American Hospital Association

# Regulatory Advisory

**August 28, 2006**

# FINAL "STARK" AND ANTI-KICKBACK REGULATIONS ON HEALTH INFORMATION TECHNOLOGY

## AT A GLANCE

### The Issue:

The Department of Health and Human Services (HHS) in the August 8 *Federal Register* published two final rules providing exceptions to the physician self-referral, or "Stark," law and safe harbors under the anti-kickback law for donations of items and services for electronic health records (EHRs) and e-prescribing. These rules take effect October 10 and expire December 31, 2013.

### Our Take:

Hospitals with a desire to provide community physicians with technology-related assistance should be able to do so without fear of violating the Stark and anti-kickback laws. In drafting the final rules, HHS took into account many comments from the AHA and others, removing several significant barriers. However, the AHA questions how certain aspects – most notably, the software interoperability requirement – will work in practice. The AHA will seek clarification to enable hospitals to make the fullest use of the new rules.

### What You Can Do:

To ensure that your organization is prepared to benefit from these final rules:

- Share this advisory with your senior management team.
- Involve your legal counsel in determining how the final rules will affect your organization's plans to assist physician IT adoption.

### Further Questions:

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*AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. An eight-page, in-depth examination of this issue follows.*

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## BACKGROUND

To realize the full promise of health information technology (IT), information must be shared across patient care settings, including physicians' offices and hospitals. Many physicians, however, do not have the financial or technical resources needed to navigate the complex IT market. While not all are in a position to do so, some hospitals may want to provide community physicians with software, connectivity or other IT-related assistance that would allow them to maintain electronic health records (EHRs) for their patients and share clinical data with the hospital. When hospitals and health systems directly or indirectly fund IT systems for physicians, however, they encounter significant barriers imposed by the physician self-referral, or "Stark," and anti-kickback laws.

Stark prohibits a physician from referring Medicare and Medicaid patients for certain designated health services to an entity if the physician – or a member of the physician's immediate family – has a financial relationship with that entity. The anti-kickback law makes it a felony for anyone to knowingly and willfully give a physician anything of value – including both cash and in-kind payments – in exchange for a referral. It is likewise illegal for physicians to ask for or receive anything of value in exchange for a referral. Both laws carry severe penalties.

In attempting to help physicians "get wired" so that patient information can be shared, health care providers remain uncertain about what would constitute violations of these laws or create a risk of litigation. Generally, exceptions to the Stark law do not directly address health IT arrangements. The anti-kickback law provides a number of safe harbors that would not impose liability for certain types of financial arrangements, but these safe harbors also do not directly address health IT arrangements.

In the August 8 *Federal Register*, the Centers for Medicare & Medicaid Services (CMS) published a final rule providing limited exceptions to the Stark law for

donations of e-prescribing and EHR technology to physicians. The same day, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) published a parallel final rule providing a safe harbor under the anti-kickback law for similar donations.

The final CMS rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-6667.pdf.

The final OIG rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-6666.pdf.

## *AT ISSUE*

Hospitals have found that the existing Stark exceptions – outside of the unworkable community-wide exception – and anti-kickback safe harbors are not specifically applicable to health IT ventures, and offer limited, if any, flexibility for working with community physicians. These new final rules will provide hospitals with greater flexibility to give physicians certain IT items and services. However, several limitations remain, including the prohibition on providing hardware under the EHR exception and a requirement that EHR-related software be interoperable, as well as administrative burdens.

## *AS IT STANDS*

### *Stark Exceptions*

The CMS final rule includes two exceptions to the Stark law: one for the sharing of IT resources to support EHRs, and one for items and services related to e-prescribing. Both exceptions cover arrangements between hospitals and physicians. Other aspects of the exceptions, including allowable donors, recipients and covered technology vary. The exceptions expire December 31, 2013.

#### Electronic health records (EHRs) exception

CMS used its existing regulatory authority to create the EHR exception, which allows hospitals and other entities that furnish designated health services to provide "software or information technology and training services" to any physician, as long as the technology is used "predominantly to create, maintain, transmit or receive" EHRs. The arrangement also must comply with the anti-kickback statute.

## Covered technology

In response to comments from the AHA and others, CMS significantly broadened the scope of covered technology in the final rule to include:

- software that meets certain conditions;
- interfaces and translation software;
- rights, licenses and intellectual property related to EHR software;
- connectivity services, including broadband and wireless Internet services;
- clinical support and information services related to patient care;
- maintenance services;
- secure messaging; and
- training and support services.

## Covered software

While CMS significantly broadened the scope of covered technology, it also placed three conditions on donated software.

First, the software must be used "predominantly to create, maintain, transmit or receive" patient EHRs. However, the software may include other functions that support patient care such as administration, scheduling, billing or clinical support.

Second, it must have an e-prescribing capability, either through an e-prescribing component or the ability to interface with a physician's existing e-prescribing system. The capability must incorporate the relevant standards of Medicare's drug program (the first set of these e-prescribing standards is codified at 42 CFR §423.160).

Third, the software must be interoperable. The final rule provides a benchmark definition of interoperability, but the preamble suggests some room for independent judgment. The final rule also establishes a "deeming" mechanism for those who want to ensure their donations meet the interoperability criteria. How this requirement will work in practice requires additional consideration.

The final rule defines interoperable software as being "able to (1) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (2) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." The preamble goes on to state that "software will not be considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community."

Software is not likely to fully meet this comprehensive definition of interoperability for many years. CMS appears to recognize this when it states in the preamble that "the ability of software to be interoperable is evolving as technology develops," and that "the appropriate inquiry is whether the software is as

interoperable as feasible given the prevailing state of technology at the time the items or services are provided."

To assess software's interoperability, the final rule recommends that donors consult the standards and criteria related to interoperability that have been recognized by HHS. In a notice published in the August 4 *Federal Register*, the HHS Secretary recognized certain standards and criteria put forth by the Certification Commission for Health Information Technology (CCHIT) (see FR Vol. 71, No. 150, p. 44295-6 and referenced documents).

If donors do not want to judge interoperability for themselves, the rule also includes a "deeming" provision. Software that has been certified by an organization recognized by the HHS Secretary within the 12 months prior to the date of the donation will be considered interoperable.

HHS has taken steps to establish a certification process. On August 4, the Office of the National Coordinator for Health Information Technology published a *Federal Register* notice including interim guidance on recognition of certification bodies, and stated its intent to pursue formal rulemaking on policies and procedures for recognizing a certification body. In the meantime, it will follow the interim guidance to recognize bodies such as CCHIT (see FR Vol. 71, No. 150, p. 44296-7 and referenced documents).

Despite these steps, certification efforts are still in their infancy and have yet to be tested in the marketplace. CCHIT only released its first round of certifications on July 18. In addition, the current criteria principally cover functional attributes of ambulatory EHR products: of more than 150 criteria, only one directly addresses interoperability (certification criteria can be found at http://www.cchit.org).

## Selection of recipients

Hospitals (or other donors) may not consider the volume or value of referrals or other business generated between the parties when making a donation to a physician. However, hospitals may use criteria not directly related to volume or value of referrals when selecting which physicians to work with. CMS has deemed several criteria to be unrelated to the volume or value of referrals, as long as they are measured with regard to the physician's overall practice, and not just the patients he or she might refer to the donor. They include:

- total number of prescriptions written by the physician across his or her practice;
- the size of the physician's medical practice (total number of patients, total number of patient encounters or total relative value units);
- the total number of hours that the physician practices medicine;
- the physician's overall use of automated technology in his or her medical practice;

- membership on the hospital's medical staff; and
- the level of uncompensated care provided by the physician.

In addition to these specific criteria, hospitals (and other donors) may use any reasonable and verifiable criteria that do not directly take into account the volume or value of referrals or other business generated between the parties. Nothing in the exception requires that technology be provided to all potential recipients at the same time.

### Limitation on donation of equivalent technology

The donated items cannot be "equivalent" to items the physician already has. While this requirement is less stringent than the one originally proposed, it still puts a burden on the donor. The donor "cannot have knowledge of or act in reckless disregard or deliberate ignorance of the fact" that the items are equivalent. CMS states in the preamble that expert consultation is not needed to make this determination. Instead, it recommends that hospitals and other donors make inquiries of physicians and other recipients about their existing resources and document the correspondence.

### Documentation requirements

The arrangement between the donor and recipient must be detailed in a written document. The document should list all of the items and services being provided, as well as the donor's costs, and be signed by all parties. If a physician receives multiple donations from a single source, the donor can meet this requirement by either keeping a master list of agreements or referencing the other agreements.

### Physician contribution

The physician must pay 15 percent of the donor's costs for the items and services provided. During an August 11 open-door forum, CMS staff indicated that the agency would view differing contribution rates across physician recipients as troubling because they could signal a link to volume or value of referrals. However, hospitals (and other donors) should feel comfortable asking for a higher rate of cost-sharing, as long as the rate is the same across all recipients. Hospitals (and other donors) cannot finance the physician's contribution.

### Other conditions

The final rule includes three other conditions:

- The hospital (or other donor) may not disable or limit any interoperability functions the technology may have. Hospitals will need to pay attention to how this provision impacts decisions related to product customization.
- The hospital (or other donor) may not limit the kind of patients for whom the physician can use the technology (e.g., by payer).

- The recipient may not make receipt of technology a condition of doing business with him/her.

## E-prescribing exception

*The Medicare Modernization Act of 2003* (MMA) required CMS to create an exception to the Stark law for e-prescribing technology. Given the limitation that donated items must be used solely for e-prescribing purposes, it is unlikely that hospitals will make broad use of this exception. The EHR exception provides greater latitude for hospitals wishing to assist physicians with IT adoption.

Under the final rule, hospitals may provide certain e-prescribing items and services to members of their medical staffs. Other donor/recipient relationships were specified in the MMA and include group practices and their physician members, as well as Medicare Part D Prescription Drug Plan sponsors or Medicare Advantage organizations and prescribing physicians and pharmacies. Clinical laboratories are not included.

Covered technology includes software, hardware, related training and support services and Internet connectivity. There is no limit on the value of the donation. However, the following conditions, similar to those found in the EHR exception, apply:

- The items must be used solely to receive and transmit "electronic prescription information," which CMS defined as information about prescriptions for drugs or any other item or service normally obtained through a written prescription.
- The items must be used to access an e-prescribing program meeting the e-prescribing standards of Medicare's drug program (the first set of these standards is codified at §423.160).
- The items are not "technically or functionally equivalent" to items the recipient already has. The donor cannot have knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the items are in fact technically or functionally equivalent to items the recipient already possesses. CMS recommends that hospitals and other donors make inquiries of physicians and other recipients about their existing resources, and document the correspondence.
- The donor cannot disable or limit any interoperability functions the technology already may have, or limit the kind of patients for whom the physician can use the technology (e.g., by payer).
- The donor cannot consider the volume or value of referral or other business generated between the parties.
- The recipient cannot make receipt of technology a condition of doing business with him/her.
- The arrangement must be detailed in a written document signed by the parties that lists the items and services being provided and the donor's costs for the donation.

## Anti-kickback Safe Harbors

The final OIG rule creates two safe harbors under the federal anti-kickback statute: one for donation of technology for EHRs, and one for e-prescribing technology. These safe harbors largely mirror the exceptions to the Stark law. However, because the anti-kickback law covers a broader range of entities than the Stark law, who may give and receive the technology varies across the Stark exceptions and safe harbors. Within the safe harbors, the e-prescribing regulations address a smaller set of actors than the EHR regulations, due to the specifications of the MMA.

### EHR Safe Harbor

The EHR safe harbor allows hospitals to provide "software or information technology and training services" to any physician, individual or organization that provides health care, as long as the donation is used "predominantly to create, maintain, transmit or receive" EHRs and meets the additional criteria. Since the anti-kickback law applies to all who bill for or influence the use of federally funded health services, the range of other protected donors is broad: people and organizations that provide health services covered by a federal health program (such as Medicare and Medicaid), as well as health plans. Protected recipients include people and organizations that provide health care.

The covered technology and conditions that must be met under the safe harbor mirror those of the Stark exception (see above). One additional requirement of this safe harbor is that the hospital (or other donor) cannot shift the costs of their items and services they provide to a federal health program.

### E-prescribing Safe Harbor

Hospitals may give certain items and services to members of their medical staffs, as long as they are used solely to receive and transmit electronic prescription information. Other donors and recipients include group practices and their physician members, as well as Medicare Part D Prescription Drug Plan sponsors or Medicare Advantage organizations and prescribing physicians (clinical laboratories are not included). The covered technology and conditions for the safe harbor are essentially the same as those in the Stark e-prescribing exception laid out above.

As with the Stark e-prescribing exception, items provided by a hospital must be used solely for e-prescribing. Consequently, the e-prescribing safe harbor is less likely to be of use to hospitals than the broader EHR safe harbor.

## NEXT STEPS

In response to comments from the AHA and others, the final rules remove several significant barriers and provide considerably greater flexibility than originally proposed. In addition to expanding the range of covered technology

and services that can be provided, the final rules:

- allow donations to any physician, not just those on a hospital's medical staff;
- allow hospitals to use criteria not directly related to volume or value of referrals in selecting which physicians to work with;
- do not limit the value of the donation (although, as noted above, the physician must share in the donor's costs); and
- set a lower bar for determining whether a physician already has equivalent technology.

Nevertheless, the final rules have some limitations, ambiguities and burdensome administrative requirements, including:

- the requirement that software be interoperable;
- the prohibition against limiting the existing interoperability of the technology, and whether it may impact customization decisions;
- the documentation requirements, including those needed to ascertain that the technology provided is not "equivalent" to something the physician already has;
- the practical implementation problems posed by the requirement that software be certified within the 12 months prior to the donation, particularly for installations rolled out over multiple years; and
- the prohibition against providing hardware.

The AHA will continue to work with CMS and OIG to address these issues so that hospitals are able to make the fullest use of the new rules.

If you have questions, please contact Chantal Worzala, senior associate director for policy, at (202) 626-2319 or cworzala@aha.org, or Lawrence Hughes, regulatory counsel at (202) 626-2346 or lhughes@aha.org.