

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

On Friday, December 27, 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 final rules in the Federal Register. These rules finalize the proposed rules, issued April 10, 2013, to 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 (collectively, the “EHR Donation Rules”). The EHR Donation Rules, which have enabled hospitals, group practices, and others to subsidize physicians’ receipt of EHR items and services since October 10, 2006, were originally set to expire, or sunset, on December 31, 2013. The final rules pushed the sunset back eight years — to December 31, 2021 — with some new restrictions.

The EHR Donation Rules originated as part of the federal government’s efforts to promote the use of interoperable EHR technology. They enabled hospitals, group practices, laboratories, 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 for the AKS safe harbor and the Stark exception. Among other requirements, the donated EHR software must be “deemed” interoperable, the physician recipient must contribute at least 15% of the total cost, and the physician recipient must not make receipt of the items or services a condition of doing business with the donor. The final rules extend the EHR Donation Rules, with some modifications, as discussed in more detail below. With the exception of this new sunset provision, which became effective on December 31, 2013, the modifications to the EHR Donation Rules become effective on March 27, 2014.

### Revisions to EHR Safe Harbor/Exception

CMS and OIG made several changes to the current EHR Donation Rules, the most significant of which are discussed in detail below. In terms of key takeaways:

- (1) the sunset date of the EHR Donation Rules has been extended to December 31, 2021;
- (2) laboratories are now excluded from the list of protected donors;
- (3) conditions that prohibit donors from taking action to limit or restrict the use, compatibility, or interoperability of donated items or services have been clarified; and
- (4) the e-prescribing functionality requirements have been eliminated.

### Extension of Sunset

Although CMS and OIG suggested as one option a revised sunset date of December 31, 2016 in the proposed rules, the agencies have ultimately adopted the sunset date of December 31, 2021, which corresponds to the end of the Medicaid EHR Incentive Program. CMS and OIG rejected comments that suggested a permanent safe harbor, stating that the December 31, 2021 sunset date would support EHR adoption while safeguarding against foreseeable future fraud risks.

## Limitations on Scope of Donors and Donor Action to Restrict Interoperability

*Scope of Protected Donors.* In the proposed rule, CMS and OIG considered enumerating specific types of eligible donors or excluding certain types of donors that serve as providers and suppliers of ancillary services associated with a high risk of fraud and abuse, such as laboratories, durable medical equipment suppliers, and home health agencies. In the final rules, CMS and OIG exclude only laboratories from the scope of protected donors.

*Donor Action to Restrict Interoperability.* Based on concerns regarding data and referral lock-in, CMS and OIG clarified the requirement that donors cannot limit or restrict the use, compatibility, or interoperability of the EHR items or services donated with “other electronic prescribing or EHR systems.” Specifically, in order to emphasize the agencies’ collective intent to have this requirement be broadly interpreted to apply to a wide array of technologies, they specified that “other electronic prescribing or EHR systems” includes, but is not limited to, health information technology applications, products, or services.

## Removal of E-Prescribing Functionality Requirement

As suggested in the proposed rules, CMS and OIG have removed the requirement for electronic prescribing technology. CMS and OIG noted that other programs sufficiently support the adoption of electronic prescribing and that requiring electronic prescribing under the EHR Donation Rules might lead to redundant and sometimes expensive software capabilities.

## Modification of the Interoperability Requirement

CMS and OIG finalized 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. The EHR Donation Rules now reflect the fact that the Office of the National Coordinator for Health Information Technology (“ONC”) authorizes the bodies responsible for certifying EHR software. CMS and OIG have also tied certification to the timing of the ONC certification process, removing the requirement that the EHR software be certified within twelve months prior to the date of donation. EHR software is now eligible for donation if, on the date it is provided to the recipient, the EHR software has been certified to satisfy any edition of the EHR certification criteria identified in the then-applicable version of ONC’s certification program, which can be found at 45 C.F.R. Part 170.

## Proposals Not Adopted

*Scope of Covered Technologies.* In the proposed rules, CMS and OIG sought commentary as to whether the scope of covered technology under the EHR Donation Rule was sufficiently clear. In the final rules, the agencies did not make any changes to the scope of covered technology. Rather, they noted that maintaining flexibility in the scope of covered technology is important, particularly as health information technology evolves, and left the scope unchanged.

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.