

CMS and OIG Release Final Rules Extending Stark Law Exception and Anti-Kickback Statute Safe Harbor for Donations of Electronic Health Records Technology

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In 2006, the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General of the Department of Health and Human Services (the "OIG") published final rules providing for an exception to the Stark Law and a safe harbor under the Anti-Kickback Statute for donations of electronic health records ("EHR") technology to physicians. Those final rules were part of an effort by the federal government to encourage the use of EHR technology by alleviating the significant costs of implementing and operating such technology. The final rules allowed health care entities to donate up to 85% of the cost of EHR technology to physicians under specified circumstances.

The 2006 final rules included a December 31, 2013, sunset provision for the Stark Law exception and the Anti-Kickback safe harbor for donations of EHR technology. Had those provisions been allowed to sunset, physicians would have had to pay fair market value for EHR-related items and services, which would have resulted in a dramatic increase in the cost to physicians of using EHR technology and presumably a corresponding decrease in the willingness of physicians to use such technology.

Instead, on December 23, 2013, CMS and the OIG released new final rules, to be published in the Federal Register on December 27, 2013, extending the sunset date to December 31, 2021. Those final rules also include a number of other changes to the 2006 final rules, including:

- Prohibiting laboratory companies from being donors of EHR technology.
- Eliminating the requirement that the donated EHR technology include electronic prescribing.
- Modifying the requirement that the donated EHR technology be interoperable with different information technology systems, software applications, and networks. The 2006 final rules provided that EHR technology would be deemed interoperable if a certifying body recognized by the Secretary of Health and Human Services certified the EHR technology as interoperable less than 12 months prior to the date it is provided to the physician. The new final rules (1) provide that the Office of the National Coordinator for Health Information Technology ("ONC"), and not the Secretary, is responsible for authorizing the certifying bodies and (2) eliminate the rigid 12-month requirement in favor of a requirement that the EHR technology be certified as interoperable according to any edition of the electronic health record certification criteria identified in 45 CFR part 170. For 2013, that would include either the 2011 or the 2014 edition.
- Modifying the requirement that the donor take no action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems. The final rules clarify that the donor also must take no action to limit the interoperability of such items or services with such systems, which systems specifically include, but are not limited to, "health information technology applications, products, or services."

The extension of the sunset date takes effect immediately, while the other changes to the 2006 final rules will take effect on March 27, 2014.

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