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HHS Announces New Federal Stark Law Exceptions and Federal Anti-Kickback Safe Harbors for Sharing Information Technology with Physicians

By J. Phillip O'Brien

On August 1, Health and Human Services (HHS) Secretary Mike Leavitt announced the issuance of final regulations (published in the Federal Register on August 8, 2006) creating new information technology exceptions under the Federal Stark law and safe harbors under the Federal Anti-Kickback statute. Proposed regulations were issued last October 11, subject to a comment period ending December 12, 2005. The issuance of these regulations substantially increases the ability of hospitals and other providers of Medicare and Medicaid services to donate information technology to physicians without violating the Stark law or Anti-Kickback statute.

I. Provision of Information Technology Items or Services to Physicians at Fair Market Value

At the outset, we note that a Medicare/Medicaid provider's provision of information technology to physicians at fair market value presents no significant regulatory issues. If the recipient physicians pay fair market value for the information technology items or services, there is no subsidy or inducement to the recipient physicians in exchange for Medicare or Medicaid referrals, and Stark law exceptions and Anti-Kickback safe harbors are available to protect such commercially reasonable market transactions. For example, the Federal Stark law has an exception for payments made by a physician as compensation for items or services that are furnished at fair market value.

This Client Advisory focuses upon situations where a hospital or other Medicare/Medicaid provider "donates" the information technology items or services to physicians or otherwise makes such technology available to physicians at less than fair market value. In those situations, regulatory risk is implicated and the information technology exceptions and safe harbors discussed in this memo are available to eliminate or minimize the regulatory risk.

II. Federal Stark Law Exceptions for Information Technology

A. Pre-Existing Exception for Community-Wide Health Information Systems

There is a Stark law exception, the exception for community-wide health information systems, that predates the exceptions created under the final regulations published August 8. This exception applies to items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that: (1) the items or services are available as necessary to enable the physician to participate in the system, and are not provided in any manner that takes into account the volume or value of referrals or other business generated by the physician; (2) the system is available to all providers, practitioners, and residents of the community who desire to participate; and (3) the arrangement does not violate the Anti-Kickback statute or any Federal or State law or regulation governing billing or claims submission.

The second requirement under this exception makes it of limited usefulness for hospitals because the information technology must be made available to all providers in the community who want to participate. This would require the system to be made available to physicians who are not even on the hospital's medical staff as well as any residents in the community who wish to participate.

B. Electronic Prescribing Items and Services

This exception was mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which created the drug benefit under Medicare Part D. It applies to non-monetary remuneration provided by a hospital to members of its medical staff or by a group practice to physicians who are members of the group practice (consisting of items and services in the form of hardware, software or information technology and training services) "necessary and used solely" to receive and transmit electronic prescription information. In order to qualify under this exception, the following conditions must be satisfied:

- (1) Items and services must be provided by a hospital to a physician who is a member of its medical staff or by a group practice to a physician who is a member of the group;
- (2) The items and services must be provided as part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided;
- (3) The donor (or a person on the donor's behalf) must not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health record systems;
- (4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor must not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient;
- (5) Neither the physician nor the physician's practice can make the receipt of items or services, or the amount or nature of the items or services, a condition for doing business with the donor;
- (6) Neither the eligibility of the physician for the items or services, nor the amount or nature of items or services, can be determined in a manner that takes into account the volume or value of referrals or the business generated between the parties;
- (7) The arrangement must be set forth in a written agreement that is signed by the parties, specifies the items and services being provided and the donor's costs of the items and services, and covers all the electronic prescribing items and services to be provided by the donor; and
- (8) The donor must not have actual knowledge of, and must 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.

C. Electronic Health Records Items and Services

An additional new Stark law exception goes beyond electronic prescription information and extends more generally to electronic health records ("EHR") defined to mean "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." This exception applies to non-monetary remuneration (consisting of items and services in the form of software or information technology and training services) "necessary and used predominantly" to create, maintain, transmit, or receive EHR, provided all the following conditions are satisfied:

- (1) The items and services are provided by a provider entity, as defined in the Stark law, to a physician;
- (2) The software is interoperable at the time it is provided to the physician. Interoperable means "able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." Software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than twelve months prior to the date it is provided to the physician.
- (3) 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 electronic prescribing or EHR systems;

- (4) Before receipt of the items or 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;
- (5) Neither the physician nor the physician's practice makes the receipt of items or services, or the amount or nature of the items or services, a condition for doing business with the donor;
- (6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, can be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties;
- (7) The arrangement is set forth in a written agreement that is signed by the parties, specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contributions, and covers all the EHR items and services to be provided by the donor; and
- (8) 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 and services equivalent to those provided by the donor;
- (9) 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;
- (10) 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;
- (11) The EHR software contains electronic prescribing capability that meets the applicable standards under Medicare Part D at the time the items and services are provided;
- (12) The arrangement does not violate the Anti-Kickback statute or any federal or state law or regulation governing billing or claims submission
- (13) The transfer of the items or services occurs and all conditions are satisfied on or before December 31, 2013.

D. Significant Issues Under the Electronic Prescription and EHR Exceptions

The following is a review of the more significant issues under both exceptions.

1. Technology Covered

The electronic prescription exception protects donations of hardware, software and information technology and training services. In contrast, the EHR exception only protects donations of software and information technology and training services. Under both exceptions, upgrades are permitted.

Thus, the major distinction between the two exceptions in terms of technology covered is hardware: permitted under the electronic prescription exception, but excluded under the EHR exception. In the commentary to the final regulations, CMS has interpreted the EHR exception to exclude the following: hardware (and operating software that makes the hardware function); storage devices; software with core functionality other than EHR (e.g., 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; and provision of staff to physicians or their offices.

In terms of items and services that are protected under the EHR exception, CMS has opined that the following are included under the exception: interface and translation software; rights, licenses, and intellectual property related to EHR software; connectivity services, including broadband and wireless Internet services (but not routers or modems necessary to access or enhance connectivity because hardware is not protected under the exception); clinical support and information services related to patient care (but not separate research or marketing support services); maintenance services; secure messaging (permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services).

2. Permissible Donor

Under the electronic prescription exception, donations may be made by a hospital to physicians on its medical staff. Under the EHR exception, all entities that furnish designated health services, as defined under the Stark law, may make protected donations to any physician.

3. “Necessary and Used Solely” v. “Necessary and Used Predominantly”

The electronic prescription exception requires that the donated technology be “necessary and used solely” to receive and transmit the subject information. In contrast, the EHR exception only requires that the donated technology be “necessary and used predominantly” to receive, transmit and maintain EHR.

The “used predominantly” requirement suggests the possibility of other incidental uses under the EHR exception. In fact, in its commentary, CMS states, “Thus, depending on the circumstances, software that relates to patient administration, scheduling functions, billing, clinical support, etc. can be donated.”

Again, the EHR exception prohibits the provision of any technology used “primarily” to conduct personal business or business unrelated to the physician’s medical practice, as well as the provision of staff to the physician or the physician’s office.

4. Interoperability Requirement

Under the EHR exception, the software must be interoperable at the time it is provided to the physician. In addition, the software must have been certified within twelve months prior to the date of donation.

The point of the interoperability requirement is to ensure that the software is interoperable with respect to systems, applications and networks that are both internal and external to the donor’s or physician recipient’s systems, applications and networks. Software will not be considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community.

5. No Limitation or Restriction on Use or Compatibility

Both the electronic prescription exception and the EHR exception stipulate that the donor entity must not take any actions to limit or restrict unnecessarily the use or compatibility of the items or services with other EHR systems.

6. Receipt of Items or Services Not Condition for Doing Business with Donor

Both exceptions stipulate that neither the physician nor the physician’s practice can make the receipt of items or services a condition for doing business with the donor.

7. Prohibition Against Eligibility for Items or Services Based on “Volume or Value of Referrals”

Both the electronic prescription exception and the EHR exception provide that neither the eligibility of a physician for items or services, nor the amount or nature of items or services, shall be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. However, there is a slight distinction in this requirement under the two exceptions. The EHR exception prohibits determinations that “directly” take into account the volume or value of referrals; whereas, the word “directly” does not appear in the comparable language under the electronic prescription exception.

The EHR exception also specifically describes situations where the determination is “deemed” not to be “directly related to the volume or value of referrals” or other business generated between the parties. Those situations are as follows: (a) where the 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); (b) where the determination is based on the size of the physician’s medical practice (for example, total patients, total patient encounters, or relative value units); (c) where the determination is based on the total number of hours that the physician practices medicine; (d) where 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); (e) where the determination is based on whether the physician is a member of the hospital’s medical staff, if the donor has a formal medical staff; (f) where the determination is based on the level of uncompensated care provided by the physician; or (g) where 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.

8. Physician Payment of 15% of Donor's Cost under EHR Exception

Under the EHR exception, perhaps the most significant change from the proposed regulations is a requirement that the physician pay 15% of the donor's cost for the EHR items and services, before receipt of the items and services. In addition, neither the donor, nor any party related to the donor, can finance the physician's payment or loan funds to be used by the physician to pay for the items or services.

In the commentary to the regulations, CMS states that, in calculation of costs, parties "should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation." CMS further states that methods of cost allocation will be scrutinized to ensure that they do not inappropriately shift costs in a manner that provides an excess benefit to the physician recipient or result in the physician paying less than 15% of the donor's true cost of technology.

9. Donated Technology Not Equivalent to Technology Physician Already Possesses

The donated technology must not be technically or functionally equivalent to technology that the physician already possesses. In the government's view, items and services are not "necessary" if the physician already possesses equivalent items and services. The provision of duplicative items and services, according to CMS and OIG, poses a "heightened risk of abuse, since such arrangements would confer independent value on the physician (that is, the value of the existing items and services that may be put to other uses) unrelated to the need" for this technology. Consequently, if a donor knows that the physician already possesses equivalent items or services, or acts in deliberate ignorance or reckless disregard of that fact, the exception will not protect the donation.

III. Parallel Safe Harbors Under Federal Anti-Kickback Statute

The final information technology safe harbors under the Federal Anti-Kickback statute are essentially identical to the information technology exceptions under the Federal Stark law.

It is important to keep in mind the distinctions between the Federal Stark law and its exceptions and the Federal Anti-Kickback statutes and its safe harbors. If the Federal Stark law applies (because there is a financial relationship between a physician and a provider of designated health services), any referral of a Medicare or Medicaid patients for designated health services is prohibited, unless the referral falls within one of the Stark exceptions. Only such referrals as qualify under one of the exceptions is permitted.

The Federal Anti-Kickback statute prohibits the offer, payment or receipt of any financial inducement in exchange for the referral of Medicare or Medicaid patients. The safe harbors provide immunity for arrangements that satisfy their requirements. The failure to qualify for a safe harbor, however, does not mean that an arrangement is unlawful. Another distinction relates to the sanctions for violating the respective statutes. Violation of the Stark law can result in civil penalties and exclusion from the Medicare, Medicaid and other federally funded programs. Violation of the Anti-Kickback statute can result in criminal penalties (imprisonment, a fine, or both), exclusion from Medicare, Medicaid and other federally funded health care programs, and civil monetary penalties. As a criminal statute, the Anti-Kickback statute is intent based, i.e., there must be a showing of criminal intent in order for a violation to exist.

IV. Federal Tax-Exemption Considerations

Section 501(c)(3) federally tax-exempt entities will need to consider the tax implications related to donation of information technology to physicians.

A. Risk to Tax-Exempt Status: Prohibitions Against Private Benefit and Inurement

Hospitals exempt from Federal income tax under Section 501(c)(3) of the Internal Revenue Code are subject to the prohibitions against private benefit and inurement. These prohibitions mean that the hospital's income and assets cannot inure to the benefit of private non-exempt persons or entities. A commercially reasonable fair market value transaction, such as where the hospital provides information technology items or services to physicians for a fair market value price, does not result in private benefit or inurement. Where, however, information technology items or services are "donated" or gifted to physicians by a tax-exempt hospital, private benefit or inurement is implicated.

In order to prevent or minimize the risk to a hospital's tax-exempt status, the hospital should be able to document and demonstrate the benefit which it or the community derives from the donation arrangement. For example, it can be argued

that providing information technology items or services to physicians on its medical staff furthers the provision of safer and more effective patient care and advances the overall health of the community served by the hospital.

B. Section 4958: Excess Benefit Transaction

Section 4958 of the Internal Revenue Code provides for excise taxes where there is an excess benefit transaction. An excess benefit transaction occurs where the value of an economic benefit provided by a Section 501(c)(3) entity to a “disqualified person” exceeds the value of the consideration received for providing the benefit. A “disqualified person” is a person with substantial influence over the exempt entity during the five year period prior to the transaction.

If a Section 501(c)(3) tax-exempt hospital donates information technology items or services to a physician who falls within the definition of a “disqualified person,” application of Section 4958 will be triggered, resulting in an excise tax on the amount of the excess benefit. Accordingly, before making such a donation, a determination needs to be made as to whether any recipient physicians are “disqualified persons.” If so, any such physicians will need to pay fair market value for the information technology items or services provided by the hospital. The services and items can be donated to all the other recipient physicians, i.e., all physicians who are not “disqualified persons,” without implicating Section 4958.

Conclusion

The issuance of the subject final regulations substantially increases the ability of hospitals and other providers of Medicare or Medicaid services to donate information technology to physicians without violating the Federal Stark law and the Federal Anti-Kickback statute. Such arrangements will need to be carefully structured with appropriate agreements compliant with the subject exceptions and safe harbors.

We Can Help

For additional information about the Federal Stark Law or other health care law matters, contact one of the following Katten Muchin Rosenman LLP attorneys:

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