRs, the single most important barrier to adoption mentioned is the relatively high initial cost for EHR hardware, software, and implementation. A survey was undertaken by the American Academy of Family Physician's Center for Health Information Technology at the end of 2005. It found that the average cost of acquiring an EHR in a three-physician family practice amounted to \$7,200 per doctor per year over a three-year period, but this amount varied greatly and could be as high as \$20,000 per year per doctor.

Furthermore, there is an EHR adoption disparity between hospitals and large medical groups and physicians practicing in small and medium-sized medical practices. A 2005 RAND study found that "Complex electronic medical records systems are, after a twenty year waiting period, rapidly diffusing in many segments of our healthcare system, with about 30% of acute care hospital providers reporting by the end of 2003 that they had ordered EHR products, and will reach 80% saturation in hospitals by about 2016." Contrast this with a recent Harvard study indicating that fewer than 10% of physicians in small practices (those with 1-5 clinicians) were EHR adopters.

At least some of this disparity can be explained as a result of the relative scarcity of financial resources necessary to finance the transition to EHRs in the small practice environment. Clearly, if small and medium-sized medical practices are not going to be left behind in this transformation, sources of funding need to be identified and made available.

## 2.0 The Opportunity Presented by Safe Harbors

Fortunately, for physicians of all specialties, there is an opportunity to help pay some of the costs of acquiring and using health information technology, including EHRs. This is the result of the federal government's relaxation of rules that previously restricted the gifts and donations made by hospitals, health plans, and other larger provider organizations to physicians practicing in their communities.

## 3.0 Key questions and answers about the Safe Harbor rulings

Creating some confusion is that there are *two* Safe Harbor rulings that physicians and administrative partners must contend with. The first ruling covers technology related to e-prescribing systems only, the "e-prescribing option," and the second ruling covers more comprehensive EHR technology, the "EHR option." The latter ruling stipulates that gifted EHRs must include the features and functions necessary to implement e-prescribing, and is therefore the more inclusive option. In 2007 and beyond, most physician and physician organization interest will focus on the acquisition and use of EHRs that can perform e-prescribing, but not on technologies limited to e-prescribing, so the answers to the questions below and the discussion points will emphasize the "EHR option." However, for purposes of completeness, the attached table (Table 1.0) is a side-by-side comparison of the provisions and criteria for the two safe harbors: e-prescribing and EHRs.

### ***What can be donated?***

The donation must consist of interoperable EHR software and the directly related technical and training services that are necessary and used predominantly to receive, transmit, and maintain electronic health records of the medical practice's or physician's patients. Hardware, such as computers and routers, are not allowable donations. An EHR system is broadly defined 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.” Up to 85% of the costs may be donated, and the physician or practice must pay the remaining 15%.

Any donation of EHR software must be capable of electronic prescribing, either through an e-prescribing component or module or through the ability to integrate with a physician’s existing e-prescribing system. Interoperability is specifically defined as “the ability [of the EHR software] 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 of the data are preserved and unaltered.” Software may be deemed interoperable if a certifying body recognized by the Secretary of DHHS has certified the software no more than 12 months prior to the date it is provided to the physician.

Further, the donated systems may not include software that is used primarily for personal or business unrelated to the physician’s medical practice, e.g. scheduling, billing, or claims software packages that don’t have EHR components. Staffing of physician’s offices cannot be included in the donation.

### ***Who can be a “donor” of EHR products and services?***

A donor may be any individual or entity that provides services covered by a Federal healthcare program and submits claims to a federal healthcare program, or a health plan. Most hospitals, group practices, nursing homes, pharmacies, laboratories, federally qualified health centers, dialysis and oncology facilities, and other provider organizations provide services covered by Medicare, the largest federal health care program. Therefore, they would qualify as donors, as would health plans, regardless of size.

Excluded by the rulings from being donors are pharmaceutical, device, or durable medical equipment manufacturers and other manufacturers or vendors that indirectly supply or furnish items or services used in the care of patients.

### ***Who can be a “recipient” of EHR products and services?***

The items or services related to EHRs may be provided to any individual or entity engaged in the delivery of health care services covered by a federal health care program. Thus, many of the individuals and entities that can be qualified donors may also qualify as recipients.

Thus, the following situations, among others, would meet the Safe Harbor requirements:

1. The items or services are provided by a hospital to a physician member of its medical staff
2. The items or services are provided to a medical practice by a group practice
3. The items or services are provided to a medical practice by a health plan
4. The items or services are provided to a physician by a clinical laboratory company that provides services to and submits claims to a Federal health care program

Under most circumstances, a medical device manufacturer or a software vendor would not be permitted under the Safe Harbor to donate items or services, e.g. EHRs, to physicians or medical practices. However, the Safe Harbor ruling does not restrict donations or discounts from manufacturers or vendors that would normally fall outside of the Physician Self-Referral Law or Anti-Kickback Statute.

### ***In what form can the donation be made?***

The Safe Harbor protects the donor and recipient from prosecution under the Self-Referral Law and Anti-Kickback Statute for “non-monetary remuneration” only. This means that cash or other forms of direct payment to recipients for EHRs and/or services are not permitted. What is permitted is for the donor to pay for up to 85% of the cost of an EHR.

### ***What are the criteria that may be used to select recipients?***

The basic rule is this: donors of EHRs may not take into account, directly or indirectly, the volume or value of physician referrals or other business generated between the parties when determining which physicians are eligible to receive donated items and services, or the nature of those items and services.

The ruling lists a number of criteria that are deemed to meet these requirements:

- The total number of prescriptions written by the physician
- The size of the physician's medical practice, e.g. total number of patients, encounters, or relative value units
- The physician's overall use of automated information technology in his or her medical practice
- The total number of hours the physician practices medicine or surgery
- Whether the physician is a member of the donor's medical staff
- The level of uncompensated care provided by the physician.

### ***What arrangements/agreements need to be made between donor and recipient?***

The arrangement must be set forth in a contract (written agreement) that specifies in detail the items and services that are being donated, the donor's costs, and covers all of the items and services that are to be provided by the donor. Before the receipt of the donated items, the physician must pay 15% of the donor's costs. Further, the donor is prohibited from financing the physician's portion of the costs.

### ***Is there a time limit on the Safe Harbor's provisions?***

Yes. The Safe Harbor exceptions covering donations of EHRs sunset on December 31, 2013.

### ***Are there any "gray areas" or issues that remain unresolved under the Safe Harbor ruling?***

Yes, there are several areas and issues that will be debated and ultimately require clarification from the Office of the Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) to ensure that the Safe Harbor rulings are administered fairly and according to the law. It is expected that both OIG and CMS will issue further opinions and clarifications or ask that clarifications and additional rulings be made by other federal agencies, e.g. the Internal Revenue Service, as the country's medical communities embrace the Safe Harbors and gain experience with this method of helping to finance EHRs.

The following is a short -- and certainly not exhaustive -- list of items and issues that in the opinion of the author are likely to cause some confusion and to require further clarification from the federal government.

- The definition of "electronic health record software" is quite broad and could apply to many different kinds of EHRs, owned and operated not only by physicians' medical

practices, but held in common by hospitals and physicians, groups of physicians, or even laboratory companies and physicians. The definition given for an EHR -- “a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions” -- lends itself to various interpretations and would appear to cover not only electronic medical records software used exclusively by doctors and health care personnel, but also to cover personal health records, or PHR, solutions as well.

This ambiguity in the wording of the Safe Harbor rulings is not necessarily a bad thing. Given the innovation that is occurring with personal health records and community health information exchange systems capable of linking patients with their providers, there may well be a benefit in a wide definition of the software that is permissible as donations.

- The area of connectivity, interfaces, and interoperability is another area addressed by the rulings that will require clarification and perhaps some time for standards to develop. The definition of interoperability provided in the Safe Harbor rulings is precise, but is nonetheless sure to result in debate. The ruling makes it clear that interoperability must be a characteristic of the donated EHR system, but leaves the decision regarding certification and standards for interoperability up to the Secretary of HHS and others to clarify in the future.

As a practical matter, at least four different groups or entities have to be involved in ascertaining both the standard(s) for interoperability and their implementation in EHRs before there will be real clarity in the marketplace. These include the Commission on Certification for Health Information Technology, or CCHIT, the ANSI Health Information Technology Standards Panel, or HITSP, and the industry representing EHR vendors themselves. And, without a doubt, the physician and medical practice users of interoperable EHRs have a real stake in the matter, as the costs of standards development and implementation are at least indirectly borne by them in the prices of the products and services that can meet with certification.

#### **4.0 Recommended approaches for physicians and medical practices wanting to take advantage of the Safe Harbor exceptions**

Naturally, the most advantageous position for any physician or group of doctors to be in relative to an offering from a donor is to possess knowledge of the Safe Harbor ruling and to understand the details of what is, and what is not, allowed. Therefore, it is recommended that physicians be proactive learners about this new and potentially significant source of funds to help them finance their transition to EHRs, and to not rely entirely on the opinions or interpretations of prospective donors or their lawyers.

Armed with this direct understanding and knowledge about the Safe Harbors, the first step in most situations will be for physicians and medical practices in a community to initiate discussions with administrators and other leaders of local hospitals or integrated health delivery systems to determine their readiness and willingness to offer the kinds of EHR donations permitted under the Safe Harbor rulings. (In some cases, this will mean that physicians or medical groups will need to consult their own legal counsel even before beginning a negotiation with a potential EHR donor entity such as a hospital or health plan).

Just as important as understanding the Safe Harbors is knowledge about EHRs themselves. It is recommended that physicians and medical groups approach potential donors only after having done the kind of preparatory investigation and study of EHRs and HIT systems that they would normally do if they were themselves going to directly purchase the technology. This means completing necessary workflow analysis and re-engineering practice operations before implementing an automated solution. Resources that have been proven effective in assisting

medical practices prepare their practices for EHRs, to select vendors appropriate to their needs, and to reach successful implementation of EHRs, are available from a number of organizations. These include leading medical specialty societies such as the AAFP, the ACP, the local state Quality Improvement Organizations (QIO), and others who have web sites with rich materials based on the accumulated knowledge and experiences of their members.

Most physicians will want a choice with respect to the EHR software they acquire and utilize under the provisions of the Safe Harbor rulings. They may also want to avoid being faced with only one EHR vendor's offering, or a limited selection of vendors' products and services, based on the needs or requirements of the donor.

It is strongly recommended that physicians and medical groups engaged in negotiations with prospective EHR donors seek to maintain the widest choice of interoperable systems and solutions possible. They must also resist any pressures that may be put upon them to accept an EHR system that is mostly free but may not be the best solution – or even appropriate and workable – for the physicians and patients in the practice. This “take it or leave it” attitude on the part of a donor may be strictly legal under the Safe Harbor ruling but is likely not a wise strategy to follow, for either the donors or the recipients. This is because both parties will benefit most from successful implementations and the consequent improvements in care, communications, and efficiency that follow from success. It is no bargain for a practice to accept a “free” EHR and then lose months of productivity, suffer from staff morale, or, in the worst case, have to replace the donated software with a product that is better suited to the practice or specialty.

It is with regard to choice of EHRs that the Safe Harbor ruling's requirements for and definition of interoperability may play a crucial role to help physicians and their practices bargain effectively with prospective donors. Donors may take the position that communications and interoperability will be maximized by consistent use of an EHR product by multiple practices in a given community or locale. Single-vendor connectivity (the author's term) may indeed offer certain advantages to hospitals or enterprises wishing to connect with medical staff and referring groups of physicians, especially should the EHR software already be in in-patient use by the hospital(s) donors. However, single-vendor connectivity is not the same thing as interoperability as defined in the Safe Harbor ruling, and, furthermore, should not be a requirement for community-based physicians to exchange patient health information amongst themselves or with donor hospitals and health care systems.

Single-vendor connectivity is when users can access most or all of the health information across an enterprise (records in a hospital, medical practices, nursing home, etc.) that uses a single or primary vendor's proprietary EHR application, but only as long as they use that vendor's product, and where data cannot easily be exchanged with another vendor's EHR product. Interoperability, however, is generally considered to require (as the definition in the Safe Harbor rulings does) the ability of an EHR vendor's software to communicate and exchange data accurately, effectively, securely, and consistently with *different information technology systems, software applications, and networks in various settings*. This means not only within an enterprise but across or between *different* enterprises.

With the emergence of the various pay-for-performance programs from commercial insurance carriers and now the federal government, it is also important to understand each product's capability to help the provider collect, maintain, analyze, and use clinical data for improved patient care and appropriate reimbursement. It is highly likely that a product used in the institutional settings to capture clinical information will not perform the same way in the ambulatory settings.

In short, there is no reason for independent, separate physicians and medical practices not to be able to be recipients of different vendors' EHR products and services from the same donor, provided all of these meet the requirements of interoperability as defined in the Safe Harbor ruling. This, in effect, means that physician recipients and donors must use EHR software applications capable of meeting the standards agreed upon by the industry, and which confer

interoperability upon their products and services. Although these standards are only now emerging, they include the ASTM Continuity of Care Record standard, ASTM E2369-06, and the CDA CCD from HL7, both of which are in the process of being “harmonized” so as to provide the options for vendors to use either without loss of data accuracy or completeness. (At the time of this writing, the CDA CCD from HL7 is not yet a formal, balloted standard, but is expected to be by mid- to late 2007.)

## About the Author

Dr. Kibbe served as the founding Director of the Center for Health Information Technology at the American Academy of Family Physicians (AAFP) from 2003-2006 and has been selected to numerous industry and governmental advisory boards and committees aimed at enhancing technology adoption by doctors and medical practices. During his tenure as the Director of the Center, he was instrumental in the design of programs and projects that contributed to the rapid increase in AAFP membership’s use of EHRs, which grew from roughly 10% to more than 30%. He retains an active role at the AAFP as Senior IT Advisor.

Dr. Kibbe is a noted expert on physician and medical practice privacy and security as these relate to HIT, and he is a co-author of the American Medical Association’s popular *Field Guide to HIPAA Implementation*, now in its third edition (AMA Press). Dr. Kibbe helped to found the Physicians EHR Coalition (PEHRC), which serves as a forum on health information policy and practice for more than 20 of the nation’s leading physician membership organizations. He is also regarded as one of the country’s most influential physician leaders in the areas of transportability and interoperability of health information, one of the co-developers of the ASTM Continuity of Care Record standard (ASTM E2369-06) for EHR-to-EHR and EHR-to-PHR health data exchange, and a much sought-after speaker on the topics of personal health records (PHRs) and the emerging deployment in healthcare of Internet standards and protocols, such as XML and web services.

## About NextGen Healthcare

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NextGen<sup>®</sup> EMR creates high-quality electronic medical records and facilitates clinical workflow with extensive content for all specialties. NextGen<sup>®</sup> EMR also interfaces to labs, hospitals, and pharmacies—enabling providers to coordinate care beyond the examination room. NextGen<sup>®</sup> EPM streamlines front- and back-office administration. This powerful and easy-to-use system includes registration, scheduling, billing, and reporting functionalities.

Table 1.0

	<b>MMA-Mandated Electronic Prescribing Safe Harbor</b>	<b>Electronic Health Records Arrangements Safe Harbor</b>
<b>Authority for Final Safe Harbor</b>	Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	Section 1128B(b)(3)(E) of the Social Security Act.
<b>Covered Technology</b>	Items and services that are necessary and used solely to transmit and receive electronic prescription information. Includes hardware, software, internet connectivity, and training and support services.	Software necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Software must include an electronic prescribing component. (Software packages may also include functions related to patient administration, for example, scheduling, billing, and clinical support.)  Information technology and training services, which could include, for example, internet connectivity and help desk support services.  <b>Does not include hardware.</b>
<b>Standards with Which Donated Technology Must Comply</b>	Final standards for electronic prescribing as adopted by the Secretary.	Electronic health records software that is interoperable. Certified software may be deemed interoperable under certain circumstances. Electronic prescribing capability must comply with final standards for electronic prescribing adopted by the Secretary.

	<b>MMA-Mandated Electronic Prescribing Safe Harbor</b>	<b>Electronic Health Records Arrangements Safe Harbor</b>
<b>Donors and Recipients</b>	As required by statute, protected donors and recipients are hospitals to members of their medical staffs, group practices to physician members, PDP sponsors and MA organizations to network pharmacists and pharmacies, and to prescribing health care professionals.	Protected donors are: (i) 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, and; (ii) health plans.  Protected recipients are individuals and entities engaged in the delivery of health care.
<b>Selection of Recipients</b>	Donors may not select recipients using any method that takes into account the volume or value of referrals from the recipient or other business generated between the parties.	Donors may not select recipients using any method that takes into account <i>directly</i> the volume or value of referrals from the recipient or other business generated between the parties.
<b>Value of Protected Technology</b>	No limit on the value of donations of electronic prescribing technology.	Recipients must pay 15% of the donor's cost for the donated technology. The donor (or any affiliate) must not finance the recipient's payment or loan funds to the recipient for use by the recipient to pay for the technology.
<b>Expiration of the Safe Harbor</b>	None.	Safe Harbor sunsets on December 31, 2013.