Shipman & Goodwin LLP

CLIENT ALERT

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ELECTRONIC HEALTH RECORDS AND E-PRESCRIBING SAFE HARBORS: LICENSE OR RESTRICTION?

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the federal government has published two safe harbor rules under the Stark and anti-kickback statutes with the goal of promoting physician use of E-prescribing and electronic health record technology. The regulations, introduced in August of 2006, allow hospitals and other health care facilities to provide hardware and software to certain recipients in order to promote the creation of an electronic health record. Although the Stark and anti-kickback rules are virtually identical, compliance with the Stark safe harbor is mandatory whereas, compliance with the anti-kickback safe harbor is voluntary. Thus, if a compensation relationship between a hospital (or other designated health service provider) and a physician does not meet all the requirements of the Stark safe harbor exception, a referral by the physician for designated services will result in a violation of the Stark law. Therefore, strict compliance with the Stark and anti-kickback rules (the "New EHR Rules") will be essential to the planning and implementation of an interconnected electronic health record system.

The following summarizes the relevant features of the New EHR Rules:

E-PRESCRIBING SAFE HARBOR.

E-Prescribing Donor and Recipient. The E-prescribing safe harbor rule permits a hospital to donate hardware, software, training and support services or any information technology or training services to a physician in order for the physician to create, receive and transmit any prescription information, related to drugs or to other items or services normally ordered by prescription (e.g., laboratory tests, DME orders). Licenses, rights of use, intellectual property, upgrades, and educational and support services, including help desk and maintenance are items and services that potentially fit in the safe harbor.

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Terms of the Donation: The arrangement must be set forth in writing, specify all of the electronic items or services to be provided, specify the donor's cost of the items and services and be signed by the parties. Although there is no limit on the value of the donation and there is no cost sharing requirement on the part of the physician, the provision of technology for personal, non-medical purposes is not protected (e.g. back office billing), nor is the provision of office staff. Moreover, the hospital cannot limit use of the system or compatibility of the items or services with other electronic prescribing or electronic health records systems (i.e., other hospitals) and the system must be capable of use for any patient without regard to payer status. Finally, neither the hospital nor the physician can make receipt of the items or services a condition of doing business with the donor, nor can the donor make the donation if it has knowledge of the fact that the physician already has the items or services being offered by the donor.

Other than the hardware to be used solely for E-prescribing, the utility of this safe harbor alone is questionable given that the electronic health record safe harbor requires an E-prescribing component in the software.

ELECTRONIC HEALTH RECORD SAFE HARBOR.

Donor and Recipient. The Electronic Health Records safe harbor permits health care facilities[1] to provide individuals engaged in health care with electronic health record software or information technology (i.e., connectivity and maintenance services) and training services necessary and used predominantly to create, maintain, or receive electronic health records.[2] Specifically, the safe harbor covers the donation of software and technology services if: (i) the items and services are provided to an individual or entity engaged in the delivery of health care by; (ii) an individual or entity that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment to the Federal health care program; or (iii) a health plan. Notably, unlike the E-prescribing safe harbor, hardware may not be donated (because hardware could present a higher risk of constituting a disguised payment for referrals), and donors and recipients are more broadly defined.

What the Software Must Do. Software, information technology and training services necessary and used predominantly for electronic health records includes the following: 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; maintenance services; secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services). It excludes storage devices, software with core functionality other than electronic health records (e.g., human resources or payroll software or software packages focused primarily on practice management or billing), or items or services used by a recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations. Routers or modems for internet connectivity are excluded. If a recipient chooses to switch electronic health records systems, data

migration services are not covered. Patient portal software is included. The purpose of the software must be predominantly for electronic health records. The core functionality of the technology must be the creation, maintenance, transmission or receipt of electronic health records. Notwithstanding, software that relates to patient administration, scheduling functions, and billing and clinical support can be included.

Interoperability. At the time of donation, the software must be interoperable as certified by a certifying body recognized by the Secretary. "Interoperable" means that 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, in various settings; and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. The software must be 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. It is not considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community. The software must contain an electronic prescribing component or the ability to interface with the recipient's existing system and the donor must not take any steps to disable the interoperability of any technology or impose barriers to compatibility of the donated technology with other technology.

Donor Selection. Donors cannot select recipients based upon the volume of referrals made by the recipient, even as it relates to priority for implementation or have knowledge that the recipient has equivalent technology. The selection of a recipient is deemed not to directly take into account the volume or values of referrals or other business generated between the parties if the determination: (i) is based on the total number of prescriptions written by the recipient but not the value or value of prescriptions dispensed or paid by the donor or billed to a Federal health program); (ii) is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units); (iii) is based on the total number of hours that the recipient practices medicine; or (iv) 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 his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor). Finally, there must be a written agreement between the parties specifying what software and services will be provided. While there is no limit on the value of the donation, the recipient must pay 15% of the donor's cost.

Challenges: Since many institutional providers have been eager to implement E-prescribing and electronic health record systems that are interoperable with the electronic health records of their physician medical staff members, the promulgation of the New EHR Rules was greatly anticipated. Whether the New EHR Rules are the answer everyone was waiting for, is yet to be seen. In May 2007, the IRS weighed in and concluded that compliance with the EHR Rules would not violate a tax-exempt entity's tax-exempt status. Nevertheless, the New EHR Rules may prove to be too restrictive to promote the full scale use of E-prescribing and electronic health record

technology. Since it is the federal government's objective to have electronic health records fully implemented by 2014, the New EHR Rules sunset as of December 31, 2013.

QUESTIONS OR ASSISTANCE?

If you have any questions, please do not hesitate to call Joan Feldman at (860) 251-5104, Alex Lloyd at (860) 251-5102, John Lawrence at (860) 251-5139, or Maureen Anderson at (860) 251-5589.

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[1]This safe harbor protects donors such as hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, FQHCs, and dialysis facilities. Donors do not include pharmaceutical, device or DME manufacturers, or other vendors that indirectly furnish items and services used in the care of patients because these entities do not provide health care items or services to patients or submit claims for services.

[2]This safe harbor protects recipients such as physicians, group practices, physician assistants, nurse practitioners, nurses, therapists, audiologists, pharmacists, nursing and other facilities, FQHCs and community health centers, laboratories and other suppliers, and pharmacies. Physicians do not need to be on the medical staff. The donor must not have knowledge that the recipient has equivalent technology.

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