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**CLIENT ADVISORY**

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**HHS ISSUES FINAL HEALTH  
INFORMATION TECHNOLOGY REGULATIONS**

**Introduction**

On August 8, 2006, the United States Department of Health and Human Services (“HHS”) issued two separate final regulations which are intended to support physician adoption of electronic prescribing (“e-prescribing”) and electronic health records technology. One set of final regulations was issued by the Centers for Medicare and Medicaid Services (“CMS”) and the other set of final regulations was issued by the Office of Inspector General (“OIG”). The CMS regulations create two new exceptions to the Stark Law (42 C.F.R. 411.357(v) and (w)). Similarly, the OIG regulations create two new safe harbors under the Anti-Kickback Statute (42 C.F.R. 1001.952(x) and (y)). These exceptions and safe harbors will allow hospitals and certain other health care organizations to provide physicians with the following: (i) interoperable electronic health record software, information technology and training services; and (ii) hardware, software or information technology and training services necessary for e-prescribing.

**Medicare Modernization Act and Health Information Technology**

The final regulations from HHS are the result of the enactment of the Medicare Modernization Act of 2003 (“MMA”). The MMA created Medicare Part D, the prescription drug benefit. In order to improve patient care and control health care costs, Section 101 of the MMA directed the Secretary of HHS to establish regulations that would permit certain arrangements to foster the adoption of e-prescribing technology. E-prescribing enables a physician to transmit a prescription electronically to the patient’s pharmacy or ancillary provider. Such a process can improve patient safety by decreasing prescription errors due to physician handwriting. Also, e-prescribing enables physicians and pharmacists to obtain information from drug plans about the patient’s eligibility and medication history. Although the health care industry was already aware of the benefits of e-prescribing, such technology represents a significant financial investment. Furthermore, the Stark Law and Anti-Kickback Statute generally prohibits hospitals, group practices and other health care organizations from providing physicians with the hardware, software and technical training necessary to support e-prescribing. Section 101 of the MMA was drafted in order to ensure that health information technology could be provided to physicians without violating the Stark Law or Anti-Kickback Statute.

The Stark Law (42 U.S.C.A., § 1395nn), or Physician Self-Referral Law, precludes a provider from referring Medicare/Medicaid beneficiaries for designated health services to entities which they, or members of their immediate family, have a financial relationship. The designated health services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including MRI, CT Scans and ultrasound services), radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; out-patient prescription drugs and in-patient and out-patient hospitalization services. The Stark Law defines a “financial relationship” as an ownership/investment interest in an entity or a direct or indirect compensation arrangement with an entity. A compensation arrangement includes any arrangement involving any remuneration (direct or indirect, overt or covert, in cash or in kind) between a physician and an entity. Certainly, the Stark Law (prior to the implementation of the new regulations) would generally preclude a hospital from providing health information technology to a physician whom refers patients for designated health services to the hospital.

The Anti-Kickback Statute (“Medicare and Medicaid Patient Protection Act of 1987”, as amended, 42 U.S.C. § 1320a-7b) generally provides for criminal penalties for directly or indirectly knowingly and willfully offering, paying for, soliciting or receiving remuneration of any kind in order to induce business (i.e. referrals) reimbursable under federal or state health care programs, including Medicare and Medicaid. The Anti-Kickback Statute defines remuneration as anything of value. Remuneration could include valuable gifts, waivers of deductibles or copays, or anything else that possesses monetary value. Given the broad nature of the Anti-Kickback Statute, it is clear that the law would generally prohibit a hospital from providing health information technology to its physicians.

### **HHS Issues Final Regulations**

In response to Section 101 of the MMA, Secretary Michael Leavitt of HHS directed the CMS and OIG to draft regulations to enable hospitals and other health care organizations to provide physicians with hardware, software and technical training necessary to support e-prescribing and electronic health records. Secretary Leavitt decided to broaden the scope of the mandate of Section 101 to allow hospitals and health care organizations to also provide physicians with the support necessary to adopt electronic health records. The benefits of electronic health records are similar to the benefits of e-prescribing in terms of reducing medical errors, coordinating care and improving efficiency. HHS issued proposed regulations in October of 2005. After a comment period, HHS made revisions and issued the final regulations on August 8, 2006. The following is an overview of the final regulations.

#### **A. E-Prescribing**

The final HHS regulations allow hospitals and other health care organizations to enter into arrangements with physicians for the provision of e-prescribing technology, without

violating the Stark Law or Anti-Kickback Statute. Specifically, hospitals and other health care organizations are permitted to provide physicians with non-monetary remuneration consisting of items and services in the form of hardware, software, or information technology and training services, provided certain conditions are met. These conditions include, but are not limited to, the following:

- The items and services are provided by: (i) hospital to a physician who is a member of the medical staff; (ii) group practice to a physician who is a member of the group; or (iii) Prescription Drug Plan sponsor or Medicare Advantage organization to a prescribing physician;
- The items and services provided must be necessary and used solely to receive and transmit e-prescription information;
- The items and services are provided as part of, or are used to access, an e-prescription drug program that meets the applicable standards under Medicare Part D;
- The donor does not take any action to limit or restrict the use or compatibility of the items or services with other e-prescribing or electronic health record systems;
- 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 of doing business with a donor;
- Neither the eligibility of the 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 the business generated by the physician;
- The arrangement is set forth in a written agreement; and
- The donor does not have actual knowledge of and did 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 regulations clearly provide that it is not permissible to donate technology that would be duplicative of a physician's pre-existing technology. The preamble to the regulations state that although a hospital or health care organization is not required to receive an attestation from the physician in this regard, some form of inquiry to the physician would be "prudent."

## **B. Electronic Health Records**

As with the final HHS regulations pertaining to e-prescribing, the final regulations for electronic health records permits hospitals and other health care organizations to provide physicians with a 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 electronic health records, provided certain provisions are met. These provisions include, but are not limited to, the following:

- The items and services are provided by an organization to a physician;
- Before receipt of the items and services, the physician pays 15% of the donor's costs for the items and services. 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;
- The donor does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other e-prescribing or electronic health records systems;
- 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 of doing business with the donor
- Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in the manner that directly takes into account the volume or value of referrals or other business generated between the parties.
- The provision of items or services is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met: (i) the determination is based on the total number of prescriptions written by the recipient; (ii) the determination is based on the size of the recipient's medical practice; (iii) the determination is based on the total number of hours that the recipient practices medicine; (iv) the determination is based on the recipient's overall use of automated technology in his or her medical practice; (v) the determination is based on whether the recipient is a member of the donor's medical staff; (vi) the determination is based on the level of uncompensated care provided by the recipient; or (vii) 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;
- The electronic health records software contains e-prescribing capability;
- The arrangement is set forth in a written agreement;
- The donor does not shift the cost of the items or services to any federal health care program; and
- The items and services do not include staffing of physician offices and are not

used primarily to conduct personal business or business unrelated to a physician's medical practice, the electronic health record software contains electronic prescribing capabilities.

One of the more notable conditions contained within the regulations pertaining to electronic health records, is the requirement that physicians pay 15% of the donor's costs for the items and services. The preamble to the regulations states that this cost-sharing provision is intended to encourage "prudent and robust electronic health records arrangements without imposing a prohibitive financial burden on physicians."

### Conclusion

The final regulations from HHS represent a significant development in the health care industry. These regulations will allow hospitals and other health care organizations to provide e-prescribing and electronic health records technology to physicians without violating either the Anti-Kickback Statute or the Stark Law. The regulations become effective on October 10, 2006. Interestingly enough, the exception and safe harbor pertaining to the donation of electronic health records will end on December 31, 2013. This termination date is consistent with President Bush's goal of adoption of electronic health records technology by 2014.

It is the recommendation of The Rogers Law Firm that any consideration to provide physicians with e-prescribing or electronic health records technology be first discussed with our office, in order that we may appropriately structure an arrangement that meets the final regulations from HHS. It is important to note that there are differences between the safe harbors and exceptions for e-prescribing and those of electronic health records. For example, the electronic health records exceptions and safe harbors have a recipient cost-sharing requirement, while the safe harbors and exceptions associated with e-prescribing do not. Furthermore, any proposed arrangement to provide physicians with e-prescribing or electronic health records technology needs to be analyzed under applicable IRS regulations pertaining to tax-exempt organizations.

It is also important to note that U.S House of Representatives recently passed the "Health Information and Technology Promotion Act of 2006." A different version of this legislation has already been passed by the U.S. Senate. There is an issue as to whether the reconciling of these two bills may lead to the preemption of the final HHS regulations. The result may be the issuance of new safe harbors and exceptions which will provide even greater flexibility for hospitals and other health care organizations to provide e-prescribing and electronic records technology to physicians. Our office will monitor any Congressional action in this regard and will provide updates accordingly.

In the interim, The Rogers Law Firm is available to discuss the final HHS regulations in further detail and provide any assistance necessary.

