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OIG AND CMS EXTEND EHR SUBSIDY REGULATIONS

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On December 27, 2013, the Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) published a set of companion rules that finalize changes to the existing Stark Law and Anti-Kickback regulations with regard to electronic health records (EHRs).

The Stark Law and Anti-Kickback Statute (AKS) prohibit certain referral relationships among healthcare providers, but also provide for certain protections, called exceptions and safe harbors respectively. Certain relationships are excluded from liability if they fit within the parameters of an exception or safe harbor. The final rules update the Stark exception and AKS safe harbor for certain arrangements involving the donation of EHR items and services. The original rules were established and harmonized, to make them essentially identical, in 2006 and were scheduled to sunset at the end of 2013. The updates:

- Extend the sunset date until December 31, 2021;
- Clarify the definition of "interoperable" to more closely follow the National Coordinator for Health Information Technology (ONC) certification program for EHRs;
- Remove e-prescribing capability as a requirement to qualify;
- Exclude laboratory companies (providing pathology or anatomic services) from the definition of "protected donors" under the safe harbor; and
- Clarify the prohibition of a donor taking action to "limit or restrict the use, compatibility, or interoperability of the donated items or services."

Because the adoption of EHR technology continues to be a top priority for HHS, OIG and CMS determined that extending the sunset date would allow for the necessary continued adoption of EHR technology. They also expressed their belief that the need for such donations would decrease over time. Thus, they chose to simply extend the sunset date despite the urging from commenters to make the protections permanent. OIG stated that a permanent adoption of the safe harbor "could serve as a disincentive to adopting interoperable [EHR] technology in the near-term" and expressed concern that a permanent safe harbor would increase the risk of inappropriate donations "to lock in data and referrals between a donor and recipient." Additionally, OIG and CMS also waived the 30-day delay that a rule would typically have before becoming effective in order to protect ongoing or new donations made after December 31, 2013.

The final rules also update the definition of "interoperability" to mean software that, as of the date it is provided to the recipient, has been certified by an ONC-authorized certifying body applying the then-applicable ONC certification criteria. This new definition removes the 12-month timeframe requirement for certification of software. The final rules note that some software that meets the definition of interoperability, but has not been certified, will nonetheless be eligible for donation. Additionally, the rules remove the e-prescribing capability requirement to quality for protection under the exception and safe harbor, but clarify that this technology remains eligible for donation under the EHR exception and safe harbor.

Due to concerns that the protections, as they were originally articulated in 2006, were allowing for inappropriate donations of EHR technology, OIG and CMS chose to remove laboratory companies from the definition of protected donors. The change is to further the goal of EHR adoption for the benefit of patients, while minimizing the opportunity for misuse by donors to gain referrals. The rules clarify that laboratory services furnished by a hospital "that is a department of a hospital for Medicare purposes and that bills for the services through the hospitals provider number" do not fall within the scope of "laboratory companies" and will continue to be eligible for protection.

The final rules also emphasize OIG's and CMS' position that the protections should not be used to "lock in" referrals or inhibit the free exchange of data. OIG and CMS reiterated their commitment to investigating abuse and stated that systems designed to limit or restrict interoperability by the donor or on its behalf would not be protected by the safe harbor or exception and would be suspect under law.

These final rules should be a welcome development for many healthcare providers who are struggling to adopt EHR technology to implement healthcare reform initiatives in the face of diminishing reimbursement.

Squire Sanders lawyers have significant experience advising clients on EHR implementation issues under the Stark Law and AKS Statute and continue to monitor regulatory changes in this area. For more information regarding how we can assist you, please contact your principal Squire Sanders lawyer or one of the lawyers listed in this publication.

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