

## CMS AND THE OIG ACT TOGETHER TO PROTECT DONATIONS OF INFORMATION TECHNOLOGY

IF YOU HAVE QUESTIONS REGARDING THIS MATTER, PLEASE CONTACT:



**Kathryn Midboe Darling**  
Partner, Austin  
600 Congress Avenue, Suite 1600  
Austin, Texas 78701  
512.499.3678  
Kathy.Darling@strasburger.com

### EDITORS

Kathy Darling & Kevin Wood

### HEALTHCARE GROUP

Tejal Banker  
Virginia A. Barry  
Debra W. Biehle  
Thomas W. Burton  
Renee Chafitz  
Merritt M. Clements  
Joseph F. Coniglio  
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David L. Ovard  
Donald Patrick Owens  
Paul W. Sheldon  
Joseph A. Turano  
Melissa Webb  
Carol D. Williamson  
Ivan Wood  
Kevin M. Wood

\*Not licensed to practice in the state of Texas.

Acting under the authority of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services acted in concert to provide exceptions to the Stark prohibitions and safe harbors to the anti-kickback rules for donations of information technology (IT) to physicians and physician groups for the express purpose of prescribing drugs under the new Part D prescription drug benefit. Under their separate authority to promulgate regulations consistent with their applicable statutes, CMS and the OIG created an exception to Stark and a safe harbor from the anti-kickback rules for donating IT and services to physicians for the purpose of producing interoperable health care records. CMS and the OIG had each published proposed rules in October, 2005. These new regulations were published on August 8, 2006, are final rules under both laws, and are effective as of October 7, 2006.

The theory behind the new exceptions/safe harbors is that electronic health records (EHR) and prescribing help physicians provide higher quality patient care and improve efficiency and patient safety. The use of an electronic format is expected to reduce handwriting and communication errors, to check automatically for drug interactions and allergies, to eliminate duplicative laboratory and diagnostic tests, and to coordinate care among a patient's various care givers. The new exceptions/safe harbors constitute an acknowledgement on the part of CMS and the OIG that physicians must be the center of the operation; that physicians are not in a position to handle the financial burden of initiating and implementing these changes; and that institutions, suppliers, prescription drug plan sponsors or Medicare Advantage organizations should shoulder the bulk of the cost.

### PROVISIONS OF THE REGULATIONS

The primary provisions of the exceptions/safe harbors are as follows:

An entity [which could be a hospital, a physician group, a health plan, or a prescription drug plan sponsor] may donate to a referring physician hardware (for electronic prescriptions only), software, information technology and training services for (a) the sole purpose of receiving and transmitting electronic prescriptions and/or (b) for the predominant purpose of creating, maintaining, transmitting or receiving electronic health records so long as all of the following conditions are met:

(1) The arrangement is set forth in a written agreement which specifies the items and services provided, the donor's cost for the items, covers all of the items and services provided by the donor (in a single document or in separate agreements which are identified on a master list);

(2) For EHR donations, the system must be interoperable, as certified by the Secretary;

(3) For EHR donations, the physician must pay 15% of the donor's cost for the items and services before the physician receives them;

(4) For prescription drug IT donations, the items and services provided meet the applicable standards under a Medicare Part D plan;

(5) The donor does not restrict use of the items or services to patients depending on payor status;

(6) The physician does not make receipt of the items or services a condition of doing business with the donor;

(7) Selection of the physician or the amount or nature of items or services provided does not take into account the volume or value of referrals or other business generated between the parties. For EHR donations, this requirement is met if ANY ONE of the following conditions is met:

(i) The physician may be included as a recipient of donated items based on the number of prescriptions written by the physician but not by the volume or value of prescriptions dispensed or paid by the donor or billed to Medicare;

(ii) The physician is included based on the size of his medical practice (total patients, total encounters, total RVUs);

(iii) The physician is included based on the total number of hours that the physician practices medicine;

(iv) The physician is included based on the physician's overall use of technology;

(v) The physician is included based on the fact that s/he is on staff or a member of the physician group;

(vi) The physician is included based on the level of uncompensated care provided by the physician; or

(viii) The physician is included in any reasonable and verifiable method which does not take into account the volume or value of referrals or other business generated.

(8) For EHR donations, the donor does not limit or restrict the use, compatibility or interoperability of the donated items or services with other electronic prescribing or EHR systems;

(9) For EHR donations, the donor is not aware (and does not act in deliberate ignorance) that the physician already possesses or has obtained items or services equivalent to those being donated;

(10) For EHR donations, the donated items and services do not include staffing of the physician's office and are not used primarily to conduct personal business or business unrelated to the physician's practice;

(11) The EHR software contains electronic prescribing capability, either through an electronic prescribing component or through interface with existing prescribing system that meets the Medicare Part D standards;

(12) The donor does not shift the costs of the donated items or services to the Medicare program; and

(13) The donations are made and received and all other conditions are met on or before December 31, 2013.

## **ADDITIONAL CONSIDERATIONS**

Of special note are several provisions which the industry requested but which were rejected in the preamble language. For example, donors will not be allowed to reimburse physicians for previously-installed IT equipment or services. The regulations only cover donations made after implementation of the regulations. However, upgrades that would assist with the interoperability requirement or that would make the software comply with the certification standards will be covered.

Some commenters wanted to prohibit commercial messaging or marketing through pop-ups or to build in protections so that differing prescribing mechanisms could steer a user to a particular product. The government response is that the "necessary and used solely" for prescribing would be the basis on which those activities would be excluded. Also, since hardware is not protected for EHR, routers or modems required to access or enhance connectivity are not protected.

In addition, CMS postulated in the preamble that physicians would likely use model agreements with the donors which will have been

drafted by national organizations representing attorneys, physicians, group practices, or designated health service entities. Standardization of agreements goes hand in hand with the interoperability requirement.

There is no cap on the value of the donated items and services. The theory is that the 15% cost-sharing component for EHR items and services will encourage prudent purchasing. The other intended purpose of the cost-sharing provision is to encourage actual use of the technology by the recipient and office staff.

The protected software required for EHR must be used predominantly to create, maintain, transmit, or receive electronic health records. The software must include an electronic prescribing component but may also include functions related to patient administration like scheduling, billing, and clinical support. The IT services can include internet connectivity and help desk support services, although it expressly precludes providing on-site staff to the physician's office.

The new exceptions/safe harbors appear to us to be the beginning of a process that will ultimately encompass the pay for performance payment methodologies and that presage the cost-sharing necessary across industry lines to accomplish the goals of efficiency in medical care. The entities/institutions that step forward first and make themselves the most invaluable to physician practices will be the entities that will determine the direction of pay for performance and the ultimate payment winners in that arena. It will be interesting to see who those players turn out to be.