American Hospital Association

Regulatory Advisory

This Regulatory Advisory, a special service to America's hospitals, contains guidance about physician self-referral and anti-kickback regulations.

Stark and Anti-kickback Regulations: Proposed Changes for E-prescribing and Electronic Health Records

A Message to AHA Members:

The Centers for Medicare & Medicaid Services (CMS) published October 11, 2005 in the *Federal Register* a proposed rule that would provide limited exceptions to the physician self-referral or "Stark" law for e-prescribing and electronic health records. On the same day, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) published a proposed rule providing a safe harbor to the anti-kickback law for e-prescribing. Comments on both proposed rules are due by December 12, 2005. No expected date for final rules was given.

The proposed CMS rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20322.pdf.

The proposed OIG rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20315.pdf.

The proposed rules aim to give hospitals more flexibility to provide physicians on their medical staffs with certain information technology (IT) items and services for e-prescribing and electronic health records (EHRs) through protections from prosecution under the Stark and anti-kickback laws. The attached *Regulatory Advisory* provides a more detailed description of the requirements of the proposed exceptions to the Stark law and the proposed safe harbor under the anti-kickback statute.

The proposed Stark exceptions apply to the provision of resources for:

- E-prescribing,
- EHRs in advance of national standards for interoperability, and
- EHRs after national standards for interoperability have been adopted and incorporated into a certification process.

The OIG rule proposes regulatory language for an anti-kickback safe harbor for e-prescribing, but does not include language for an EHR-related safe harbor. The proposed

rules limit what resources hospitals can provide to their medical staffs and include significant conditions that may be difficult for hospitals to meet. In its current form, the proposed Stark exceptions are not likely to provide hospitals with the needed protection to help physicians adopt EHRs, particularly in the near term. Also, without a corresponding safe harbor for EHRs under the anti-kickback law, hospitals still could be vulnerable under the Stark exception, since it requires that the arrangements comply with the anti-kickback statute. The AHA continues to examine the implications of these proposals for hospitals and will submit comments on both before the December comment deadline.

To ensure that your organization is prepared to share its perspective on these proposed rules with CMS and OIG, check off the following items from your to-do list:

- Share this advisory with your senior management team.
- Ask your legal counsel to examine how the proposed rules would affect your organization's plans to assist physicians in adopting IT.
- Submit your comments on the proposed rules to CMS and the OIG before the December 12 deadline. Feel free to use the AHA's comment letter as a guide; it will be available in early December at **www.aha.org**.

Although hospitals should not be required to help physicians develop their IT resources, the AHA supports efforts to allow hospitals that want to provide appropriate IT assistance to do so without running afoul of the Stark and anti-kickback laws. By working together, we hope to persuade CMS and the OIG to provide more meaningful exceptions and safe harbors. The AHA also will continue to work with Congress so that legislative efforts ensure that hospitals have the needed flexibility to assist physicians in adopting IT. If you have questions please feel free to contact Chantal Worzala, senior associate director for policy, at (202) 626-2319 or cworzala@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

November 7, 2005

American Hospital Association

Regulatory Advisory

Stark and Anti-kickback Regulations: Proposed Changes for E-prescribing and Electronic Health Records

November 7, 2005

Background

The Centers for Medicare & Medicaid Services (CMS) published October 11, 2005 in the *Federal Register* a proposed rule that would provide limited exceptions to the physician self-referral or "Stark" law for e-prescribing and electronic health records (EHRs). On the same day, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) published a proposed rule that would provide a safe harbor to the anti-kickback law for e-prescribing. Comments on both proposed rules are due by December 12, 2005. No expected date for final rules was given.

The proposed CMS rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20322.pdf.

The proposed OIG rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20315.pdf.

The proposed rules aim to give hospitals more flexibility by providing protections from prosecution under the Stark and anti-kickback laws when they provide physicians on their medical staffs with certain information technology (IT) items and services for e-prescribing and electronic health records (EHRs). This *Regulatory Advisory* provides a more detailed description of the requirements of the proposed exceptions to the Stark law and the proposed safe harbor under the anti-kickback statute.

Both the Stark and anti-kickback laws impose severe penalties on hospitals and physicians for any violations, and fear of potential violations is inhibiting progress in IT adoption. The federal physician self-referral (or Stark) law prevents physicians from referring Medicare and Medicaid patients to organizations in which they have a financial interest, including inpatient and outpatient hospital care. The anti-kickback law prohibits any remuneration in exchange for referring a patient covered by a federal health program. Under either statute, remuneration includes both cash and in-kind payments. Both laws come into play when a hospital considers providing physicians with hardware, software or other technology-related assistance that would allow the physicians to maintain electronic health records for their patients and thus improve the continuity and quality of care.

The use of EHRs within hospitals and physician offices promises to improve quality of care. Even greater benefits can be obtained by sharing information across health care providers so that, for example, emergency department staff can see medical histories, and primary care physicians can know what medications were given during an inpatient stay. However, many physicians are wary of investing in IT because of the costs and risks of these investments, and because staff lacks IT experience.

Some hospitals' IT systems are more advanced than those of the physicians practicing in the community. Hospitals also have greater access to capital for financing health IT's considerable costs – recent estimates put the price tag at $156 billion – and have larger and more experienced IT staff that can help physician offices adopt EHRs. Some hospitals have indicated a desire to provide community physicians with hardware, software or other technology-related assistance that would allow them to share clinical information and facilitate quality improvement goals.

Hospitals, however, have found that the Stark law's current exceptions and the anti-kickback statute's existing safe harbors are not specifically applicable to health information technology ventures and offer limited – if any – flexibility to hospitals wishing to work with community physicians. With passage of the Medicare Modernization Act (MMA), the HHS Secretary is required to provide a Stark exception and anti-kickback safe harbor for e-prescribing technology. Hospitals and others have advocated for an additional exception and safe harbor for a broader scope of health IT items and services. After a long wait, the Secretary has provided details on these proposed Stark exceptions and anti-kickback safe harbors that are described below.

Proposed Stark Exceptions

CMS' proposed rule includes three exceptions to the Stark law. The exceptions would allow hospitals to provide certain IT items and services to physicians on their medical staffs, but would not apply to physicians who do not routinely furnish services at the hospital. It would not protect remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital. Other covered donors include prescription drug plans (PDPs) and Medicare Advantage plans working with participating pharmacies, pharmacists and prescribing physicians, as well as physician group practices (PGPs) working with their members.

E-prescribing exception: Donors (e.g., hospitals) would be allowed to provide software, hardware, related training and support services, and connectivity, with the following conditions:

- The items are used solely for e-prescribing.

- The items are used to access an e-prescribing program that meets the e-prescribing standards of Medicare's drug program (Part D), which were proposed in Spring 2005 and should be final this fall.

- The items are not "technically or functionally equivalent" to items the recipient already has. The recipient must certify that this is the case. 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.

- The donor does not 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 does not consider the volume or value of referral or other business generated between the physician and the donor.

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

- The arrangement is detailed in a written document and kept up to date.

The proposed rule discusses and seeks comment on an exception that would allow provision of hardware or connectivity that has multiple functions (e.g., a computer, PDA, or internet connection that is used for more than e-prescribing). However, no regulatory language is provided. It also asks for cost estimates and comments on whether to limit the value of the technology.

The AHA is concerned about the usefulness of an exception that is based on a stringent requirement that the IT be used solely for e-prescribing and the paperwork burden imposed by the documentation and reporting requirements.

Electronic health records (EHRs) exceptions: In setting out proposed EHR-related exceptions to the Stark law, CMS identifies two stages of IT development: one before national interoperability standards and a certification process are established, and one after.

In both periods, the same donors and recipients are covered as under the e-prescribing exception (for hospitals and members of the medical staff). Donors (e.g. hospitals) would be allowed to provide only EHR software that includes an e-prescribing component compliant with the Part D standards and related training, but not hardware or connectivity. CMS also indicated in the preamble to the proposed rule that it is considering requiring a component for computerized physician order entry (CPOE) and compliance with public health information network standards, such as those in BioSense. CMS asks for specific comments on these potential additional requirements.

In the pre-interoperability period, the software could not include any billing, scheduling, or other practice management functions. In the post-interoperability period, these functions would be allowed as long as the core function of the software is electronic health records and the software has been certified in accordance with product certification criteria adopted by the Secretary.

Regardless of the developmental stage, the arrangement also must comply with the anti-kickback statute. Other conditions of the EHR exceptions, whether in the pre- or post-interoperable stage, are essentially the same as those for the e-prescribing exception. Specifically:

- The items are not "technically or functionally equivalent" to items the physician already has.

- The donor does not disable or limit any interoperability functions the technology may have or limit the kind of patients for whom the physician can use the technology (e.g., by payer).

- The donor does not consider the volume or value of referral or other business generated between the physician and the donor.

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

- The arrangement is detailed in a written document and kept up to date.

CMS also seeks comments on whether to limit the value of the technology provided through a cap and estimates of costs.

The AHA is particularly concerned about the exception's limits on who can receive the IT items and services, the scope of the items and services that can be provided, the additional conditions that must be met to come within the exception, and the burden of the documentation and reporting requirements. We also are concerned about the impact that a possible cap on the value of the items and services provided may have. Finally, we question the necessity of distinguishing between the pre- and post-interoperability periods and the appropriateness of the certification mechanism for determining that donated software is interoperable.

Proposed Anti-kickback Safe Harbor

The proposed OIG rule would grant a safe harbor under the federal anti-kickback statute for the donation of technology for e-prescribing. The conditions for complying with this safe harbor are essentially the same as those that apply to the exception to the Stark law for e-prescribing.

The proposed OIG rule does not include a safe harbor for EHR systems. The proposed rule states that the OIG does "not have sufficient information at this time to draft appropriate safe harbor language," but asks for comments on the features of a safe harbor that might be drafted. The features discussed in the preamble to the proposed rule are essentially those discussed under the proposed Stark exceptions.

The AHA is disappointed that that the OIG has not proposed regulatory language for an anti-kickback safe harbor for EHRs. Without a corresponding safe harbor for EHR under the anti-kickback law, hospitals still may be reluctant to pursue important IT arrangements with physicians that are clearly permissible under the Stark exceptions, fearing that those arrangements may violate the anti-kickback statute. The AHA will encourage the OIG to establish such a safe harbor, outlining our recommendations for appropriate regulatory requirements for ensuring that the safe harbor is workable and useful for hospitals that want to provide EHR-related items and service to physicians.

Summary

The AHA supports giving increased flexibility for hospitals that want to provide IT items and services for physicians. This position is part of a broader IT strategy being developed with the guidance of the AHA's Member Advisory Group on IT. Hospitals should not be required to help physicians develop their IT resources. However, hospitals that want to provide appropriate IT assistance should be able to do so without fear of violating the Stark and anti-kickback laws.

The AHA is concerned that, as currently constructed, the proposed Stark exceptions are not likely to provide hospitals with needed protection if they are to help physicians adopt EHRs, particularly in the near term. Additionally, without a corresponding safe harbor for EHRs under the anti-kickback law, hospitals still could be vulnerable under the Stark exception, as it requires that the arrangements not violate the anti-kickback statute.

The AHA continues to examine the implications of the proposals for hospitals, and will submit comments on both before the December comment deadline. The AHA also will continue working with Congress so that legislative efforts ensure that hospitals have the needed flexibility to assist physicians in adopting IT. If you have questions please feel free to contact Chantal Worzala, senior associate director for policy, at (202) 626-2319 or cworzala@aha.org.