

Health Law Bulletin

August 2006

New Stark Law Exception and Anti-Kickback Statute Safe Harbor for E-Prescribing and Electronic Health Record Technology

On August 8, 2006, the Centers for Medicare and Medicaid Services (“CMS”) and the Office of the Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”) published final regulations under the Stark Law and the Anti-Kickback Statute concerning the donation of electronic prescribing (“e-prescribing”) and electronic health records (“EHR”) technology. The rules are designed to improve patient safety, efficiency, and quality of care by removing existing barriers to adoption and use of health information technology by physicians. These final rules differ considerably from the proposed rules published by the agencies in October 2005, and the scope of permitted donors and recipients of health information technology is broader. Both rules will be effective on October 10, 2006.

Regulatory Framework

The Stark Law prohibits physicians from making referrals for certain “designated health services” (“DHS”) payable by Medicare to an entity with which the physician has a financial relationship, unless an exception applies. The Stark Law prohibits entities from submitting claims to Medicare for DHS furnished as a result of a prohibited referral. Familiar exceptions to the Stark Law include the exception for in-office ancillary services and the exceptions for office space and equipment rentals.

The Anti-Kickback Statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward referrals for services or items reimbursable under a federal health care program. Prohibited remuneration includes kickbacks, bribes and rebates, whether direct or indirect, and in cash or in kind. Because of the facially broad reach of the statute, multiple “safe harbors” have been developed over the past 15 years to permit certain nonabusive arrangements and to encourage beneficial or innocuous arrangements.

Assistance provided by hospitals to physicians on their medical staffs in connection with the installation and operation of health information systems could constitute a transfer of remuneration or value prohibited by the Stark Law and/or the Anti-Kickback Statute. Concerns about these types of potential violations have presented a barrier to cooperation between hospitals and physicians in adopting health information technology. Recognizing this, Congress called for HHS to create standards for e-prescribing and mandated an exception and a safe harbor for arrangements involving the provision of e-prescribing technology as part of the new Medicare prescription drug benefit (“Medicare Part D”) established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”). In connection therewith, CMS and the OIG each developed a second exception and safe harbor for arrangements involving the donation of EHR software or information technology and training services.

E-Prescribing Stark Law Exception and Anti-Kickback Statute Safe Harbor

E-prescribing allows physicians to transmit prescriptions electronically to pharmacies and ancillary providers and enables physicians and pharmacies to obtain information concerning a patient's medication history from plan sponsors and other pharmacies. The MMA requires prescription drug plan sponsors and Medicare Advantage organizations that participate in Medicare Part D to support e-prescribing, while e-prescribing is currently voluntary for physicians and pharmacies. CMS's final rule establishing the mandated e-prescribing exception to the Stark Law and the OIG's final rule establishing the e-prescribing safe harbor under the Anti-Kickback Statute provide as follows:

Stark Law E-Prescribing Exception 42 C.F.R. §411.357(v)	Anti-Kickback Statute E-Prescribing Safe Harbor 42 C.F.R. §1001.952(x)
The items and services must consist of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit e-prescription information.	The items and services must consist of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit e-prescription information.
The items and services are provided by a hospital to a physician who is a member of its medical staff, by a group practice to a physician who is a member of the group, or by a prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician.	The items and services are provided by a hospital to a physician who is a member of its medical staff, by a group practice to a prescribing health care professional who is a member of the group, or by a prescription drug plan sponsor or Medicare Advantage organization to participating pharmacists or pharmacies and to prescribing health care professionals.
The items and services are provided as part of, or are used to access, an e-prescription drug program that meets applicable standards under Medicare Part D at the time the items and services are provided.	The items and services are provided as part of, or are used to access, an e-prescription drug program that meets applicable standards under Medicare Part D at the time the items and services are provided.
The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other e-prescribing or EHR systems.	The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other e-prescribing or EHR systems.
For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.	For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.
Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.	Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

<p align="center">Stark Law E-Prescribing Exception 42 C.F.R. §411.357(v)</p>	<p align="center">Anti-Kickback Statute E-Prescribing Safe Harbor 42 C.F.R. §1001.952(x)</p>
<p>Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.</p>	<p>Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.</p>
<p>The arrangement is set forth in a written agreement that (i) is signed by the parties, (ii) specifies the items and services being provided and the donor’s cost of the items and services, and (iii) covers all of the e-prescribing items and services to be provided by the donor.</p>	<p>The arrangement is set forth in a written agreement that (i) is signed by the parties, (ii) specifies the items or services being provided and the donor’s cost of the items and services, and (iii) covers all of the e-prescribing items and services to be provided by the donor (or an affiliate).</p>
<p>The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.</p>	<p>The donor does not have actual knowledge of, and does not 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.</p>

EHR Stark Law Exception and Anti-Kickback Statute Safe Harbor

Interoperable EHR technology, like e-prescribing technology, assists in reducing medical errors, coordinating care and improving efficiency. HHS recognizes that the implementation of interoperable EHR technology is a critical step “in achieving secure and seamless information exchange and improving our health care system.” CMS’s final rule establishing the EHR exception to the Stark Law and the OIG’s final rule establishing the EHR safe harbor under the Anti-Kickback Statute are outlined below.

Each rule defines EHR as a “repository of consumer health status information in computer processable form used for clinical diagnosis and treatment of a broad array of clinical conditions.” Interoperable means “able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software application, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.”

<p align="center">Stark Law EHR Exception 42 C.F.R. §411.357(w)</p>	<p align="center">Anti-Kickback Statute EHR Safe Harbor 42 C.F.R. §1001.952(y)</p>
<p>The items and services must consist of software or information technology and training services that are necessary and used predominately to create, maintain, transmit or receive EHR.</p>	<p>The items and services must consist of software or information technology and training services that are necessary and used predominately to create, maintain, transmit or receive EHR.</p>

Stark Law EHR Exception 42 C.F.R. §411.357(w)	Anti-Kickback Statute EHR Safe Harbor 42 C.F.R. §1001.952(y)
<p>The items and services are provided by an entity to a physician.</p>	<p>The items and services are provided to an individual or entity engaged in the delivery of health care by (i) an individual or entity that provides services covered by a federal health care program and submits claims for requests or payments, either directly or through reassignment, to the federal health care program, or (ii) a health plan.</p>
<p>The software is interoperable at the time it is provided to the physician. (Software is deemed to be interoperable if a certifying body recognized by HHS has certified the software no more than 12 months prior to the date it is provided to the physician).</p>	<p>The software is interoperable at the time it is provided to the recipient. (Software is deemed to be interoperable if a certifying body recognized by HHS has certified the software no more than 12 months prior to the date it is provided to the recipient).</p>
<p>The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other e-prescribing or EHR systems.</p>	<p>The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other e-prescribing or EHR systems.</p>
<p>Before receipt of the items and services, the physician pays 15% of the donor's cost for the items and services, and the donor does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.</p>	<p>Before receipt of the items and services, the recipient pays 15% of the donor's cost for the items and services, and the donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.</p>
<p>Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.</p>	<p>Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.</p>
<p>Neither the eligibility of a physician for the items or services, 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.</p>	<p>Neither the eligibility of a recipient for the items or services, 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.</p>
<p>The arrangement is 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 the items and services, and the amount of the physician's contribution, and (iii) covers all of the EHR items and services to be provided by the donor.</p>	<p>The arrangement is 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).</p>

Stark Law EHR Exception 42 C.F.R. §411.357(w)	Anti-Kickback Statute EHR Safe Harbor 42 C.F.R. §1001.952(y)
The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.	The donor does not have actual knowledge of, and does not 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.
For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the physician’s right or ability to use the items or services for any patients.	For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient’s right or ability to use the items or services for any patients.
The 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.	The items and services do not include staffing of the recipient’s office and are not used primarily to conduct personal business or business unrelated to the recipient’s clinical practice or clinical operations.
The EHR software contains e-prescribing capability, either through an e-prescribing component or the ability to interface with the physician’s existing e-prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.	The EHR software contains e-prescribing capability, either through an e-prescribing component or the ability to interface with the recipient’s existing e-prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.
The arrangement does not violate the Anti-Kickback Statute, or any federal or state law or regulation governing billing or claims submission.	The donor does not shift the costs of the items or services to any federal health care program.

According to a 2005 study by the RAND Corporation, effective implementation of interoperable health information technology systems in the health care industry could eventually save an estimated \$81 billion annually, and technology-enabled prevention and management of disease has the potential to save even more time and resources in the health care system. One of the President’s goals on this front is for every American to have electronic health records by 2014. Consistent with this commitment, the EHR exception and safe harbor sunset on December 31, 2013.

These new rules are a useful step by the federal government toward national adoption and implementation of health information technology systems and electronic medical records for each patient. Other steps include the development of standards for health information technology to ensure interoperability and the confidentiality of patients’ electronic medical records, which is also being facilitated by HHS.

While the final rules concerning the donation of e-prescribing and EHR technology are helpful, concerns remain that the provision of health information technology to physicians by hospitals could implicate individual State anti-kickback and self-referral laws. In addition, tax-exempt hospitals must remain mindful that their provision of health information technology to physicians on their medical staff would not be deemed an “excess benefit transaction” under Internal Revenue Service rules prohibiting private inurement. Finally, concerns remain as to the interpretation of certain requirements in the final rules, such as how a donor is to calculate the true cost of items and services in order to allocate 15% of the donor’s cost of the technology to the recipient.

We will keep readers advised of important regulatory developments concerning health information technology. Should you have any questions regarding this bulletin or other health law issues, please contact Richard H. Sanders, Esq., Health Law Practice Area Leader (312/609-7644), Amy L. Young, Esq. (312/609-7822), or any other Vedder Price attorney with whom you regularly work.

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