DONATIONS OF ELECTRONIC HEALTH RECORDS TECHNOLOGY

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On August 8, 2006, the Department of Health and Human Services' Office of Inspector General ("OIG"), and the Center for Medicare and Medicaid Services issued a safe harbor under the federal anti-kickback law and an exception to the federal physician self-referral law that permits certain donations of electronic health records ("EHR") software or information technology and training services. The OIG's stated purpose for the new safe harbor and exception was to "lower perceived barriers to the adoption of health information technology" by promoting "the adoption of open, interconnected, interoperable electronic health record systems." The safe harbor and exception will both currently terminate on December 31, 2013.

Under the EHR safe harbor and exception, laboratories and other permitted donors can subsidize the cost of compliant EHR technology to physicians at 85% of the cost of such technology. The EHR technology is not required to be certified by the OIG. However, the standards and criteria related to interoperability that are recognized by the Department of Health and Human Services should be consulted.

Persons and entities that are considering donating or receiving a donation of EHR technology are advised to review the rule and related supplementary information from the OIG very carefully. Assuming other safe harbor and exception conditions are met, the following requirements are set forth under the EHR technology safe harbor and exception:

A. Permitted Donors and Recipients

Donors: The safe harbor and exception apply to protect any donor that is an individual or entity that provides patients with health care items or services covered by a federal health care program and submits claims or requests for payment for those items or services (directly or pursuant to reassignment) to Medicare, Medicaid, or other federal health care programs. This is a bright-line test designed to focus on those individuals and entities with a substantial and central stake in patients' EHR. Individuals and entities that can satisfy the test include, for example, laboratories, hospitals, group practices, physicians, nursing and other facilities, pharmacies, oncology centers, community health centers, federally qualified health centers, dialysis centers and health plans.

The OIG has informally acknowledged the concern about the potential for abuse by ancillary service providers and suppliers, including laboratories. According to the OIG, it will be alert to patterns of increased utilization correlated with transfers of nonmonetary remuneration in the form of EHR technology. The OIG also noted that, notwithstanding the safe harbor and exception, parties remain liable under various federal and state laws for billing abuses, including over-billing and billing for items and services that are not medically necessary.

Recipients: The final rule permits the donation of protected remuneration to a physician or physician practice. The final rule permits donors to use selective criteria for choosing recipients, provided that neither the eligibility of the recipient, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. If any one of seven selection criteria set forth in the final rule is met, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties. The selection criteria are as follows:

1. The determination is based on the total number of prescriptions written by the recipient (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);

2. The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);

3. The determination is based on the total number of hours that the recipient practices medicine;

4. The determination is based on the recipient'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);

5. The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;

6. The determination is based on the level of uncompensated care provided by the recipient; or

7. 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.

B. Covered Technology

EHR Defined: Under the final rule, "electronic health record" 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."

Software/Information Technology and Training Services: Only nonmonetary remuneration that consists of items and services in the form of software or information technology and training services that are necessary and used predominantly to create, maintain, transmit, or receive EHR are protected under the rule. Covered items and services include, interface and translation software; rights, licenses and intellectual property related to EHR software; connectivity services, including broadband and wireless internet services (including connectivity fees); clinical support and information services related to patient care (but not separate research or marketing support services); maintenance services; secure messaging (i.e., permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services). Hardware (e.g., routers and modems) is not covered, nor is operating software that makes the hardware function; storage devices; software with core functionality other

than EHR (e.g. human resources or payroll software, or other software focused primarily on practice management or billing); or items or services used by the recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations. The provision of staff to recipients or their offices is also not covered.

Necessary Requirement: Software and services are not "necessary" if the recipient already possesses equivalent software or services. Under the rule, if a donor knows that the recipient already possesses equivalent items or services, or acts in deliberate ignorance or reckless disregard of that fact, the donor will not be protected by the safe harbor and exception. Accordingly, prudent donors should make reasonable inquiries to recipients and document these communications. The rule does not preclude upgrades of items or services that enhance their functionality (e.g. a software upgrade).

Predominance Requirement: EHR functions must be predominant. The core functionality of the technology must be the creation, maintenance, transmission or receipt of individual patient's EHR. The items and services cannot be used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations. The safe harbor and exception do protect arrangements involving software packages that include other functionality related to the care and treatment of patients (e.g., patient administration, scheduling functions, billing and clinical support).

Interoperability Requirement: The donated EHR software must be interoperable at the time it is provided to the recipient. "Interoperable" means that, at the time of the 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, in various settings; and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. The donor (or any person on the donor's behalf) cannot take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems.

Interoperability must apply in various settings, meaning that the software must be capable of being interoperable with respect to systems, applications, and networks that are both internal and external to the donor's or recipient's systems, applications, and networks. Software is not interoperable if it can only communicate or exchange data within a limited health care system or community. Interoperability is to be evaluated given the prevailing state of technology at the time the items or services are provided to the recipient.

Parties must have a "reasonable basis" for determining that software in interoperable. Standards and criteria related to interoperability that are recognized by the Department should be consulted. Compliance with these standards will provide greater certainty to donors and recipients that products meet the interoperability requirement and may be relevant in any enforcement activities. To avoid uncertainty, parties can avail themselves of the "deeming" provision. This provides that software is deemed to be interoperable if a certifying body recognized by the Secretary of the Department has certified the software within no more than 12 months prior to the date it is provided to the recipient.

Electronic Prescribing Required: The EHR software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface

with the recipient's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

Other: For items or services that are of the type that can be used for any patient without regard to payor status, the donor cannot restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

C. Value of Technology

The final rules offers protection only if the recipient pays 15% of the donor's cost of the technology. This payment is required to be made before the recipient's receipt of the items and services being donated. All donated software and health information technology and training services are subject to the cost-sharing requirement. Any updates, upgrades, or modifications to the donated EHR system that are not covered under the initial purchase price for the donated technology are subject to separate cost sharing obligations by the recipient (to the extent that the donor incurs additional costs). Donors (and their affiliated individuals and entities) are prohibited from providing financing or making loans to recipients to fund the recipient's payment for the technology. Under the final rule, there is no cap on the amount of protected technology that can be donated.

D. Written Agreement Required

The arrangement between the donor and the recipient must be documented in a written agreement that sets forth the following:

1. Is signed by the parties;

2. 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

3. Covers all of the EHR items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary of the Department upon request. The master list should be maintained in a manner that preserves the historical record of agreements.