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ELECTRONIC HEALTH RECORD DONATION ARRANGEMENTS

This article provides a summary of the electronic health record ("EHR") Stark Law exception and safe-harbor under the Anti-Kickback Statute (collectively "EHR Regulations"), the associated memorandum released by the Internal Revenue Service regarding impermissible private benefit and inurement and some practical guidance regarding the implementation of an EHR donation program structured to navigate this regulatory landscape.

Executive Summary

The EHR Regulations allow a hospital to provide non-monetary remuneration in the form of items and services necessary and used predominantly to create, maintain, transmit or receive EHRs by donating up to 85% of *qualifying cost* for a physician practice's purchase, implementation and maintenance of an EHR system meeting certain specified criteria. Hospitals have many options when considering how to structure an EHR donation program in a manner that will be consistent with the EHR Regulations. For many hospitals, an EHR donation arrangement is the first time the hospital is directly involved in the operation of the medical staff's private practices (i.e., if the hospital elects to provide a hosted EHR solution, the medical staff's private practices will be operating on a software hosted and maintained by the hospital). The development of a donation program, defining its scope and having a clear understanding of the technology design (physician hosted, hospital hosted, third party hosted) are all considerations that should be resolved *before* entering into contracts with third party vendors to license an EHR solution. We have found that those hospitals that first focus on developing an EHR incentive program and then negotiate appropriate third party agreements for the underlying technology have the greatest level of success in maintaining physician satisfaction.

EHR Regulations

Donation arrangements must be structured to meet the following 14 requirements of the EHR Regulations:

1. Scope of Donors and Recipients

The hospital and recipient physicians must be within the class of donors and recipients identified by the EHR Regulations.

Donors. With regard to the Stark Law, the EHR Regulations permit "entities" to be donors. For purposes of the Stark Law, any entity that furnishes designated health services is an "entity." There are numerous designated health services, including inpatient and outpatient hospital services. With regard to the Anti-Kickback Statute, the EHR Regulations permit a "donor" to be any individual or entity that provides services covered by a federal health care program and submits claims or requests for payment under that program.

Recipients. With regard to the Stark Law, physicians are the only eligible "recipients" since the Stark Law covers only financial relationships with physicians. With regard to the Anti-Kickback Statute, eligible "recipients" include any individual or entity engaged in the delivery of health care.

2. Scope of Items and Services

In order to gain protection under the EHR Regulations, the items or services donated must be "*software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.*" An EHR is 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."¹ In the comments to the EHR Regulations, the OIG elaborated, saying: "...the safe harbor provides that the electronic health records function must be predominant..." While the EHR's purpose must be predominant, the EHR Regulations protect arrangements involving software packages that include other functionality related to the care and treatment of individual patients (e.g., patient administration, scheduling functions, billing and clinical support).² Finally, the EHR Regulations expressly exclude "software with core functionality other than electronic health records (for example, human resources or payroll software packages focused primarily on practice management or billing)."³ Specific consideration should be given to defining what will be included in the EHR donation program at the time of licensing such technology.

3. Interoperability

The EHR Regulations define "interoperable" as "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."⁴ Software will meet the definition of interoperable if, at the time of donation, the software is able to: (i) communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. Otherwise, the



software will be deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient. For many vendors, interoperability is established through CCHIT (Certification Commission for Health Information Technology).

4. No Limitations on Donation by Hospital

The donor (or any person on the donor's behalf) may not take any action to limit or restrict the use, compatibility or interoperability of donated items or services with other electronic prescribing or EHR systems. Donors may not attempt to create closed or limited EHR systems by offering technology that effectively locks in business for the donor. Arrangements that seek to induce a recipient physician to change loyalties from other providers or plans to the donor are not protected by the EHR Regulations.

5. No Conditions on Receipt by Physician

The receiving physician must not place any conditions on the receipt of the items or services. The EHR Regulations specifically state that neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

6. Eligibility Not Based on Volume/Value

A hospital may not determine the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. Indirect relationships to volume or value, however, are permissible. The EHR Regulations set forth numerous examples of situations where a determination of eligibility of a recipient would be deemed not to directly take into account the volume or value of referrals or other business generated between the parties. Specifically, the EHR Regulations provide that eligibility of a recipient for the items or services will not be deemed to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

- (i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);
- (ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters or total relative value units);
- (iii) The determination is based on the total number of hours that the physician practices medicine;
- (iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);
- (v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;
- (vi) The determination is based on the level of uncompensated care provided by the physician; or
- (vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.⁵

7. Written Documentation

The arrangement must be set forth in a written agreement that: (i) is signed by the parties; (ii) specifies the items and services being provided, the donor's cost of those items and services and the amount of the recipient's contribution; and (iii) covers all of the EHR items and services to be provided by the donor (or any affiliate). Donors and recipients can meet this requirement through separate agreements between the donor (and affiliated parties) and the recipient so long as those agreements incorporate each other by reference or if they cross-reference a master list of agreements. Any such master list must be maintained and updated centrally in a manner that preserves the historical record of agreements and is available for review by the Secretary upon request.

8. Knowledge of Equivalent Items or Services

The donor must not have actual knowledge, act in reckless disregard, or deliberate ignorance, of the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor. In commenting on this requirement, CMS noted that "software and services are [not] necessary if the recipient already possesses the equivalent software or service."⁶ CMS went on to comment that the provision of equivalent items and services poses a heightened risk of abuse, since such arrangements potentially confer independent value on the recipient unrelated to the need for the EHR. Finally, CMS noted that the "necessary" requirement would not preclude items or services that result in standardization of systems among donors and recipients, provided that the standardization enhances the functionality of the EHR system (and any software is interoperable). CMS and the OIG recommend that donors may want to make reasonable inquiries to potential recipients regarding whether they already possess equivalent items or services and document those communications accordingly.

9. No Patient Restrictions

The EHR Regulations require that the items or services donated can be used for any patient without regard to payor status and prohibit the donor from



restricting or taking any action to limit the recipient's right or ability to use the items or services for any patient.

10. Staffing/Relation to Clinical Operations

The EHR Regulations specifically prohibit the donor from contributing physician office staff or assistance in converting paper medical files to electronic medical records as part of the implementation process.

11. E-Prescribing Capabilities

Donated EHR software must contain an electronic prescribing capability either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system. That capability must meet the applicable standards under Medicare Part D at the time the items and services are provided.

12. Cost Sharing

The EHR Regulations require that, *before receipt* of the items and services, the recipient pay not less than 15% of the donor's cost for the items and services qualifying for the donation. Qualifying items and services consist of software or information technology and training services necessary and used predominantly to create, maintain, transmit or receive EHRs.⁷ Additionally, the donor (or any affiliated individual or entity) may not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services. Any updates, upgrades or modifications to previously donated items and services that were not covered under the initial purchase price also are subject to this cost-sharing requirement.

13. No Cost Shifting

The donor may not shift the costs of donated items or services to any federal health care program.

14. Sunset Date

The safe-harbor and exception provided under the EHR Regulations expire December 31, 2013.

IRS Memorandum

A 501(c)(3) organization desiring to provide a donation pursuant to the EHR Regulations should also structure the donation in a manner that is consistent with the direction set forth in the Internal Revenue Service ("IRS") May 11, 2007 Memorandum ("IRS Memorandum") regarding *Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records*. Specifically, the IRS Memorandum states that the IRS will not treat a donation provided to the medical staff physicians of a hospital operating as a 501(c)(3) organization as impermissible private benefit or inurement in violation of section 501(c)(3) if: (i) to the extent permitted by law, the hospital may access all of the EHRs created by a physician using the donated items and services; (ii) the hospital ensures that the donated items and services are available to all of its medical staff physicians; and (iii) the hospital provides the same level of donation to all of its medical staff physicians or varies the level of donation by applying criteria related to meeting the health care needs of the community.

Implementation of an EHR Donation Program

The obligation to provide the donation to all medical staff physicians under the IRS Memorandum encourages hospitals to take a planned, purposeful approach in determining how, when and for what purpose the hospital will provide a donation for EHR items and services. Many factors may contribute to how a hospital develops its donation program, including, but not limited to:

- The financial capacity of the hospital to fund a donation program;
- The operational capacity of a hospital's information technology staff to support the interfaces between the hospital's clinical systems and the physician office's EHR system;
- The technological sophistication of the hospital's medical staff, giving specific consideration to the current use of EHR technology among the medical staff and anticipated rates of adoption of EHR technology by the medical staff in their private practices;
- The impact the ability to move patient information seamlessly between the hospital, its clinics and physician offices will have on the physician-hospital relationship;



- Whether the hospital is located in a market where physician records may be accessible by more than one hospital;
- What, if any, impact the implementation of an EHR system will have on the flow of patients to hospital owned clinics;
- The hospital's referral patterns, giving specific consideration to the number of points of patient treatment; and
- Community need for physician access to patient records from multiple points of treatment.

Specifically, it is likely that a hospital will not have the financial resources available to provide a donation to all of its medical staff at the maximum rate allowed by the EHR Regulations. Likewise, the hospital may not have the technological capacity to interface between various forms of EHR technology implemented by its medical staff in order to meet the access requirements set forth by the IRS and in order to maximize the benefit of widespread adoption of EHR technology. Finally, the hospital should consider the added load that will be placed on the hospital's information technology staff and infrastructure as it interfaces with the various physician office EHR systems.

Generally, when a hospital desires to establish a program to provide a donation in accordance with the EHR Regulations and IRS Memorandum, it will take one of three approaches:

1. **Hospital Negotiated Master License/Hospital Hosted EHR.** The hospital may select one or more preferred EHR vendors. The hospital will then negotiate a set of terms under which its medical staff can purchase the EHR system from a preferred vendor. In such situations, the hospital may further attempt to drive down the cost of implementation and maintenance by hosting the EHR system in the hospital's data center. In this approach, the hospital's objective is to provide its medical staff with leverage to negotiate as a combined block and maximize efficiencies of scale when all of the medical staff move as one. Under this model, the hospital may also elect to provide the EHR to non-medical staff physicians on a cost basis. This model may serve as a foundation for further development of a physician hospital organization ("PHO") or an accountable care organization ("ACO").
2. **EHR Funding Pool.** The hospital can allocate a fixed amount of funds for donation in a given year. The hospital can limit the availability of the donation funds by further defining qualifying expenses (i.e., making the donation available only for the cost of EHR software purchase instead of cost of software purchase, implementation and ongoing maintenance). After accepting applications for the donation, the hospital can award donations and either allocate the funds on a pro rata basis or first come, first served basis. In this approach, the hospital's objective is to distribute donations while providing medical staff and their individual practices with maximum autonomy.
3. **EHR Stipend.** The hospital can, on a one time basis, provide a stipend to all medical staff who are implementing a qualifying EHR (e.g., the hospital will provide a stipend of the lesser of \$5,000 or 85% of qualifying costs). In this scenario, the hospital treats the donation arrangement as a one time event. This approach reflects a desire by the hospital to be responsive to the request of the medical staff for some level of donation under the EHR Regulations while also balancing the hospital's obligation to operate in a financially responsible manner. Specifically, the hospital may find that significant and sufficient incentives exist for "meaningful use" of certified EHR technology to induce physicians to adopt EHR technology and that the financial resources of the hospital are better directed in accordance with the mission of the hospital to other programs.

The three scenarios set forth above are by no means the exclusive methods of implementing a donation program, but serve to illustrate some of the various approaches health systems and hospitals have taken to facilitate the adoption of EHR technology by their medical staff. Each hospital has unique factors to consider as it balances physician autonomy, financial need, community demand and hospital resources.



If you have any questions or would like additional information about this topic, please contact Michael T. Batt at 317.977.1417 or mbatt@hallrender.com or your regular Hall Render attorney.

¹ Medicare Program; Physicians' Referrals To Health Care Entities With Which They Have Financial Relationships; Exceptions For Certain Electronic Prescribing And Electronic Health Records Arrangements ("Exception"), 71 Fed. Reg. 45140, 45149; Safe Harbor, 71 Fed. Reg. at 45123.

² 45151; *See also* Safe Harbor, 71 Fed. Reg. at 45124.

³ Safe Harbor, 71 Fed. Reg. at 45125; Exception, 71 Fed. Reg. at 45151.

⁴ Safe Harbor, 71 Fed. Reg. at 45126; Exception, 71 Fed. Reg. at 45155.

⁵ Exception, 72 Fed. Reg. at 45170; *see also* Safe Harbor, 71 Fed. Reg. at 45137.

⁶ Exception, 71 Fed. Reg. at 45154.

⁷ Exception, 71 Fed. Reg. at 45170.