



VCU Medical Center

Office of Health Innovation

Final Rule - Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships: Exception for Certain EHR Arrangements

Description: This final rule revises the exception to the physician self-referral law that permits certain arrangements involving the donation of electronic health records items and services. Specifically, this final rule extends the expiration date of the exception to December 31, 2021, excludes laboratory companies from the types of entities that may donate electronic health records items and services, updates the provision under which electronic health records software is deemed interoperable, removes the electronic prescribing capability requirement, and clarifies the requirement prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services.

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Major Provisions

New Expiration Established

- The Stark and antikickback protections for health IT donations were set to expire on December 31, 2013. The final rules extend the protections until Dec. 31, 2021, with some important modifications in the permissible donation arrangement.
- These regulations apply to donation by allowed entities of electronic prescribing technology to physicians and other entities in the form of hardware, software or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information are allowed.
- In addition, CMS and the OIG in the final rules waived the usual 30-day delay in the effective date of the rules specifically for the provision changing the sunset date.

Donation Arrangements

- Under the final rules, software is deemed as interoperable and eligible for protected donation if, on the date it is provided to the recipient, it has been certified by a certifying body authorized by ONC to an edition of the EHR certification criteria that is specified in the then applicable definition of Certified EHR Technology issued by ONC.
 - Under the rules that would have expired at the end of this year, software must have been certified as interoperable no earlier than 12 months prior to the date it is provided.
- Under these regulations, permissible donors and recipients do not apply to pharmaceutical companies, device manufacturers or vendors, durable medical equipment manufacturers or vendors, or health information technology vendors.

- Laboratory companies are prohibited under the final rules from making permitted donations of EHR items and services under the exception and the safe harbor.
 - Applies to laboratories that provide anatomic pathology services as well as those that provide clinical pathology services.
- The final rules eliminate the requirement that donated software must include electronic prescribing capability at the time it is provided to the recipient.