American Hospital Association

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December 5, 2005

Daniel R. Levinson, Esq.
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Room 5246
Cohen Building
330 Independence Ave., S.W.
Washington, DC 20201

Re:OIG-405-P; Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute; Proposed Rule.

Dear Mr. Levinson:

On behalf of our 4,800 member hospitals, health care systems, other health care organizations, and 33,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed rule outlining an e-prescribing-related safe harbor under the anti-kickback statute. These regulations, together with the Physician Self-Referral, or Stark regulations, pose a significant barrier to hospitals and physicians working together to realize the promise of health information technology (IT) to improve the coordination and quality of patient care.

The use of electronic health records (EHRs) within hospitals and physician offices promises to improve quality of patient care. Even greater benefits can be obtained through sharing information across health care providers so that, for example, emergency department staff have access to medical histories, and primary care physicians can know what medications were given during an inpatient stay. To facilitate this sharing of clinical information, hospitals may want to provide community physicians with hardware, software or other assistance that would allow physicians to maintain electronic health records for their patients, and thus improve the continuity and quality of care.

Hospitals that wish to do so, however, must be careful of the anti-kickback statute. The anti-kickback law specifically prohibits any remuneration – whether cash or in-kind payments – in exchange for referring a patient covered by a federal health program. The anti-kickback law

imposes severe, criminal penalties on hospitals and physicians that violate it, and the fear of violating this law is inhibiting progress in IT adoption.

The proposed rule aims to give hospitals more flexibility by providing protections from prosecution under the anti-kickback statute when they provide physicians on their medical staffs with certain IT items and services for e-prescribing. The proposed rule sets out the protected arrangements, including those between hospitals and members of their medical staff that routinely furnish services at the hospital, and limits the covered technology that may be provided. The rule includes further limiting conditions such as documentation requirements and a requirement that the donated items are not "technically or functionally equivalent" to items the recipient already has. The proposed safe harbor also states that the donor must not consider the volume or value of referral or other business generated between the physician and the donor.

But the proposed rule falls short in several respects. Most important, it does not offer actual regulatory language for an anti-kickback safe harbor for providing EHR software and directly-related training. The AHA believes the Office of Inspector General (OIG) should set out specific regulatory language for an EHR-related safe harbor to the anti-kickback law. Without safe harbors that parallel any Stark exception for donation of EHR technology, hospitals will not feel confident that they can donate IT items and services without risk of prosecution. The absence of clear guidance likely will inhibit action by hospitals because they continue to fear they may be subject to severe penalties for violating the anti-kickback statute despite its requirement that the donor act with intent. The OIG's failure to provide an anti-kickback safe harbor imperils an important opportunity to increase physician use of EHRs and thereby significantly improve quality of care for all patients.

An anti-kickback safe harbor for EHRs should mirror the Stark exceptions. Consequently, our detailed comments on the recently proposed Stark EHR exception also apply to the creation of a useful anti-kickback safe harbor. These comments are laid out in the attached comment letter to the Centers for Medicare & Medicaid Services (CMS) on its proposed rules. Key recommendations from our comments:

- The AHA urges the OIG to adopt a single anti-kickback safe harbor for EHRs without the certification requirements – not two safe harbors for pre- and post-implementation periods – given the uncertainties surrounding certification for interoperability. The OIG and CMS could revisit the safe harbor at a later time to require compliance with interoperability standards once they have been agreed upon. This strategy would ensure sufficient time for the standards to be developed, tested and implemented while simultaneously putting vendors and potential purchasers clearly on notice that progress toward interoperability is essential as the field moves ahead to expand IT adoption. This single exception also would need to broaden the scope of covered technology and address other specific concerns noted in our comments.
- If the OIG adopts the pre- and post-interoperability approach, it must finalize the post-interoperability safe harbor at the same time as the pre-interoperability safe harbor. Otherwise, hospitals will not be able to plan effectively.

- The covered technology discussed in the proposed rule must be broadened to include hardware, software and training for EHRs, connectivity, secure messaging, and on-going support and maintenance, as well as interfaces to allow physician offices to exchange EHR data with hospital systems.
- The specification of a covered arrangement should be changed to physicians on the medical staff whose patients frequently receive inpatient and/or outpatient care at the hospital. The increase in the number of hospitalists and intensivists means that a growing number of physicians frequently admit patients to the hospital without furnishing services there.
- As a practical matter, hospitals will need to use criteria to select the physicians with which to work. The use of criteria related to improved quality of care and ensuring successful adoption by physicians must be allowed.

The AHA also urges the OIG to expand the list of covered recipients under the safe harbor. In addition to physicians in their offices, hospitals must share data with other practitioners and institutions to ensure coordination across the continuum of care. The OIG should expand the covered recipients to include physician assistants and nurse practitioners, as well as other institutions, such as skilled nursing facilities and federally qualified health centers.

The AHA strongly urges the OIG to rethink the limited approach discussed in this proposed rule. Safe harbors that address hospitals' concerns will go far toward achieving the policy goal of increasing physician use of IT and expanding information exchange. Without these changes, hospitals will not have the needed flexibility to work constructively with physicians to realize the promise of IT for improving quality of care.

The AHA stands ready to assist the OIG in addressing the concerns outlined. Questions about our comments can be directed to me, Chantal Worzala, senior associate director of policy, at (202) 626-2319 or cworzala@aha.org, or Lawrence Hughes, regulatory counsel and director, member relations, at (202) 626-2346 or lhughes@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Attachment: Letter to Dr. Mark McClellan.