

CMS and OIG Propose Extension of Federal Stark Exception and Anti-Kickback Safe Harbor for Electronic Health Record Donations

On Wednesday, April 10, 2013, the Centers for Medicare & Medicaid Services (“CMS”) and the Office of the Inspector General (“OIG”) of the Department of Health and Human Services published complementary proposed rules in the Federal Register. The rules, if adopted, would extend the federal physician self-referral (“Stark”) law exception and anti-kickback statute (“AKS”) safe harbor for the donation of eligible electronic health record (“EHR”) items and services (the “EHR Donation Rules”). The EHR Donation Rules, which have enabled physicians to receive partially subsidized EHR items and services through “donations” from hospitals, group practices, and other entities since October 10, 2006, are set to expire on December 31, 2013. The proposed rules seek to extend the EHR Donation Rules until at least December 31, 2016, as well as to revise certain other requirements.

The EHR Donation Rules were originally created as part of the federal government’s efforts to promote the use of interoperable EHR technology. They enabled hospitals, group practices, laboratory companies, durable medical equipment suppliers, and other entities to partially “donate” eligible EHR items and services to physicians through subsidies. Finalized in regulations published in the Federal Register on August 8, 2006, the EHR Donation Rules established parallel requirements in order for arrangements to qualify for the safe harbor and exception. Among other requirements, the donated EHR software must be “deemed” interoperable within twelve months of the donation, the physician recipient must contribute at least 15% of the total cost of all donated items and services, and the physician recipient must not make receipt of the items or services a condition of doing business with the donor. The proposed rules both extend the EHR Donation Rules and modify certain requirements, as discussed in more detail below. Comments on the proposed rules are due by June 7, 2013.

Although not final, the proposed rules provide the medical community and information technology industry with significantly more certainty in planning and supporting high-cost EHR extension and donation programs.

Proposed Revisions to EHR Safe Harbor/Exception

CMS and OIG propose three revisions to the current EHR Donation Rules. Most important, the proposed rules extend the existing sunset date. The other proposed modifications related to the existing interoperability and e-prescribing functionality requirements, and are intended to better reflect the technological and regulatory environment surrounding current technology. CMS and OIG also sought comment on additional proposals and considerations related to the EHR Donation Rules.

Extension of Sunset

Although CMS and OIG previously stated that the need for EHR donations should diminish substantially over time, they now acknowledge that EHR technology has not yet been universally adopted nationwide and that continued EHR adoption remains an important goal. As such, CMS and OIG propose a revised sunset date of December 31, 2016, extending the availability of donations for another three years. The proposed sunset date corresponds to the last year that eligible hospitals and professionals may receive incentives from the Medicare EHR Incentive Program, or initiate participation in the Medicaid EHR Incentive Program. As an alternative, CMS and OIG are considering a later sunset date of December 31, 2021, which corresponds

to the end of the Medicaid EHR Incentive Program. CMS and OIG invite comment on these and alternative sunset dates.

Modification of the Interoperability Requirement

Recognizing that existing interoperability requirements were established prior to many regulatory developments in this area, CMS and OIG proposed changes to the way in which eligible EHR technology is “deemed” interoperable by a certifying body “recognized” by the Secretary of the Department of Health and Human Services. CMS and OIG propose modifying the EHR Donations to reflect the fact that the Office of the National Coordinator for Health Information Technology (“ONC”) now authorizes the bodies responsible for certifying EHR software. Further, recognizing that the ONC certification process currently runs on a two-year regulatory interval and ties certification to the applicable definition of “Certified EHR Technology,” CMS and OIG seek to remove the requirement that the EHR software be certified within twelve months prior to the date of donation. Instead, they propose that EHR software be eligible for donation if, on the date it is provided to the recipient, the EHR software has been certified to any edition of ONC’s EHR certification criteria that is identified in the then applicable definition of Certified EHR Technology.

Removal of E-Prescribing Functionality Requirement

In light of developments since the adoption of the EHR Donation Rules, CMS and OIG assert that the e-prescribing functionality currently required for donated EHR technology is no longer necessary. CMS and OIG explain that the e-prescribing functionality requirement was included in the EHR Donation Rules to create incentives for wide-spread adoption of e-prescribing technology; however, substantial progress towards this goal has already been achieved as a result of subsequent Congressional action to incentivize adoption of e-prescribing technology (including passage of the Medicare Improvements for Patients and Providers Act of 2008 and the Health Information Technology for Economic and Clinical Health Act in 2009), as well as general industry acceptance of this technology. Accordingly, OIG and CMS believe that the policy rationale for this requirement in EHR Donation Rules no longer exists and propose removal of the requirement.

Additional Proposals and Considerations

CMS and OIG also sought comment on additional proposals and considerations related to the EHR Donation Rules.

Scope of Protected Donors. In response to fraud and abuse concerns, CMS and OIG are seeking comment on whether they should limit the scope of protected donors to just hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations, as originally contemplated in earlier rulemaking. Alternatively, they are considering excluding certain types of donors that serve as suppliers of ancillary services associated with a high risk of fraud and abuse, such as laboratory companies, durable medical equipment suppliers, and home health agencies.

Data Exchange/Referral Lock-In. Based on concerns regarding data and referral lock-in, CMS and OIG are also seeking comment as to whether other new or modified conditions should be added to the EHR Donation Rules to further ensure that donors cannot limit or restrict the use, compatibility, or interoperability of the EHR items or services donated. Despite technical compliance with the existing EHR Donation Rules, CMS and OIG are concerned that certain donors’ policies and practices effectively limit physician recipients’ ability to exchange information across organizational and vendor boundaries.

Scope of Covered Technologies. CMS and OIG are seeking comment as to whether the EHR Donation Rules should be modified to explicitly name the types of items and services eligible for donation, which were described in commentaries to the August 2006 final rules, but not included in the text of the regulations.

We continue to monitor developments with respect to the EHR Donation Rules and related health information technology regulations, especially those changes that may affect the hospital, physician, and information technology communities. If you have questions on the EHR Donation Rules, please contact the Ropes & Gray attorneys with whom you regularly work.