

# Regulatory Compliance

## THE REGULATORY FRAMEWORK FOR QUALIFYING EHR DONATIONS BY DANIEL F. GOTTLIEB, McDERMOTT WILL & EMERY LLP

### EXECUTIVE SUMMARY

*A healthcare organization considering the roll-out of EHR technology to physicians or other referral sources should prepare a careful plan to assure that the expectations of CMS and/or the OIG are met. In particular, donation recipient selection criteria and the proper allocation of EHR technology acquisition expenses can be complex and fact-specific and prevent one size fits all approaches.*

Following the issuance of proposed regulations for the Medicare and Medicaid incentives for the meaningful use of certified electronic health record (EHR) technology earlier this year, hospitals and other providers have received new and renewed requests from physicians and other referral sources to subsidize their transition or upgrade to certified EHR technology. Particularly in this context, CIOs and other decision-makers within hospital-based organizations need to make sure that any plan for rolling out EHR technology to referral sources is consistent with federal and state fraud and abuse laws.

For hospitals and other providers of Stark-designated health services (DHS) to provide the assistance to physicians or physician organizations who refer Medicare patients to the provider, the assistance, in most cases, must be structured to comply with the Stark Law exception for the donation of EHRs. Likewise, EHR donations to referral sources for Medicare or other federal health care program patients must be structured to comply with the federal Anti-Kickback Statute. To facilitate compliance with both laws, the Office of Inspector General (OIG) of the Department of Health & Human Services (HHS) adopted an EHR-donation safe harbor to the Anti-Kickback Statute that is substantially the same as the Stark Law EHR donation exception adopted by the federal Centers for Medicare & Medicaid Services (CMS).

### STARK ANTI-KICKBACK STATUTE REQUIREMENTS

The Stark EHR donation exception and Anti-Kickback Statute EHR donation safe harbor identify parties (donors) that may donate EHR software, information technology and training services, to physicians and other referral sources for items

and services reimbursed by federal health care programs. The Stark exception requires an EHR technology donation by a DHS provider to a referring physician to meet the following standards:

- The donation must be in the form of software or information technology and training and support services necessary and used predominantly to create, maintain, transmit, or receive EHRs (Covered Technology). A donor may not donate hardware (such as routers, modems, storage devices and software that makes the hardware function), staffing (e.g., to migrate data), and items and services to conduct personal business or business unrelated to the physician's medical practice.

- The EHR software must have an e-prescribing component that meets Medicare Part D standards at the time of donation.

- The recipient cannot already have items and services equivalent to those provided by the donor.

- Donated software must be interoperable with other EHR technology at the time it is provided and the donor cannot restrict interoperability. Software is deemed interoperable if certified as interoperable by a certifying body recognized by the Secretary of HHS no more than 12 months prior to the date of the donation to the physician. The Secretary has designated the Certification Commission for Health Information Technology (CCHIT) as the certifying body for this purpose. Note that this certification is not the same as the EHR technology certification required for purposes of demonstrating meaningful use of certified EHR technology under the Medicare and Medicaid EHR incentive programs.

- The EHR donation recipient must pay 15 percent of the total cost for the donated Covered Technology before receiving the donation. If a donor purchases hardware or other items and services from a vendor that are not Covered Technology, the recipient must reimburse the donor for 100 percent of the cost of the non-Covered Technology. Accordingly, when a donor purchases or licenses both Covered Technology and non-Covered Technology from a vendor, it should create an itemized list of EHR technology assets to be donated and specify whether the donor will subsidize up to 85 percent of the cost



Daniel F. Gottlieb

of each item of Covered Technology and allocate 100 percent of the cost of non-Covered Technology to the recipient.

- Neither the physician nor the physician's practice (including employees and staff members) 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.

- The donor cannot limit the physician's right to use the donated EHR technology with any

patient when the technology can be used for any patient without regard to payer status.

- The donor cannot directly take the volume or value of referrals or other business between the parties into account when determining a physician's eligibility or the amount or nature of a donation. Permissible criteria for selecting donation recipients under this requirement are discussed below.

- The donation must be documented in a signed agreement that specifies the items and services to be provided and the donor's cost.

- The transfers must be completed and all conditions satisfied by December 31, 2013.

The Anti-Kickback Statute safe harbor is essentially identical to the Stark Law exception aside from the fact that the safe harbor addresses donations to referral sources other than physicians and physician organizations.

**COVERED EHR TECHNOLOGY**

While CMS and the OIG did not want to create an exhaustive list of EHR technology that may be donated, the agencies have indicated the following items and services may be donated if necessary and used predominately to create, maintain, transmit or receive EHRs: interface and translation software; rights, licenses and intellectual property related to EHR software; connectivity services (including broadband and wireless internet services); clinical support and information services related to patient care (but not separate research or marketing support); maintenance services; secure messaging; and training and support services.



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**BUNDLED SOFTWARE AND FUNCTIONALITY**

An EHR donation may include up to 85 percent of the cost of other software and functionality bundled with the EHR module and directly related to the care and treatment of individual patients such as patient administration, scheduling functions, billing and clinical support software. However, the predominant or core functionality of the donated technology must be the creation, maintenance, transmission, or receipt of patients' EHRs.

**UPGRADES AND ENHANCEMENTS**

The EHR donation must be necessary, but CMS and the OIG do not interpret this standard to preclude upgrades that enhance functionality or standardize systems among donors and recipients. However, the term necessarily does exclude donations of technology that the physician already possesses. The donation does not satisfy the Stark exception or Anti-Kickback Statute safe harbor if the donor knows or acts in reckless disregard or deliberate ignorance of the fact that the recipient possesses equivalent technology. The agencies have counseled that donors may want to make reasonable inquiries of proposed donation recipients regarding their existing technology and document such communications, but they do not provide guidance concerning the factors (e.g., a comparison of features and functions, the technology platform or architecture) that are relevant to determining whether the recipient already possesses equivalent EHR technology.

It seems likely that CMS and the OIG would not consider EHR technology that has been certified for purposes of the Medicare and Medicaid EHR incentive programs to be equivalent to legacy EHR technology that has not been certified.

**SELECTION OF DONATION RECIPIENTS**

As noted above, the EHR donation exception and safe harbor only prohibits the use of recipient selection criteria that directly take into account the volume or value of referrals or other business generated between the parties. Stated differently, they permit determinations of eligibility made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated. In an effort to provide bright-line guidance on the volume/value standard, the exception and safe harbor provide six alternative and non-exclusive criteria that a donor may use that would be deemed not to directly take into account the volume or value of business generation:

- The total number of prescriptions written by the physi-

**FOR EXAMPLE, IT IS UNCLEAR WHETHER A HOSPITAL COULD STAGE A ROLL-OUT OF EHR TECHNOLOGY TO ITS MEDICAL STAFF BEGINNING WITH THE MEDICAL SPECIALTY OR DEPARTMENT THAT ACCOUNTS FOR THE GREATEST UTILIZATION OF THE HOSPITAL.**

cians (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a federal health care program);

- The size of the physician's medical practice, such as total patients, total patient encounters or total Medicare relative value units, which units are established by the Medicare Physician Fee Schedule;
- The total number of hours that the physician practices medicine;
- The physician's overall use of automated technology in his or her medical practice (without reference to the use of technology in connection with referrals made to the donor);
- Membership on the donor's medical staff; or
- The level of uncompensated care provided by the physician or other permitted recipient.

Notwithstanding the agencies' efforts to provide bright-line guidance for permissible selection criteria for donation recipients, the guidance creates some ambiguity. For example, it is unclear whether a hospital could stage a roll-out of EHR technology to its medical staff beginning with the medical specialty or department that accounts for the greatest utilization of the hospital. There are a number of good business, operational, and clinical reasons for a hospital to take this approach; however, it is not clear under current guidance whether this approach would be sufficiently indirect to qualify for the EHR exception or safe harbor.



**INDEPENDENT PHYSICIAN USE OF EHR TECHNOLOGY IN HOSPITALS**

A hospital or other provider may purchase inpatient or ambulatory EHR technology for use by employed and independent physicians while they provide services to hospital patients in hospital-based facilities without charging the physicians for the use. This is because the availability of an EHR under these limited circumstances is not considered remuneration to the physicians and, accordingly, does not implicate either law.

For example, a hospital may purchase EHR licenses from the vendor to permit hospital-based physicians such as anesthesiologists, pathologists, radiologists, emergency medicine physicians, and hospitalists to use its EHR without requiring the physicians to pay 15 percent of the cost of the licenses. On the other hand, a hospital's donation of ambulatory EHR technology to an anesthesiology group for the group's office-based pain management practice would be remuneration and need to comply with the Stark Law and Anti-Kickback Statute. When structuring a donation to a group with both a hospital-based and office-based practice, it may be necessary to treat physicians in the group differently based on whether the physician has both an office-

and hospital-based practice, exclusively a hospital practice or exclusively an office practice.

Physicians analyzing the financial benefit of an election to participate in the Medicaid EHR incentive program instead of the Medicare program should consider whether an EHR donation will reduce their Medicaid incentive payments. This is because the Medicaid incentives are reduced by any payment to the Medicaid-eligible professional that is from a source (other than a state or local government) and directly attributable to payment for certified EHR technology or support services. Under the proposed Medicare EHR incentive program regulations, the receipt of donated EHR technology will not affect the potential value of Medicare EHR incentive payments.

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Daniel F. Gottlieb is a partner in the Health Law Department of law firm McDermott Will & Emery LLP, and is based in the firm's Chicago office. He focuses on advising clients regarding compliance with federal and state health care laws, with significant experience counseling on health information technology and Medicare and other government program reimbursement and fraud and abuse issues. For more information: [dgottlieb@mwe.com](mailto:dgottlieb@mwe.com)

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