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Myth Busters
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MYTH: Providers violate federal law by accepting donated EHR software

FACT: Federal health care program fraud and abuse laws protect donations of EHR software provided certain requirements are met.

The Federal Anti-kickback Law and the Physician Self-Referral Law (commonly known as the Stark Law) regulate financial arrangements among healthcare industry participants. The Federal Anti-Kickback Law prohibits anyone from offering or accepting remuneration (i.e., anything of value) in return for referring a patient for services reimbursable by a federal health care program. The Stark Law prohibits physicians from referring patients for certain health services payable by Medicare to providers with which the physician (or an immediate family member) has a financial relationship (such as compensation and ownership). However, there are a number of exceptions ("safe harbors" in the Anti-Kickback Law) that protect certain arrangements that pose low or no risk of program or patient abuse.

Donated EHR Exception On August 8, 2006, the HHS Office of Inspector General (OIG) published an exception to the Anti-Kickback Law allowing certain entities to provide software or information technology and training and services necessary and used primarily to create, maintain, transmit, or receive electronic health records (EHRs) to other healthcare providers. This exception excludes such donations from the definition of "remuneration," so that an entity may donate an EHR system to a healthcare provider from which it is receives patients referred for services payable by a federal health care program without violating the Anti-Kickback Law. The Centers for Medicare & Medicaid Services (CMS) issued an almost identical regulation at the same time excluding such donations from the definition of "financial relationship" so that physicians can refer patients to entities that donated EHR systems to the physician without violating the Stark Law. These dual regulations were scheduled to sunset on December 31, 2013. On December 27, 2013, both the OIG and CMS issued final rules extending the EHR safe harbor/exception through December 31, 2021.

Exception Criteria The EHR exception in both laws contain twelve distinct criteria – in order to qualify for this exception, EHR donations must meet each of these criteria exactly as written. The requirements cover everything from contractual specifications (e.g., the arrangement must be in writing and specify all the items and services to be provided) to impermissible uses (e.g., the donated items cannot be used primarily to conduct business unrelated to the recipient's clinical practice) to financial requirements (e.g., the recipient must pay 15% of the donor's cost for the items and services). The updated regulations amended a few criteria in this exception. The new regulations exclude laboratory companies from donating EHR systems, update the interoperability requirement to reflect HHS Office of the National Coordinator (ONC) Certification standards, eliminate the requirement that EHR software contain electronic prescribing capability, and clarify certain other provisions.

The extension of the expiration date for the exception went into effect on December 31, 2013, while the other modifications go into effect on March 27, 2014.

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