AMERICAN COLLEGE OF SURGEONS
Inspiring Quality:
Highest Standards, Better Outcomes
100 years

Chicago Headquarters:
633 N. Saint Clair St.
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org

Washington Office:
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
ACS website: *www.facs.org*

June 7, 2013

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

Re: Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute

Dear Mr. Levinson:

On behalf of the over 79,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute* that was published in the *Federal Register* on April 10, 2013.

The anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs. Because of the broad reach of the statute, Congress allows for safe harbor provisions that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. The Office of Inspector General (OIG) published a safe harbor to protect certain arrangements involving the donation of interoperable electronic health records (EHRs) software or information technology and training services from protected donors (for example, a hospital) to physicians. This safe harbor is scheduled to sunset on December 31, 2013.

In this rule, the OIG proposes to amend the current safe harbor by: (1) updating the provision under which EHRs are deemed interoperable; (2) removing the requirement related to electronic prescribing (eRx) capability; and (3) extending the sunset date. We discuss each of these proposals below.

1. Deeming Provision

The current EHR safe harbor specifies that the donated software must be interoperable at the time it is provided to the physician and must be certified by the appropriate body (the Office of the National Coordinator for Health Information Technology (ONC)) no more than 12 months prior to the date it is provided to the physician. The OIG proposes to modify the 12-month requirement to conform to the ONC's two-year regulatory process for adopting certification criteria because the 12-month requirement is not in line with the ONC's two-year regulatory interval. As such, the OIG proposes that software will be eligible for deeming if, on the date it is provided to the physician, it has been certified to any applicable edition of the EHR certification criteria in the ONC definition of Certified EHR Technology. For example, for 2013, the applicable definition of Certified EHR Technology identifies both the 2011 and 2014 editions of EHR certification criteria, so in 2013, software certified to meet either the 2011 or 2013 editions could satisfy the safe harbor as the OIG proposes to modify it. However, the definition of Certified EHR Technology applicable for 2014 only identifies the 2014 edition of EHR certification criteria. So in 2014, only software certified to the 2014 edition could satisfy the new OIG proposal.

We appreciate the OIG's flexibility and recognition that the 12-month requirement might be unnecessary in cases where the definition of Certified EHR Technology includes editions from more than one year (e.g. 2011 and 2014 editions of EHR certification criteria are identified for the 2013 definition of Certified EHR Technology). **We support this proposal, but we urge the OIG to allow software to be eligible for deeming under this safe harbor if it has been certified to any edition of the EHR criteria that is in the applicable definition of Certified EHR Technology at the time of donation (the OIG's proposal) OR certified within the past 12 months (the OIG's current policy).**

2. eRx Provision

The EHR safe harbor specifies that donated software must contain eRx capability, either through an eRx component or the ability to interface with the physician's existing eRx system. The eRx capability must meet applicable standards at the time the EHR software is donated. The OIG proposes to no longer retain an eRx requirement for the purposes of the EHR safe harbor. The OIG believes that because Congress has enacted the eRx Incentive Program, because there is an eRx provision included in the EHR Incentive Program (also referred to as "Meaningful Use"), and because the industry has made great

Chicago Headquarters:
633 N. Saint Clair St.
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office:
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
ACS website: *www.facs.org*

progress toward eRx, it is no longer necessary to include the eRx requirement as part of the EHR safe harbor as well. **We agree with the OIG that there are sufficient alternative policy drivers supporting the adoption of eRx capabilities, and we support the removal of the eRx requirement from the EHR safe harbor.**

3. Sunset Provision

The EHR safe harbor is scheduled to sunset on December 31, 2013. The OIG acknowledged that the need for donations of EHR technology should diminish substantially over time, and that while there has been progress, the use of such technology has not yet been universally adopted nationwide. Because continued EHR technology adoption remains an important goal of the Department of Health and Human Services (HHS), the OIG proposes to extend the sunset date of the safe harbor to December 31, 2016 (the last date that an Eligible Professional may receive a Medicare EHR incentive payment and the last date an Eligible Professional may initiate participation in the Medicaid EHR incentive program). Alternatively, the OIG proposes extending the sunset date to December 31, 2021, which corresponds to the end of the Medicaid EHR incentive program.

We appreciate the OIG's recognition that this sunset should be extended; however we urge the OIG to not include a sunset date at all. If HHS intends to keep EHR technology a high priority for the future, one way HHS can continue to encourage EHR adoption is by not including a sunset for this exception. In addition, whereas the EHR Incentive Program bonus payments will end on December 31, 2021, there is no definitive end date for the penalties. The EHR safe harbor should not only be tied to the incentives, rather, the safe harbor should also be tied to the penalties. **For this reason also, we recommend that no sunset apply to this exception. If the OIG were to extend the sunset for this safe harbor, we ask that it be extended to December 31, 2021.** We agree that although there has been significant advancement in the adoption and meaningful use of EHRs, there are still many physicians and physician practices who have not adopted this technology and the EHR safe harbor is an important component of the implementation of these policies.

Chicago Headquarters:
633 N. Saint Clair St.
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office:
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
ACS website: *www.facs.org*

AMERICAN COLLEGE OF SURGEONS
Inspiring Quality:
Highest Standards, Better Outcomes
100 years

We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with the OIG on these important issues. If you have any questions about our comments, please contact Bob Jasak, Deputy Director for Regulatory and Quality Affairs, in our Division of Advocacy and Health Policy. He may be reached at bjasak@facs.org or at (202) 672-1508

Sincerely,

David B. Hoyt

David B. Hoyt, MD, FACS
Executive Director

Chicago Headquarters:
633 N. Saint Clair St.
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office:
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
ACS website: *www.facs.org*