EHR Donation: Compliance with Stark Law and the Anti-Kickback Statute

Digital Medical Office of the Future: Driving Toward Meaningful Use

Las Vegas, NV
September 9, 2010

Lawrence W. Vernaglia, J.D., M.P.H.
Foley & Lardner LLP
617.342.4079
lvernaglia@foley.com
Agenda

- Stark law ("Stark") and Anti-kickback Statute ("AKS")
- Donation of electronic health records ("EHR")
- Questions and Answers
Overview of Stark and AKS

- **Stark** – civil law; prohibits MD referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he has a financial relationship (ownership or compensation), unless an exception applies.

- **AKS** – criminal law; prohibits “knowing and willful” offer or receipt of remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.
What is a donation?

- “Information” has no independent value
- 5/08 Stark Advisory Opinion: donation of custom software interface not remuneration because used solely to communicate the results of tests or procedures (CMS-AO-2008-01).
Stark/AKS EHR Regulations

- August 8, 2006, CMS and OIG final rules
- Permit donation of health information technology items and services for e-prescribing and EHR.
- 12 elements
Summary of Safe Harbor/Exception

1. Donated EHR items and services must be used predominately to create, maintain, transmit, or receive EHR.

EHR software may have ancillary functions, provided that the EHR functions predominate and that the ancillary functions directly relate to the care and treatment of individual patients;
2. The EHR software must be interoperable at the time it is provided to the physician.

Deemed interoperable if a certifying body recognized by the HHS certified the software no more than 12 months prior to the date it is provided to the recipient;
3. The donor must not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other prescribing or EHR systems;
4. Before receipt, MD pays at least 15% of the donor’s cost for the items and services (the “Physician Contribution”).

The donor can’t finance the Physician Contribution or loan funds to be used by the physician to pay for the items and services;
5. MD can’t make receipt of items or services a condition of doing business with the donor;
6. Neither eligibility of MD, nor the amount or nature of the items and services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties;

(Regulations list seven circumstances in which the arrangement is deemed to not directly take this into account.)
7. Written agreement between the parties sets forth the costs and other terms of the arrangement;
Summary of Safe Harbor/Exception

8. MD must not already have such technology.

Donor can’t have actual knowledge, reckless disregard, deliberate ignorance;

May upgrade items or services to enhance MD’s existing technology, or standardize systems among MDs;
9. Donor does not restrict MD’s right or ability to use the items and 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 unrelated to the physician’s medical practice;
11. Donor does not shift the costs to any Federal health care program; and
12. The EHR contains electronic prescribing capability.
In a memorandum dated May 11, 2007, the IRS provided comfort to tax-exempt entities that their subsidies of EHR technology will not jeopardize their tax-exempt status as long as:

- The hospital and physicians comply with the Stark and AKS EHR Regulations,
- The EHR subsidy arrangement provides that, to the extent permitted by law, the hospital may access the electronic medical records created by the physicians,
Tax Exempt Status risks? (cont.)

- Participation is open to all medical staff members on an equal basis, and
- The hospital provides the same level of subsidy to all of its medical staff physicians or varies the level of subsidy by applying criteria related to meeting the healthcare needs of the community.
Typical arrangements

- Direct EHR donations by hospitals.
- Tripartite arrangements.
- Joint venture arrangements.
How to measure costs for Physician Contribution?

- Donation caps;
- Projection of costs over roll-out;
- Timing;
- Annual subsidies;
What technology can be donated?

- Software or information technology and training services in which the EHR function predominates.
- Software must contain e-prescribing capability.
- Interface and translation software, rights, licenses and intellectual property related to software, connectivity services (including wireless and broadband), clinical support and information services related to patient care, maintenance services, secure messaging, and help desk and similar support.
- Not hardware, staff (e.g., staff to transfer paper records to electronic format), or monetary remuneration.
- EHR must be predominant use.
Additional exceptions - not for discussion today

- Electronic prescribing items and services
- Community-wide health information systems
Incentive Funding Under the HITECH Act

- Billions of dollars in financial incentives for the adoption of EHR technology made available under the HITECH Act.
- Hospitals and “eligible professionals” (EPs) may be eligible for incentive payments for their use of EHR. Requirements include:
  - Use of “certified” EHR
  - “Meaningful use” of EHR
- Final regulations regarding “meaningful use” and other aspects of incentive payments published on July 28, 2010 (effective September 27, 2010).
“Hospital-based eligible professionals” are ineligible for incentive payments.

The final regulations define “hospital-based EPs” as EPs who provide more than 90 percent of their covered professional services in inpatient or emergency room settings, as defined by POS codes 21 and 23.

The Continuing Extension Act of 2010, signed into law on April 15, 2010, and the final EHR regulations clarify that EPs practicing in hospital outpatient clinics will not be considered “hospital-based.”
Questions?

Lawrence W. Vernaglia
Foley & Lardner, LLP

617.342.4079
lvernaglia@foley.com