NEW STARK EXCEPTIONS AND FRAUD AND ABUSE SAFE HARBORS

On April 26, 2004, President Bush announced his goal of universal adoption of electronic health records technology by 2014. It appears Congress has listened. In parallel Final Rules issued on August 8, 2006, the Centers for Medicare and Medicaid Services (CMS) and the Department of health and Human Services' (HHS) Office of the Inspector General (OIG) announced new regulations that are expected to encourage the adoption of electronic prescribing and electronic health records technology. These Final Rules followed The Medicare Modernization Act (MMA) which directed the Secretary of HHS, currently Mike Leavitt, to adopt standards for electronic prescribing as well as adopt a new Stark Exception and Fraud and Abuse Safe Harbor relating to electronic prescribing. The Final Rules went further and added a second Stark Exception and Fraud and Abuse Safe Harbor.

The previous presenters discussed why we want electronic health records and the benefits of adopting their usage. These aspirations must be aligned with the reality that we are in the healthcare world. This means acknowledging the Stark and Fraud and Abuse issues that will necessarily arise out of financing the use of electronic health records. In addition, we must also be cognizant that the new Stark Exceptions and the Fraud and Abuse Safe Harbors do not end our inquiry. In the healthcare context, we must be aware of the fact that there are many issues still unresolved in this "push" to adopt electronic health records. For example, it is unclear how the new Stark Exceptions and Fraud and Abuse Safe Harbors interact with federal tax law. Is it a private benefit to a physician on a nonprofit hospital's medical staff to receive electronic health record software free of charge? We simply don't know. For this reason, the author would submit to the reader that he or she shouldn't end their risk analysis with the new Stark Exceptions and Fraud and Abuse Safe Harbors.

Prior to entering into a detailed discussion of the new Stark Exceptions and the Fraud and Abuse Safe Harbors we must ask ourselves who is going to pay for these items. What types of relationships are going to be formed in order for electronic health records to be implemented. Fortunately, the answer is simple. Physicians are going to look to institutional providers to supply the capital. Incidentally, hospitals and managed care organizations are the most likely candidates for financing the implementation of electronic health records. It should come as no surprise that hospitals, trade associations and vendors submitted the most comments regarding the new Stark Exceptions and the Fraud and Abuse Safe Harbors.

With this background we now turn to the question of what is permissible under the new Stark Exceptions and Fraud and Abuse Safe Harbors.

Stark

Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), Phase I of the final rules promulgated thereunder (42 C.F.R. Pt. 411, Subpt. J) (the "Regulations"), and the commentary to the Regulations, as set forth in 66 Fed. Reg. No. 3, pp. 856–952 and 69 Fed. Reg. No. 59, pp. 16053-16146 (the "Commentary") (collectively, "Stark") address the issue of physician self referral.

Generally, unless an Exception(s) applies, Stark prohibits any physician who has a "financial relationship" with an entity from making a referral to that entity for the furnishing of "designated health services" ("DHS") for which payment otherwise may be made under Medicare. Stark further prohibits the DHS provider from billing any individual, third party payor, or other entity for services provided pursuant to a prohibited referral. *See* 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353.

Essentially, this means we need (1) a physician, who (2) has a financial relationship, with (3) an entity. The physician in any given analysis is usually the easiest to identify. On the other hand, the entity is often more difficult to identify.

The Stark regulations define "entity" as any person (individual, corporate or otherwise) furnishing DHS. 42 C.F.R. § 411.351. A person is deemed to be furnishing DHS if it is, "(i) the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or (ii) is the person or entity to which the right to payment for the DHS has been reassigned pursuant to § 424.80..." 42 C.F.R. § 411.351.

Once the physician and the entity have been identified we must next determine if the physician and the entity have a financial relationship. This determination is critical because the Exceptions available to any given arrangement are contingent upon the type of financial relationship existing between the referring physician and the entity. Stark defines financial relationship as either (1) an ownership or investment interest or (2) a compensation arrangement.

This background is important to understanding the new Exceptions listed in 42 C.F.R. § 411.357. For instance, 42 C.F.R. § 411.357 only applies to compensation arrangements. For this reason, a physician who has an ownership interest in an entity will still need an additional Stark Exception (i.e. the physician services Exception or the in-office ancillary services Exception) to cleanse his or her ownership interest. The following provides an overview of the new Stark Exceptions.

A. Electronic Prescribing Exception

The Electronic Prescribing Exception is found at 42 C.F.R. § 411.357(v). The first requirement of the Electronic Prescribing Exception is that the entity provide non-monetary remuneration. The Exception specifically indicates that this may include hardware, software,

information technology and training services. The Commentary tells us that it also includes broadband or wireless internet connectivity, licenses, rights of use, intellectual property, upgrades, educational and support services (including help desk and maintenance services), upgrades and possibly operating software and interfaces fit within the Exception. However, nonmonetary remuneration can not include billing, scheduling, administrative and other general office software.

The nonmonetary remuneration must be **necessary and used solely** to receive and transmit prescriptions. This means that the physician can not already have the items or services. In addition, this prevents DONORS from using non-monetary remuneration as a marketing tool. Furthermore, software that bundles general office management, billing, scheduling, electronic health records, or other functions with the electronic prescribing features are neither necessary nor used solely to receive and transmit electronic prescription information.

DONORS and RECIPIENTS are dictated by the Exception. Permissible DONORS include hospitals, group practices, Prescription Drug Program (PDP) or Medicare Advantage (MA) organizations. Stark only applies to physicians and therefore the permissible RECIPIENTS are physicians. More directly, eligible physician RECIPIENTS include physicians on a hospital's medical staff, members of a group practice (as defined by Stark), and prescribing physicians.

Generally, DONORS must not select RECIPIENTS based on the volume or value of referrals or other business generated between the parties. The Commentary provides that DONORS can select RECIPIENTS based on the total number of prescriptions written. On the other hand, DONORS cannot select based on number or value of prescriptions dispensed or paid

by DONOR, on overall value of prescriptions, or on the volume or value of prescriptions reimbursable by the Medicare program.

The Electronic Prescribing Exception contains several additional requirements worth briefly noting.

- Items and services are provided pursuant to an electronic prescription drug program that meets applicable standards under Medicare Part D at the time provided.
- DONOR cannot restrict use or compatibility of items and services with any other prescription or electronic health records system.
- DONOR cannot restrict use with regard to payor status of patient. RECIPIENT cannot make receipt of items a condition of doing business.
- The parties must put the arrangement in writing.
- The Electronic Prescribing Exception also places a burden on DONOR to ensure that RECIPIENT does not possess items or services equivalent to those provided by the DONOR.

B. Electronic Health Records Exception

The Electronic Health Records Exception, at 42 C.F.R. § 411.357(w), applies to certain nonmonetary remuneration in the form of software, information technology and training services. More specifically, nonmonetary remuneration can include interface and translation software; rights, licenses, and intellectual property related to electronic health records 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 services); Maintenance services; Secure messaging (for example, permitting physicians to

communicate with patients through electronic messaging); and Training and support services (such as access to help desk services). Patient portal software is also permissible nonmonetary remuneration. Items and services cannot include **hardware** (or operating software that makes hardware function); Storage devices; Software with core functionality other than electronic health records (for example, human resources or payroll software); Items or services used by a physician primarily to conduct personal business or business unrelated to the physician's practice; Routers or modems. It is worth noting that DONORS cannot provide staff to transfer paper records to electronic records either.

The items and services must be **necessary** and used **predominantly** to create, maintain, transmit, or receive electronic health records. Basically, this means that the **core functionality** of the technology must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records. This also means that protected software packages may also include other software and functionality directly related to the care and treatment of individual patients (for example, patient administration, scheduling functions, billing, clinical support software, etc.).

Mirroring the AKS Safe Harbor, the new Stark Exception defines EHR 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."

The EHR Exception also dictates eligible DONORS and RECIPIENTS. Broadly, items and services can be provided by an entity (DHS provider) to a physician. Otherwise, Stark does not apply. This means that eligible RECIPIENTS include any physician. It is likely that DONORS can include a "consortia" of permissible DONORS (or in Stark language "entities"). Laboratories are permissible DONORS, however, no group practice to group practice donation is

allowed. Pharmaceutical manufacturers, RHIO's, research entities, manufacturing entities, biopharmaceutical industry, and health information technology vendors are not permissible DONORS.

Any software donated must be interoperable. Interoperable is defined as "(1) able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (2) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." With that being said, software is not interoperable if it is capable of communicating or exchanging data only within a limited health care system or community. Parties can ensure that software is interoperable by choosing software certified as interoperable within 12 months of the date provided by a body recognized by the Secretary.

The EHR Exception contains a cost sharing obligation on the part of the RECIPIENT. The RECIPIENT must pay the cost sharing up front. In fact, prior to receipt of donated items or services, the RECIPIENT must pay 15% of DONOR'S **cost**. DONOR (or any affiliated individual or entity) must not loan or finance RECIPIENTS cost sharing obligation. The cost sharing obligation is ongoing for any updates, upgrades or modifications.

Neither eligibility or amount of items and services can be determined in a manner that takes into account volume or value of referrals or other business generated between the parties. The parties comply with this requirement if RECIPIENTS are chosen by one of the following methods: 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); 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); The determination

is based on the total number of hours that the physician practices medicine; 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); 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; The determination is based on the level of uncompensated care provided by the physician (also could include the total number of Medicaid patients served by the practice); 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 (catchall).

Notably, the arrangement also must not violate the AKS, or any other Federal or state law or regulation governing billing or claims submission.

The EHR Exception places restrictions on the items and services. In fact, the EHR Exception mandates that items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice. Items and services must have electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided. Importantly, all items and services must be provided and all conditions of the Exception must be satisfied before December 31, 2013.

The remaining requirements of the EHR Exception are straightforward. For example, the agreement between the parties must be in writing. Also, DONOR cannot limit or restrict use, compatibility or interoperability with other electronic prescribing or electronic health records systems. Likewise, physician or physician's practice can't make receipt of items or services a

condition of doing business with entity. DONOR cannot restrict use of items or services with regard to payor status. Finally, the Exception places burden on DONOR to ensure that RECIPIENT does not possess items or services equivalent to those provided by the DONOR.

AKS

Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b(b)) and 42 C.F.R. Part 1001 (collectively, the "Fraud and Abuse Laws") broadly address the issue of kickbacks in exchange for the government's business. The Fraud and Abuse Laws provide criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit or receive "remuneration" in order to induce business for which payment may be made under a federal health care program. Under authority granted by the Fraud and Abuse Laws, the Secretary of the Department of Health and Human Service has adopted certain "Safe Harbor" regulations, which set forth the elements of certain practices and arrangements that are not subject to the Fraud and Abuse Law prohibitions because such practices and are not likely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. A transaction or arrangement which satisfies all of the requirements of a Safe Harbor will immunize the entities involved in the transaction or arrangement from prosecution or sanctions under the Fraud and Abuse Laws with respect to such arrangement. Failure to comply with all of the elements of any given Safe Harbor, however, does not result in a *per se* violation and a transaction or arrangement may comply with the provisions of the Fraud and Abuse Laws without satisfying all of the elements of a Safe Harbor.

A. Electronic Prescribing Safe Harbor

The Electronic Prescribing Safe Harbor published at 42 C.F.R. § 1001.952(x), allows a DONOR to provide a RECIPIENT with nonmonetary remuneration. The Commentary states that this can include broadband or wireless internet connectivity, training, information

technology support services, and other items used in the transmission or receipt of electronic prescribing information. In addition, DONOR'S can provide licenses, rights of use, intellectual property, upgrades, educational and support services (including, for example, help desk and maintenance services), operating software that is necessary for the hardware to operate, and patches designed to link. Nonmonetary remuneration does not include billing, scheduling, administrative and other general office software, software used for personal or non-medical purposes, or the provision of office staff.

The items and services must be necessary and used solely to transmit medically appropriate prescriptions. The golden rule that comes out of this language is that items and services are not necessary if you already have it. This language also requires that the items and services are electronic tools that provide information **necessary to formulate, transmit, or receive a medically appropriate prescription**. Items and services which can serve this purpose, although not intuitively, include electronic clinical support tools identifying alternative drug therapies, drug to drug interactions, or a payor's formulary information. Items and services are not "necessary and used solely" if used for marketing purposes. Incidentally, advertisements from DONOR to the RECIPIENT are not necessary and used solely.

It is also important to note which persons are permissible DONORS and RECIPIENTS. Permissible DONORS include hospitals, group practices, and PDP sponsors. Notably, clinical laboratories were excluded from this list. Permissible RECIPIENTS include physicians on the medical staff, members of a group practice, pharmacists, pharmacies, and prescribing health care professionals. Independent contractors are not eligible RECIPIENTS.

Next, the electronic prescribing Safe Harbor provides some specific rules. Among these, items and services must be provided as part of an electronic prescription drug program that meets

Medicare Part D standards at the time provided. Further, DONOR must not restrict use or compatibility with other electronic prescribing or EHR systems. Likewise, DONOR cannot place restrictions with regard to payor status. On the other hand, the RECIPIENT is prohibited from making receipt of items or services a condition of doing business with the DONOR.

Luckily, the Safe Harbor provides explicit guidance on how a DONOR can choose a RECIPIENT. DONORS may select RECIPIENTS based upon the total number of prescriptions written by the RECIPIENT, but cannot select them based upon the number or value of prescriptions written by the RECIPIENT that are dispensed or paid by the DONOR (or on any other criteria based on any other business generated between the parties). DONORS cannot select RECIPIENTS based on "overall value" of prescriptions written or on volume or value of prescriptions written by the RECIPIENT that are reimbursable by any Federal health care program.

The Electronic Prescribing Safe Harbor concludes by mandating that the arrangement is set forth in writing and places a burden on the DONOR to ensure that the RECIPIENT does not already have items or services equivalent to those being provided by the DONOR.

B. Electronic Health Records Safe Harbor

The Electronic Health Records Safe Harbor can be found at 42 C.F.R. § 1001.952(y). The Electronic Health Records Safe Harbor allows certain non-monetary remuneration in the form of software, information technology and training services. The Commentary states that, "Some software that relates to patient administration, scheduling functions, billing and clinical support can be included." Otherwise, common software includes interface and translation software, rights, licenses, intellectual property related to electronic health records software, and patient portal software. Information technology includes connectivity, maintenance services,

including broadband and wireless internet services, clinical support and information services related to patient care, general maintenance services and secure messaging (permitting physicians to email with patients). Training services can include help desk and other similar support or training and support services.

Non-monetary remuneration can not include several items and services. By definition, hardware is excluded. Additionally, the Commentary excludes operating software that makes the hardware function, storage devices, software with core functionality other than EHR (e.g. human resources or payroll software or software packages focused primarily on practice management or billing), and software primarily for personal business or RECIPIENT'S clinic.

The items and services must be necessary and used predominantly to create, maintain, or receive EHR. Similar to the Electronic Prescribing Safe Harbor, it's not necessary if you already have it. However, necessary items include upgrades of items or services that enhance the functionality of the items or services, including, for example, upgrades that make software more user-friendly or current. Necessary items also include standardization of systems among DONORS and RECIPIENTS, provided that standardization enhances the functionality of the electronic health records system (and any software is interoperable).

The items and services must also be predominantly used to create, maintain, transit or receive EHR. The Safe Harbor defines Electronic Health Record 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."

RECIPIENTS and DONORS include a wide array of persons and entities. RECIPIENTS include individuals or entities engaged in the delivery of health care. Common examples include physicians, group practices, physician assistants, nurse practitioners, nurses, therapists,

audiologists, pharmacists, nursing and other facilities, FQHC's and community health centers, laboratories and other suppliers, and pharmacies. DONORS can include individuals or entities who (1) provide services covered by a Federal health care program and (2) submit requests for payment to the Federal health care program or health plans. Examples of permissible DONORS are hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, FQHC's, and dialysis facilities. DONORS do not include research entities, health information technology vendors, pharmaceutical, device, or durable medical equipment manufacturers, or other manufacturers or vendors that indirectly furnish items and services used in the care of patients. On the other hand, a consortia of protected DONORS are possibly protected.

RECIPIENTS can not be selected in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. The Safe Harbor provides seven methods for DONORS to select RECIPIENTS. These include determination based on total number of prescriptions written by the RECIPIENT (not the volume or value of prescriptions dispensed or paid by the DONOR or billed to a federal health care program), size of RECIPIENTS medical practice (total patients, total patient encounters, or total RVUs), total number of hours RECIPIENT practices medicine, RECIPIENTS overall use of automated technology in his or her medical practice, RECIPIENT is a member of the DONOR'S medical staff, selection based on level of uncompensated care provided by the RECIPIENT (rural health care providers), or any method that does not directly take into account the volume or value of referrals (catchall).

Any software given by DONOR must be interoperable at the time it is provided. Interoperable defined as "(i) able to 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 parties can also comply with the Safe Harbor's deeming provision. The deeming provision provides that software is also deemed interoperable if it is certified by a certifying body recognized by the Secretary (certified within 12 months prior to donation).

The EHR Safe Harbor contains a Cost Sharing obligation on the part of the RECIPIENT. In fact, prior to receipt of donated items or services, the RECIPIENT must pay 15% of DONOR'S **cost**. DONOR (or any affiliated individual or entity) must not loan or finance RECIPIENTS cost sharing obligation. The cost sharing obligation is ongoing for any updates upgrades or modifications.

The EHR Safe Harbor contains several boilerplate requirements, including the following:

- RECIPIENT cannot make the receipt of items or services, or the amount or nature of the items and services, a condition of doing business with the DONOR
- DONOR cannot take any action to restrict the use, compatibility, or interoperability with other electronic prescribing or electronic health records systems
- EHR software must possess electronic prescribing capability or the ability to interface with RECIPIENT'S existing electronic prescribing system.
- The electronic prescribing capability must comply with Medicare Part D standards.
- The agreement must be in writing.
- RECIPIENT cannot already have items or services

- Safe Harbor places burden on the DONOR to ensure that RECIPIENT does not already have items or services
- DONOR cannot restrict items and services based on payor status.

Lastly, DONOR cannot shift costs of providing items and services to Federal health care programs and all transfers must occur and all conditions of the Safe Harbor must be satisfied prior to December 31, 2013.

1120607.1