



*Healthcare Information and Management Systems Society*

**Physician Self Referral Regulation Exemptions and Anti-Kickback Safe Harbors  
Recommendation to Congress  
June 2010**

**Ask #3: HIMSS recommends that Congress work with the Obama Administration to make permanent the current physician self referral regulation exemptions (Stark exemptions) and anti-kickback safe harbors for EHRs.**

**Problem:** The physician self referral regulation exemptions (Stark exemptions) and anti-kickback safe harbors established in 2006 for electronic health records (EHRs); known as the “EHR Donation Rules”, expire in 2013. If the rules are not made permanent, providers will have new challenges in financing EHRs to achieve the meaningful use of certified EHR technology and engage in the wide-scale electronic exchange of health information.

**Background:** Enacted in 1972, the anti-kickback statute makes it illegal for providers to knowingly and willfully accept remuneration or bribes in return for, or to induce referrals of, business covered under federal health programs. The statute has been revised to allow for more than 20 “safe harbors”, under the anti-kickback statute to permit arrangements that might otherwise implicate the statute but that do not create a real risk that arrangements will impermissibly induce or reward referrals. The Stark law is a civil statute enacted in 1989, which prohibits physician referrals of a patient within a federal health program to an entity (laboratories, testing centers, etc.) in which the physician has a vested interest, such as ownership or a compensation arrangement.

In 2006, the Department of Health and Human Services (HHS), due to the Administration’s desire for all Americans to have an EHR by 2014, published final rules protecting eligible entities that provide EHR items and services to eligible recipients, which are referred to as the Stark exemptions and anti-kickback safe harbors for EHRs (EHR Donation Rules).<sup>1</sup> The EHR Donation Rules allow nonmonetary remuneration (includes items and services in the form of software or training services) necessary and used predominately to create, maintain, transmit or receive EHRs. Hardware is not considered covered technology. To qualify for the safe-harbors and exemptions, the software must be “interoperable” at the time of donations. In addition, software must receive certification within 12 months of when they are provided to the recipient to be deemed interoperable.

The EHR Donation Rules sunset on December 31, 2013. The sunset clause reflects the original reasoning that the need for the safe harbors and exemptions would diminish over time as EHR technology becomes a standard of practice. Unfortunately, EHR technology has not become a standard of practice. As the federal government works to increase the use of certified EHR

technology through EHR incentive programs established through the American Recovery and Reinvestment Act of 2009 (ARRA) it is most important that the final regulations do not sunset in December 2013.

**Solution:** To ensure the advancement of meaningful use of certified EHR technology and allow for better care coordination and information sharing among care or clinical providers (i.e. physicians, nurses, pharmacists, etc.) and their patients, HIMSS recommends that Congress work with the Obama Administration to **make permanent the current physician self referral regulation exemptions and anti-kickback safe harbors for EHRs.** In carrying out this recommendation, the Secretary should implement necessary measures and requirements to protect against conflict of interest and improper relationships among providers, and require that such exemptions and safe harbors only apply to software and related devices that apply federally recognized standards and interoperability specifications and are certified by federally recognized certification and testing bodies.

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<sup>i</sup> 71 FR 45110 Anti-Kickback Safe Harbors and 71 FR 4510 Stark Exceptions. Office the Inspector General, HHS. Available at: <http://oig.hhs.gov/authorities/docs/06/OIG%20E-Prescribing%20Final%20Rule%20080806.pdf> .