<u>Electronic Health Record Exceptions under Federal Anti-Kickback Law and Physician Self-Referral Law Extended</u>

The Federal Anti-Kickback Law and the Physician Self-Referral (Stark) Law prohibit the offer or receipt of kickbacks, bribes, or rebates as well as certain financial arrangements among healthcare entities including providers and health plans. The laws protect against fraud and abuse in federal healthcare programs (e.g., Medicare). Recognizing that there are certain financial arrangements in healthcare that pose low or no risk of program or patient abuse, each law includes exceptions ("safe harbors" in the Anti-Kickback Law) that protect innocuous arrangements from penalty. Of critical importance to expanding health information exchange across providers and care settings are the newly extended Electronic Health Record (EHR) exceptions.

Electronic Health Record Exception

This exception protects the donation of items and services necessary and used primarily to create, maintain, transmit, or receive EHRs. This exception was to expire on December 31, 2013, but was reissued on December 23, 2013; modifications in the new version are in bold. An entity that receives payment for services covered by a federal healthcare program may donate an EHR system to a provider if the following conditions are met:

- 1.) The donor is a healthcare provider (other than a laboratory company) or a health plan;
- 2.) The software is deemed interoperable on the date it is provided to the recipient by a certifying body authorized by the Office of the National Coordinator for Health Information Technology in accordance with the applicable version of EHR Certification Criteria;
- 3.) The donor may not limit the use, compatibility, or interoperability of the items or services with other EHRs;
- 4.) The recipient must pay 15% of the donor's cost for the items and services before receipt;
- 5.) The amount, nature, or receipt of items or services may not be a condition of doing business with the donor;
- 6.) Determination of the recipient's eligibility to receive the items or services and/or their amount or nature may not take into account the volume or value of referrals or other business between the parties;
- 7.) The arrangement must be in writing and signed by the parties; specify the items and services provided, the donor's cost, and the amount of the recipient's contribution; and cover all the items and services provided;
- 8.) If the recipient already has items or services equivalent to those provided by the donor, the donor may not know or act in reckless disregard or deliberate ignorance of this fact;
- 9.) If the items or services can be used for any patient without regard to payer status, the donor may not restrict the recipient's right or ability to use the items or services for any patient;
- 10.) The items and services do not include staffing the recipient's offices and are not used primarily for personal or other business unrelated to the recipient's medical/clinical practice or clinical operations;
- 11.) The arrangement does not violate Anti-Kickback or any billing or claims submission law or regulation (Stark);
- 12.) The donor does not shift costs of the items or services to any federal health care program (Anti-Kickback); and
- 13.) The transfer of the items or services occurs and all conditions are satisfied on or before December 31, 2021.

The new regulations also omit the requirement that donated software contain electronic prescribing capability.

For more information on state and federal healthcare program integrity laws, see here. Follow us on Twitter at @HealthInfoLaw

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