June 10, 2013

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD  21244-1850

Subject:  (CMS-1454-P; 78 FR 2 1308) Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain EHR Arrangements; Comments of the American College of Radiology

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services’ (CMS) Notice of Proposed Rulemaking (NPRM) regarding “Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements,” which was published in the Federal Register on April 10, 2013.

General Comments
ACR strongly supports secure and appropriate exchange of diagnostic images and imaging information to improve the quality and safety of patient care.  We encourage the federal government, including CMS, to continue to advance and facilitate the ability for physicians, providers, and patients to engage in this type of information sharing.  Moreover, we believe CMS and other regulatory agencies should actively promote data exchange between disparate systems and technologies, and aggressively combat any direct or indirect attempts by hospitals and/or IT vendors to use donated EHRs to prevent or discourage referrals for diagnostic imaging services to competitors outside of donors’ systems.

Many physicians rely on the EHR exception/safe harbor to self-referral/anti-kickback requirements to obtain access to the certified EHR technology and IT support needed for eventual participation in the Medicare/Medicaid EHR Incentive Program (or “meaningful use”).  On the other hand, CMS and HHS OIG must be conscious of, and take steps to thwart, potential abuses that would directly contravene the important intent of the EHR exception/safe harbor.
Direct and/or Indirect Abuses of Self-Referral EHR Exception and Anti-Kickback Safe Harbor

In our April 15, 2013 response to CMS’ Request for Information regarding “Advancing Interoperability and Health Information Exchange” (CMS-0038-NC; 78 FR 14793), ACR described concerns from the ambulatory imaging community about questionable actions by hospitals, health systems, and/or vendors to discourage referrals to competing or unaffiliated imaging physicians/providers by placing inappropriate barriers to the choice of provider. This is accomplished when donors or their vendors refuse to adequately interface or connect EHRs with disparate technologies, thereby restricting the ability of users of the donated technology to order or schedule examinations at unaffiliated facilities. In the most serious cases, even when doctors or patients have strong preferences for external entities (due to location, a higher quality of care, and/or better customer service), they are unable to because of an inability to connect with those entities using donated EHRs. The lack of connectivity and exchange also disadvantages unaffiliated imaging providers by restricting their ability to send images and reports to the records of patients in the donated technology. This practice invariably results in significantly decreased options for patients and increased healthcare costs due to more hospital-provided services.

Furthermore, some hospitals and health systems are compounding the above problems by providing misinformation to EHR donation recipients (primary care physicians, etc.) about Stage 2 EHR Incentive Program requirements for image results accessibility. Specifically, some primary care physicians and other EHR donation recipients are reportedly led by donors and/or EHR vendors to believe the only way to comply with the menu set objective at 42 CFR 496.6(k)(1) is through advanced connectivity with donors.

Deeming “Interoperability” With Certification

While the EHR exception/safe harbor to self-referral/anti-kickback requires donated products to be “interoperable,” this prerequisite has historically been implemented in such a way that mere certification of the product by an HHS-recognized body is deemed satisfactory. EHR donors are also prevented from disrupting the certified technological capabilities. CMS proposed that this 2006 methodology continue with relatively minor modifications. ACR strongly believes this paradigm is no longer sufficient; HHS-recognized product certification is now ubiquitous, and it does not equate to inherent readiness to exchange imaging information.

Deeming certified products to be interoperable because of technical capability, without requiring true electronic exchange in practice and without aggressively forbidding business practices that discourage exchange beyond the donors’ systems, does little to address the political and financial barriers to health information exchange between disparate systems. Moreover, in the years since the exception/safe harbor and EHR Incentive Program were implemented, technology has advanced such that connectivity and exchange between disparate systems could easily become commonplace if the non-technological barriers were addressed.

Recommended Improvements to 42 CFR 411.357(w) and 42 CFR 1001.952(y)

ACR recommends that HHS take the following actions to begin to address these concerns:
• CMS and the HHS Office of Inspector General self-referral/anti-kickback regulations should require EHR donors to, upon request, enable their donation recipients to engage in bi-directional exchange with competitors outside of the system using the donated technology, and without additional cost beyond what would be incurred if it were an exchange between the EHR recipient and the EHR donor.

• For the above, enabling requested bi-directional exchange with competitors should involve, but not be limited to, financing or implementing standardized interfaces between donated EHRs and competitors’ technology, including disparate Radiology Information Systems/Picture Archiving and Communication Systems.

• CMS and related HHS offices should work with the imaging informatics community, national radiology associations, radiology IT vendors, and EHR vendors to identify various acceptable standards/tools to ensure interoperability between donated EHR products and external RIS/PACS. The “imaging data interoperability tool kit” should be released within a year following publication of the final rules by CMS and HHS OIG and updated periodically.

• CMS and the HHS Office of the Inspector General should establish a centralized contact number or online application for reporting situations in which hospitals, health systems, or vendors are suspected of gaining a competitive edge from donated EHRs and/or from providing misinformation about EHR Incentive Program requirements. CMS and the HHS OIG should promptly investigate any credible reports of hospitals and health systems “gaming” the EHR exception/safe harbor to reduce regional competition for imaging services.

As always, the ACR welcomes the opportunity for continued dialog with CMS and HHS OIG on all things related to health information technology and/or radiology. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 202-223-1670 / mpeters@acr.org with questions.

Sincerely,

Paul H. Ellenbogen, M.D.
Chair, Board of Chancellors
American College of Radiology

Keith J. Dreyer, DO, PhD, FACR
Chair, IT and Informatics Committee
American College of Radiology
June 10, 2013

Patrice Drew
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

Subject: (OIG-404-P; 78 FR 21314) Medicare and State Health Care Programs: Fraud and Abuse; EHR Safe Harbor Under the Anti-Kickback Statute; Comments of the American College of Radiology

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Office of Inspector General’s (OIG) Notice of Proposed Rulemaking (NPRM) regarding “Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute,” which was published in the Federal Register on April 10, 2013.

General Comments
ACR strongly supports secure and appropriate exchange of diagnostic images and imaging information to improve the quality and safety of patient care. We encourage the federal government, including HHS OIG and CMS, to continue to advance and facilitate the ability for physicians, providers, and patients to engage in this type of information sharing. Moreover, we believe HHS OIG, CMS, and other regulatory agencies should actively promote data exchange between disparate systems and technologies, and aggressively combat any direct or indirect attempts by hospitals and/or IT vendors to use donated EHRs to prevent or discourage referrals for diagnostic imaging services to competitors outside of donors’ systems.

Many physicians rely on the EHR safe harbor/exception to anti-kickback/self-referral requirements to obtain access to the certified EHR technology and IT support needed for eventual participation in the Medicare/Medicaid EHR Incentive Program (or “meaningful use”). On the other hand, HHS OIG and CMS must be conscious of, and take steps to thwart, potential abuses that would directly contravene the important intent of the EHR safe harbor/exception.
Direct and/or Indirect Abuses of Self-Referral EHR Exception and Anti-Kickback Safe Harbor

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Furthermore, some hospitals and health systems are compounding the above problems by providing misinformation to EHR donation recipients (primary care physicians, etc.) about Stage 2 EHR Incentive Program requirements for image results accessibility. Specifically, some primary care physicians and other EHR donation recipients are reportedly led by donors and/or EHR vendors to believe the only way to comply with the menu set objective at 42 CFR 496.6(k)(1) is through advanced connectivity with donors.

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Recommended Improvements to 42 CFR 1001.952(y) and 42 CFR 411.357(w)

ACR recommends that HHS take the following actions to begin to address these concerns:
• HHS OIG and CMS anti-kickback/self-referral regulations should require EHR donors to, upon request, enable their donation recipients to engage in bi-directional exchange with competitors outside of the system using the donated technology, and without additional cost beyond what would be incurred if it were an exchange between the EHR recipient and the EHR donor.

• For the above, enabling requested bi-directional exchange with competitors should involve, but not be limited to, financing or implementing standardized interfaces between donated EHRs and competitors’ technology, including disparate Radiology Information Systems/Picture Archiving and Communication Systems.

• HHS should work with the imaging informatics community, national radiology associations, radiology IT vendors, and EHR vendors to identify various acceptable standards/tools to ensure interoperability between donated EHR products and external RIS/PACS. The “imaging data interoperability tool kit” should be released within a year following publication of the final rules by HHS OIG and CMS and updated periodically.

• HHS OIG and CMS should establish a centralized contact number or online application for reporting situations in which hospitals, health systems, or vendors are suspected of gaining a competitive edge from donated EHRs and/or from providing misinformation about EHR Incentive Program requirements. HHS OIG and CMS should promptly investigate any credible reports of hospitals and health systems “gaming” the EHR safe harbor/exception to reduce regional competition for imaging services.

As always, the ACR welcomes the opportunity for continued dialog with HHS OIG and CMS on all things related to health information technology and/or radiology. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 202-223-1670 / mpeters@acr.org with questions.

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