

## Health System Donations of Ambulatory IT to Physicians: Taking the Government's Lead Toward Early Adoption

### Summary

On August 8, 2006 two agencies of the federal government<sup>1</sup> released regulations that are designed to provide the health care industry guidance on the ability of certain health care providers, including hospitals and health systems (collectively referred to as “hospitals”) to donate information technology to physicians as part of efforts to improve the quality and efficiency of clinical services in the nation. These regulations, along with an Executive Order issued by President Bush<sup>2</sup>, represented efforts by the federal government to push the health care industry toward interoperable health records, and their accompanying promotion of “transparency” relating to health care quality and price. While these regulations were a “step in the right direction”, they did not resolve all of the difficult and complex questions that hospitals face in seeking to create clinically integrated networks with affiliated independent physicians on their medical staffs (“physicians”).

As more fully discussed below, the regulations left many unanswered questions for hospitals desiring to cooperate with physicians (i) to enhance patient satisfaction, (ii) to improve clinical quality outcomes, (iii) to move towards access to a community-based health record and (iv) to create opportunities for cost savings and other efficiencies that are possible with information technology. Nevertheless, hospitals can use the new regulations as the foundation to “*jump start*” clinical integration activities and solidify their market position as an early adopter of cutting edge clinical information technology. A brief description of the key elements of the regulations, a discussion of some of the questions that remain unanswered in the regulations, as well as our recommendations that hospital should proceed to implement information technology systems with physicians, even in the face of such questions, are set forth below.

### A. Release of “Safe Harbors” and Stark Exceptions.

The regulations released by the two federal agencies<sup>3</sup> are designed to provide guidance and comfort under two (2) laws that represent significant impediments to hospitals providing support for physicians to participate in information technology donated by the hospital.<sup>4</sup> One law, (the *federal anti-kickback law*) provide criminal penalties or individuals or entities that knowingly or willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under

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<sup>1</sup> See, regulations issued August 8, 2006 by the United States Department of Health and Human Services, Office of Inspector General, 42 CFR Part 1001 and Centers for Medicare & Medicaid Services, 42 CFR Part 411.

<sup>2</sup> See, President Executive Order dated August 22, 2006 entitled “*Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs*”.

<sup>3</sup> See summary of the new the Stark Exceptions set forth in *Exhibit A*, and the new ‘Safe Harbors’ set forth in *Exhibit B*.

<sup>4</sup> These are by no means the only two laws that would constrain the ability of a hospital to provide financial support to physicians to support the acquisition and use of information technology.

any federal health care program. To address the constraints of the anti-kickback laws, the regulations issue new “safe harbors” that define business arrangements between donors and recipients of information technology that will not be regarded as illegal. Another law, (the so-called *Stark law*) prohibits (i) a physician from making a referral for certain designated health services payable by Medicare to an entity with which he/she has a financial relationship, unless an exception exists, and (ii) the entity from submitting claims to Medicare, billing the beneficiary or third party payer for those services, unless an exception exists. To address the legal risks presented by the Stark law, the regulations spell out the specific exceptions that will take donation out of the prohibitions of the statute.

Collectively the regulations provide specific regulatory guidance concerning the donation of information technology on the acquisition, use and maintenance<sup>5</sup> of both (i) electronic prescriptions, and (ii) electronic health records. For the most part, the regulations provide consistent rules for each of the two laws for the donation of information technology for both electronic prescriptions and electronic health records. However, there are a few notable exceptions between the rules for electronic prescribing and the rules for the electronic health records that include:

1. Hardware. Information technology “hardware” can be donated under the “safe harbors” for electronic prescribing and electronic health records exception, but not for electronic health records;
2. Co-payments. One hundred percent (100%) of an item or service can be donated under the “safe harbors” for electronic prescribing and under the Stark law exception. However, under the rules for electronic health records the recipient must pay for at least fifteen percent (15%) of the item or service;
3. Selection Methodology. Under the electronic prescription rules, a donor cannot use any method to select recipients that takes into account, directly or indirectly, the volume or value of referrals, while under the electronic health records rules, a donor cannot use any method to select a recipient that takes into account, directly, the volume or value of referral; and
4. Sunset. The legal authority for the adoption of the rules concerning electronic prescriptions was part of the adoption of the Medicare Modernization Act. For electronic health records however, the legal basis for the rules is the general authority of CMS and the OIG to promulgate regulations for business practices that pose a risk of program or patient abuse. These regulations include a “sunset” provision requiring that

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<sup>5</sup> “Covered” technology under the regulations extends to (i) interface and translation software, (ii) rights, licenses and intellectual property related to that software, (iii) connectivity services, (iv) clinical support and information services related to clinical care, (v) maintenance, (vi) training software and support, and (vii) for electronic health records, packages that include other functionalities related to individual patient care. The regulations do **not** cover (i) hardware for electronic health records, (ii) storage devices, (iii) software with core functionality other than for patient care, (iv) patient management systems for physicians’ offices or (v) items or services used primarily to conduct personal business of the physician.

all donations for electronic health records under both of these federal laws must be made on or before December 31, 2013.

Providing consistent guidance in the regulations to the health care industry was particularly important for the federal government because of the need to balance competing policy interests. On the one hand, both the regulations and the Executive Order are designed to advance the interests of the federal government to encourage and promote the use of information technology as a key step towards its initiatives to enhance the quality of clinical care and to improve patient safety. On the other hand, the government seeks to maintain its long-standing policy interests that economic incentives paid to providers can result in an unnecessary increase in utilization driving up program costs and exposing patients to clinical risks. The regulations then, as the final product of this “balancing” process, should be viewed as a compromise for these two health care policy positions but not as the final word on information technology in the health care industry. More importantly, the regulations along with the Executive Order should be seen as a major step forward in the implementation of a national health care policy that seeks to advance the adoption of information technology into the health care delivery system on an expedited basis despite the open issues that remain unresolved.

## **B. Questions That Remain to Implementing Clinical Integration Technologies.**

Despite the fact that the regulations do represent a step forward in the implementation of information technology as part of a national health policy, they do leave unanswered important questions. Several of these questions will have a very practical impact on the ability of hospitals to make donations to physicians to become participants in information technology networks sponsored by the hospital. We would like to discuss a few of, what we believe to be, the most significant questions.

1. *Tax-exempt Status.* While the regulations provide some comfort to providers making donations for electronic prescriptions and electronic health records for potential violations of federal anti-kickback laws and Stark violations, the regulations do not specifically address risks to tax-exempt status or intermediate sanctions for such donations by nonprofit provider organizations. However, on May 11, 2007 the IRS released an internal memorandum regarding its position on tax-exempt hospitals providing electronic health record services to physicians on its medical staffs at below-market fair market levels. In its internal memorandum, the IRS takes the position that if tax-exempt hospitals comply with the final regulations issued by the OIG and CMS in August 2006, the IRS will not regard financial support provided to medical staff physicians will not be regarded as illegal private inurement or an excess benefit transaction. Despite the long-awaited clarity from the IRS, it is important for tax-exempt hospitals to appropriately create and adopt a specific Information Technology Donations Policy (“Policy”) that it demonstrates that its activities are advancing a charitable public purpose consistent with the tax-exempt status of the hospital. To that end, we suggest that the Policy should include some of the following elements:

- Community Benefits Study. The Policy should carefully examine and document a community benefits analysis that demonstrates the need in the community served by the hospital for improved communication of clinical information and the barriers presented by the lack of a common information technology platform.
- Improved Access of Providers. The Policy should also carefully demonstrate that by making donations for the purpose of advancing improvements in connectivity of small and individual physician practices, or in rural areas, that would not otherwise be able to afford participation in a clinical information technology systems, the hospital is advancing a clear public purpose in providing such access.
- Need for Interoperability. The Policy should also document the need for interoperability of many different physicians to participate in the information technology in order to improve clinical outcomes and/or improve patient safety will also be an important factor to document.
- Selection Criteria. The Policy should stress that the selection of physicians to participate in the information technology donations is based upon selection criteria that is designed to advance the community's access to information technology and not simply enhance the hospital's market position or bottom line.

In short, until such time that the IRS issues formal guidance on the issue of donations for participation in information technology systems, it is prudent for tax-exempt hospitals to build support for donations by (1) adopting a Policy, and (2) developing a specific business plan for the implementation of each component of that Policy that makes a compelling case for the fact that any donations made by the hospital to physicians both fully comply with the regulations and advance the charitable purpose of the hospital.

2. Attribution of Physician Income. There is a very real likelihood that donations of information technology to physicians who participate in clinical information technology systems will be regarded as taxable "income" to the physicians. If the donations are regarded as "income" it will be necessary for the donor to issue a Form 1099 for the value of the donation. The determination of whether a donor must issue a Form 1099 to physicians participating in its information technology network will require a careful review of the tax laws. Specifically, the amount of donation will be readily identified by the donor to establish compliance with the 15% co-payment obligation of the recipient for electronic health records. A decision will need to be made by the donor whether to report its donation to the recipient as taxable income. Such decision will need to consider factors such as whether the physician is an employee of the donor for tax purposes (rather than simply state law purposes) or whether the payment is a legitimate "fringe" benefit payment by the donor. It is suggested that this issue be addressed directly and that the position of the hospital be included in the Policy.

3. Co-payment Pricing. The regulations (i) require that donations for participation in electronic health record technology impose a 15% co-payment obligation on the recipient, and (ii) prohibit the donor from “financing” the co-payment obligation of the recipient. These two requirements make the development of a practical and realistic Policy highly problematic and raise some important questions.

- How should the donor calculate its actual costs in setting the amount of the 15% co-payment?
- Can the donor apply the co-payment obligation only to the incremental cost of the technology or must it include its fully loaded acquisition, use and maintenance costs even though only a small portion of the system can be used by a physician?
- If fully loaded costs must be applied to the co-payment obligation, should the donor purchase the information technology in “phases” so that it can make the cost of physician participation more affordable?
- If a donor cannot finance the acquisition of the technology, will a long-term participation price for the physician that includes the amortized cost of the acquisition technology be regarded as “financing” the costs under the prohibitions of the regulations?

Because physician participation of any information technology system will be a critical element of its success, a hospital must develop a realistic yet supportable pricing policy for participation. We believe that there is some room in the regulations for the hospital to carefully develop and use “reasonable and verifiable” methods of allocating costs for the information technology and to build an affordable and defensible pricing policy that will be made available to support physician participation. Again the basis of the cost allocation methodology should be carefully set forth in the Policy and applied carefully on an application-by-application basis. Finally, hospitals can also be creative in seeking to arrange for financing of physician participation through third parties. The Policy can include the steps taken by the hospital to arrange for financing of physician co-payments for participation on electronic health records through arrangements with third party vendors, or where necessary, arrange with a financial institution acquisition funding that can be secured by physicians to meet their co-payment obligations for participation.

4. Interoperability. A specific requirement of the regulations is to permit the donation of information technology for electronic prescriptions and electronic health records only if that the technology is interoperability<sup>6</sup>. However, the rules define

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<sup>6</sup> Under the regulations this requirement can be met one of two ways: (i) the technology must be 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 meaning of the data are preserved and unaltered, and (ii) the software must be “as interoperable as feasible” given the state of technology at the time of donation.

interoperability in a manner that is not likely to be fully achieved for many years. As a result, many question whether the requirement set forth in the regulations that the software be “deemed” interoperable by certification of body recognized within 12 months of the donation is a realistic timeframe given the dynamic nature of information technology. While the timing of establishing national standards for interoperability of electronic health records is uncertain, it is certain that specific efforts are being undertaken to establish those standards. The Certification Commission for Healthcare Information Technology (“CCHIT”) is now officially recognized as the certifying body for the federal government and has already certified a number of electronic health records systems according to the criteria for functionality, security and interoperability. Currently, the only interoperability requirement for ambulatory electronic health records is the ability to receive laboratory results. It is anticipated that more comprehensive standards will be adopted soon by the CCHIT. The interoperability requirement should be viewed as an “evolving” goal of the regulations and should not preclude the selection of information technology that will support both the hospital and physician participation in the system and its clinical objectives

5. Private Use Limitations. The regulations impose clear limitations that the donation of information technology must not be for the “private” use of the physician, nor duplicate existing technology used by the physician. These limitations can present some very difficult planning obstacles for a donor and places a premium on being the first to provide donations so that little or no duplication exists with existing information technology systems. For example, a mobile device that also enables the physician to maintain a patient schedule, record professional services, make cell phone calls, access the internet, and use a global positioning system may well fall outside the scope of permissible donations because it may be also be used for the “personal” activities of the physician. Yet, with the convenience and availability of such technology to physicians, is it realistic to expect that he/she will be willing to use, and pay for, multiple devices just to meet the donor’s limitations? In our view, this is one of those circumstances where there is benefit to becoming an early adopter even where the precise scope of the limitations on duplication and private use have not been fully clarified. We believe that a hospital articulate the limitations imposed on existing technology by a physician and the limitations under which donated technology can be used in its Policy. For example, the Policy could require that recipients of donated information technology sign annual attestations that (i) the technology provided by the hospital is not duplicative of existing technology possessed by the physician, and (ii) the physician did not use the technology donated for personal use in any substantial degree.

### **C. Be an Early Adopter.**

Despite the significant questions that still remain following the adoption of the regulations and the real practical issues that need to be addressed in the adoption of a Policy, we recommend that the hospital proceed forward in a thoughtful, yet deliberate manner and become an “early adopter” of the information technology using the regulations as a foundation for its adoption. Not only do the demands of Medicare and third party payers for improved clinical quality, efficiency, price transparency and

improved patient safety compel a committed response by a hospital, but timing is of the essence. Given the limitations imposed by the regulations that donations not duplicate existing technology for recipients and do not permit private use by those recipients, there is a very real risk that the failure to be an innovative early adopter could result in a hospital being practically shut out of the opportunity. This could result in key physicians being “linked” on both a clinical and financial basis to other hospitals who position themselves to address the demands of the marketplace and who were willing to work with their physicians to form the information technology linkages necessary to create clinically integrated networks that can bring value to patients, consumers and participants alike. To begin taking this process, we suggest that a hospital work with its physicians to develop a Policy and to discuss and debate all of the key elements of the Policy as an integral component of its total information technology plan. It seems very likely that no hospital will be able to implement a comprehensive information technology network with independent physicians<sup>7</sup> without involving some degree of donating information technology. Hospitals should position themselves on the leading edge of this sea change and become early adopters of a Policy.

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<sup>7</sup> We believe it is possible for a hospital to invest in information technology as part of an organized clinically integrated network that is made available to participating physicians in that network without having to make a donation.

## Summary of Stark Exceptions

### Exhibit A

The Centers for Medicare & Medicaid Services has created two exceptions under the Stark Law. These exceptions must be met by any hospital that bills the Medicare program when it has a financial relationship with a physician that has referred a patient to that facility for a designated health service.

1. **Electronic Prescription Exception.** The Stark e-prescription exception is based upon the specific authority set forth in section 101 of the Medicare Modernization Act.<sup>8</sup>
  - a. Donation. The form of donation for electronic prescription technology must be non-monetary items and services including (i) hardware, (ii) software, (iii) information and (iv) training services relating to prescriptions for drugs, medical supplies, durable medical equipment and laboratory tests. Donations can include upgrades of equipment and software that enhance the functionality of an item or service. However, donations of items or services that duplicate what a physician already has in place are not protected.
  - b. Protected Participants. Participants protected include (i) hospitals to physicians who are on its medical staff, (ii) group practices to physicians in the group practice, and (iii) PDP sponsors or MA organizations to physicians.
  - c. Selection Criteria. In selecting recipients for the donations, a donor may not take into account, directly or indirectly, the volume or value of business of the physician's referrals, or other business generated between the parties. However, the donor can take into account the total number of prescriptions written by that physician.
  - d. Donor Prohibitions. A donor may not (i) take any action or limit or restrict the use or compatibility of the items or services donated, or (ii) place limits on the physician's ability to use the items or services for any patient with regard to payer status.
  - e. Recipient Prohibitions. Neither the physician, nor his/her employer, may make receipt of items or services (or the amount or nature of such items or services) a condition of doing business with the physician.
  - f. Agreement. The arrangement between the donor and the recipient must be in writing that specifies (i) the items and services provided, (ii) the donor's costs, and (iii) all of the electronic prescribing items and services provided by the donor.

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<sup>8</sup> Medicare Modernization Act, Section 1860D-4(e)(6).

- g. Good Faith Compliance. The donor must not have actual knowledge of, or act in reckless disregard or deliberate ignorance, of the fact that the physician possesses or has obtained items or services equivalent to those provided to the donor.
  - h. Compliance with Standards. The items or services donated must be part of, or used to access, an electronic prescription drug program that meets standards of Medicare Part D at the time that the items or services are provided.<sup>9</sup>
- 2. Electronic Health Records Exception.** Under its statutory authority to regulate financial relationships that do not pose a risk of program or patient abuse, the CMS created a second broader safe harbor for electronic health records.
- a. Donation. The donation is limited to “interoperable” electronic health records software and direct related training services that are necessary to receive, transmit and maintain electronic health records of the donor’s or physician’s patients. The term “*interoperable*” means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings. Software may be deemed interoperable if a certifying body certifies it no more than 12 months before donation. Any electronic health records software must contain electronic prescription capability or the ability to interface with the physician’s existing system if it meets the applicable standards under Medicare Part D. Finally, the items or services donated may not be primarily used to conduct the personal business of the physician.
  - b. Protected Participants. Under the rules, protected participants include all individuals or entities that provide designated health services as defined under Stark, but do **not** include, health care entities that are not subject to Stark such as regional health information organizations, research-based biopharmaceutical laboratories or health information technology vendors.
  - c. Selection Criteria. As in the rules for electronic prescriptions, the selection of recipients may not take into account, directly or indirectly, the volume or value of physician referrals or other business generated between the parties. Unlike the rules for electronic prescriptions, the exception for electronic health records lists explicit considerations upon which donor selection may be based. This selection criteria includes (i) total number of prescriptions written by a physician, (ii) the size of the practice, (iii) the total number of hours that the physician practices medicine, (iv) the physician’s overall use of technology in his/her practice, (v) whether the

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<sup>9</sup> Final standards for the Medicare Part D Program must be in place by April 1, 2008 and will be effective one year later.

physician is a member of the donor's medical staff, (vi) the degree of uncompensated care provided by the physician, or (vii) any reasonable and verifiable manner that does not take into account the value or volume of referrals or other business generated between the parties.

- d. Donor Prohibitions. A donor may not (i) take any action or limit or restrict the use or compatibility of the items or services donated, or (ii) place limits on the physician's ability to use the items or services for any patient with regard to payer status.
- e. Recipient Prohibitions. Neither the physician, nor his/her employer, may make receipt of items or services (or the amount or nature of such items or services) a condition of doing business with the physician.
- f. Agreement. The arrangement between the donor and the recipient must be in writing that specifies (i) the items and services provided, (ii) the donor's costs, and (iii) all of the electronic health records items and services provided by the donor.
- g. Good Faith Compliance. The donor must not have actual knowledge of, or act in reckless disregard or deliberate ignorance, of the fact that the physician possesses or has obtained items or services equivalent to those provided to the donor.
- h. Required Co-payments. Before receipt of donated items or services to support electronic health records, the physician must pay 15% of the donor's costs for the items and services. The donor however, may not provide financing to support the physician's payment.
- i. Compliance with Other Fraud and Abuse Laws. The arrangement must comply with state and federal fraud and abuse laws or regulations governing billing and claims submission.

## Summary of Safe Harbors

### Exhibit B

The Office of Inspector General has promulgated two safe harbors under the federal anti-kickback law. These safe harbors define activities that will not be prosecuted as violations of the federal anti-kickback laws. Unlike Stark violations, the failure of a donor to meet each and every one of the elements of the safe harbor may not be deemed to be a violation of federal law.

1. **Electronic Prescription Safe Harbor.** For a payment practice to meet the safe harbor, it must meet each of the conditions that follow.
  - a. Donation. The payment practice must be limited to non-monetary items and services consisting of (i) hardware, (ii) software, (iii) information and (iv) training services relating to prescriptions for drugs, medical supplies, durable medical equipment and laboratory tests. Donations can include upgrades of equipment and software that enhance the functionality of an item or service. However, donations of items or services that duplicate what a physician already has in place are not protected.
  - b. Protected Participants. Participants protected include (i) hospitals to physicians who are on its medical staff, (ii) group practices to physicians who are members of the group, and (iii) PDP sponsors or MA organizations to pharmacists and pharmacies and to prescribing health care professionals.
  - j. Selection Criteria. In selecting recipients for the donations, a donor may not take into account, directly or indirectly, the volume or value of business of the physician's referrals or other business generated between the parties. However, the donor can take into account the total number of prescriptions written by a physician.
  - k. Donor Prohibitions. A donor may not (i) take any action or limit or restrict the use or compatibility of the items or services donated, or (ii) place limits on the physician's ability to use the items or services for any patient without regard to payer status.
  - l. Recipient Prohibitions. Neither the physician, nor his/her employer, may make receipt of items or services (or the amount or nature of such items or services) a condition of doing business with the physician.
  - m. Agreement. The arrangement between the donor and the recipient must be in writing that specifies (i) the items and services provided, (ii) the donor's costs, and (iii) all of the electronic prescribing items and services provided by the donor.

- n. Good Faith Compliance. The donor must not have actual knowledge of, or act in reckless disregard or deliberate ignorance, of the fact that the physician possesses or has obtained items or services equivalent to those provided to the donor.
  - o. Compliance with Standards. The items or services donated must be part of, or used to access, an electronic prescription drug program that meets standards of Medicare Part D at the time that the items or services are provided.<sup>10</sup>
- 2. Electronic Health Records Safe Harbor.** Under its statutory authority to regulate financial relationships that do not pose a risk of program or patient abuse, the OIG created a second broader safe harbor for electronic health records.
- a. Donation. The donation is limited to “interoperable” electronic health records software and direct related training services that are necessary to receive, transmit and maintain electronic health records of the donor’s or physician’s patients. The term “*interoperable*” means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings. Software may be deemed interoperable if a certifying body certifies it no more than 12 months before donation. Any electronic health records software must contain electronic prescription capability or the ability to interface with the physician’s existing system if it meets the applicable standards under Medicare Part D. Finally, the items or services donated may not be primarily used to conduct the personal business of the physician.
  - b. Protected Participants. Under the rules protected participants include all individuals or entities that provide designated health services covered by a federal health care program and submit claims or requests for payment, either directly or through reassignment to the federal health care program. This definition includes hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, FQHCs, dialysis facilities, DME providers and a broad array of health plans. However, the safe harbor does **not** extend to donors of pharmaceutical devices or manufacturers or other manufacturers or vendors that indirectly furnish items or services used in the care of patients.<sup>11</sup>
  - c. Selection Criteria. As in the rules for electronic prescriptions, the selection of recipients may not take into account, directly or indirectly, the volume or

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<sup>10</sup> Final standards for the Medicare Part D Program must be in place by April 1, 2008 and will be effective one year later.

<sup>11</sup> The decision to exclude these providers was based on the experience of the OIG with “unscrupulous” manufactures.

value of physician referrals or other business generated between the parties. Unlike the rules for electronic prescriptions, the exception for electronic health records lists explicit considerations upon which donor selection may be based. This selection criteria includes (i) total number of prescriptions written by a physician, (ii) the size of the practice, (iii) the total number of hours that the physician practices medicine, (iv) the physician's overall use of technology in his/her practice, (v) whether the physician is a member of the donor's medical staff, (vi) the degree of uncompensated care provided by the physician, or (vii) any reasonable and verifiable manner that does not take into account the value or volume of referrals or other business generated between the parties.

- d. Donor Prohibitions. A donor may not (i) take any action or limit or restrict the use or compatibility of the items or services donated, or (ii) place limits on the physician's ability to use the items or services for any patient with regard to payer status.
- e. Recipient Prohibitions. Neither the physician, nor his/her employer, may make receipt of items or services (or the amount or nature of such items or services) a condition of doing business with the physician.
- f. Agreement. The arrangement between the donor and the recipient must be in writing that specifies (i) the items and services provided, (ii) the donor's costs, and (iii) all of the electronic health records items and services provided by the donor.
- g. Good Faith Compliance. The donor must not have actual knowledge of, or act in reckless disregard or deliberate ignorance, of the fact that the physician possesses or has obtained items or services equivalent to those provided to the donor.
- h. Required Co-payments. Before receipt of donated items or services, the physician must pay 15% of the donor's costs for the items and services. The donor however, may not provide financing to support the physician's payment.
- i. No Cost Shifting. The donor may not shift the costs of items or services to any federal health care program