



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

May 13, 2013

Submitted Electronically

Daniel R. Levinson
Inspector General
Department of Health and Human Services
Attention: OIG-404-P, Room 5541C
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: OIG-404-P; Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor under the Anti-Kickback Statute; Proposed Rule (Federal Register, Vol. 78, No. 69, April 10, 2013)

Dear Mr. Levinson:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services Office of Inspector General's (OIG) proposed rule that would extend the regulatory protections under the federal antikickback law for hospitals that want to provide assistance to physicians in adopting certain health information technology (IT). We support the agency's decision to extend the protections, which were scheduled to expire at the end of this year, for at least another three years until Dec. 31, 2016. **However, we urge the agency to make the regulatory protections permanent.** We believe that they will continue for the foreseeable future to be of critical importance to the nation's efforts to adopt and expand operation of a robust national health IT infrastructure.

Hospitals already are – and plan to continue – using the protections to support physician adoption and use of interoperable electronic health records (EHRs) and other forms of health IT to provide community benefit. One stand-alone rural hospital in the Midwest, for example, needs the protections to ensure that every provider in its community has access to health IT; the hospital is providing support for two rural health clinics and one physician office. A health care system in the Midwest also is providing support, including ongoing training and maintenance assistance, to more than 350 physicians to assist in their adoption of EHRs. A health system on the west coast with more than 200 affiliated physicians in 100 locations across three states is focusing on ensuring connectivity across providers and needs the regulatory protections to



continue doing so. These are only a few examples of how important the protections continue to be for hospitals to extend support properly to physicians who otherwise have constrained financial and technical resources that might limit their opportunity to use EHRs and share information across settings to improve patient care.

The need for such voluntary assistance continues despite the availability of financial assistance to eligible physicians and other professionals provided through the Medicare and Medicaid EHR incentive programs. Not all providers are eligible for the current incentives, and new physicians will begin to practice after the incentives have expired. One rural hospital in the Pacific Northwest has developed plans to use the protections to support EHR adoption by a tribal health clinic that is not eligible for the incentives. Even for those physicians and providers that are eligible, the incentive payments are time-limited and generally do not cover the full costs of adopting and maintaining an EHR over time. Furthermore, advances in connectivity will introduce the need for all physicians to adopt new interoperable technologies that allow systems to share information. **The final rule should continue to explicitly include all hospitals and health systems within the scope of donors protected by the regulations and, therefore, eligible to provide assistance to physicians to support these important efforts.**

We believe that the current regulatory text, when read in light of the preamble discussion in the 2006 final rule, is sufficiently clear to include within the scope of covered technology those “services that enable the interoperable exchange of electronic health records data.” As explained in the preamble to the 2006 final rule, the term “software, information technology and training services necessary and used predominantly” for EHR purposes includes the following examples of covered technology:

- Interface 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 (but not separate research or marketing support services);
- Maintenance services;
- Secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging); and
- Training and support services (such as access to help desk services).

As a result, we are confused by the statement in the preamble to the proposed rule, which states that whether services that enable the interoperable exchange of EHR data fall within the scope of covered technology under the regulatory protections depends on the exact items or services that are being donated. **We urge that this confusing statement be removed from the preamble when the final rule is published, or that the discussion include additional explanation about precisely how potential donors should make a determination that any particular items and services that enable the interoperable exchange of EHR data would not come within the scope of the regulatory protections.**

We also support the decision to eliminate the requirement that donated technology must include electronic prescribing capability at the time it is provided to the recipient. We agree with the agency's assessment that developments since the release of the previous final rule make it unnecessary to retain that requirement in this final rule.

We do not see the need to modify or add new conditions in the final rule to prevent donors of approved information technology and services from "locking-in" to the donor's exclusive benefit patient data and referrals from recipients of the donation. The rule already includes sufficient and effective safeguards to prevent such arrangements, including requirements that:

- The donating hospital cannot directly take into account the volume or value of referrals or other business from the physician to the hospital in determining the physicians who will receive the donated health IT resources and the amount or type of the donation.
- The physician or the physician practice, including its employees and staff members, cannot compel the donation, or the amount or type of the donation as a condition of doing business with the donating hospital.
- The donated health IT must be "necessary and used predominately to create, maintain, transmit, or receive electronic health records" and may not be used "primarily to conduct personal business or business unrelated to the physician's medical practice" to ensure that benefit from the donation is exclusively the exchange of relevant information necessary for patient care and quality improvement.
- The donated health IT must be capable of transmitting and receiving relevant information from the larger health care system rather than solely between the parties participating in a specific health IT arrangement. Donated health IT must be "interoperable" at the time it is provided to the physician.
- The donating hospital cannot alter or modify the technology in any way that would "limit or restrict its use, compatibility, or interoperability with other electronic health records or electronic prescribing systems." In addition where the technology can be used for patients without regard to payer status, the donor cannot "restrict or take any action to limit the physician's right or ability to use the technology for any patient."
- The physician's share of the costs of purchasing and using the health IT received cannot be paid or financed, including through loans to the physician to pay for any items or services, by the donating hospital or by any party related to the donating hospital.

Mere allegations or rumors received by the OIG in comments to its annual solicitation of safe harbors and special fraud alerts suggesting that abusive donations are being made would seem to be insufficient justification to expand the conditions required for the regulatory protections to apply to the donation. **Rather than adding greater complexity to the existing regulatory requirements for permissible donation arrangements and thereby significantly increasing the administrative burdens for hospitals that want to make appropriate donations to**

Daniel R. Levinson

May 13, 2013

Page 4 of 4

physicians, the agency would be better served by strengthening efforts to identify and specifically target for enforcement actual individual abusive arrangements.

We urge the agency to issue quickly a final rule consistent with our recommendations. If you have questions about our recommendations, please contact Lawrence Hughes, assistant general counsel, at (202) 626-2346 or lhughes@aha.org, or Chantal Worzala, director of policy, at (202) 626-2313 or cworzala@aha.org.

Sincerely,

/s/

Richard J. Pollack
Executive Vice President