

Extension of and Modification to Regulatory Protections for Donated EHR

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SUMMARY

In the December 27, 2013 edition of the Federal Register, the Office of Inspector General (“OIG”) and Centers for Medicare and Medicaid Services (“CMS”), both within the U.S. Department of Health and Human Services (“HHS”), released substantially similar final rules regarding the donation of electronic health records (“EHR”) software and services (78 Fed. Reg. 78751 and 79202, respectively, and collectively, the “Final Rules”). The Final Rules amend the then-final regulations that were published in the Federal Register on August 8, 2006.

The Final Rules among other things: (i) extend the protections for EHR donations until December 31, 2021; (ii) prohibit laboratories from being a donor of EHR software and services; and, (iii) clarify when EHR software is deemed interoperable.

The proposed regulations that resulted in the adoption of the Final Rules were the subject of an earlier Saul Ewing alert (<http://www.saul.com/publications-alerts-1048.html>).

The donation of EHR is protected as an exception to the Physician Self-Referral Statute (commonly known as the “Stark Law”), which is enforced by CMS, and by a safe harbor to the federal Anti-Kickback Statute, which is enforced by the OIG, provided certain conditions are met in the exception and the safe harbor. Before publication of the Final Rules, these regulatory protections were set to expire on December 31, 2013.

One significant change in the Final Rules is that laboratories are now specifically excluded from the types of entities that may donate EHR items and services. In the preambles to the respective Final Rules, the regulators noted that commenters had raised concerns that laboratory companies were explicitly or implicitly conditioning donations of EHR items and services on the receipt of referrals from the recipients. The regulators addressed these concerns in the Final Rules.

Another modification in the Final Rules is the standard by which EHR is deemed to be interoperable. Interoperable is defined in 42 CFR 411.351 as “... able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.” In the Final Rules, the organization that deems interoperability of EHR is the Office of the National Coordinator for Health Information Technology (“ONC”), rather than the HHS Secretary in the current regulations. Further, the EHR software is deemed interoperable if, on the date it is provided to the physician, it has been certified as such by an ONC-approved body in accordance with the ONC’s most recently published regulatory criteria. The

current regulations require the donated software to be certified no more than 12 months prior to the date of donation.

In the Final Rules, EHR is no longer required to have electronic prescribing capabilities. While noting the importance of electronic prescribing, the regulators stated their belief that other existing policies sufficiently support the adoption of electronic prescribing.

The Final Rules add clarity to the current language that prohibits donors (or anyone on their behalf) from limiting or restricting the "use, compatibility, or interoperability" of the donated EHR items or services with other electronic prescribing or EHR systems. The Final Rules add a parenthetical that such other EHR systems could include, but not be limited to, "health information technology applications, products or services." The additional language is, according to the regulators, intended to prohibit donors' actions that limit the use, compatibility or interoperability of donated items or services with any other health information technology.

There are still many providers that have not adopted or effectively utilized EHR technology. The Final Rules extend for eight years the ability for providers to benefit from the receipt of EHR donations conditioned upon compliance with the Stark Law exception. Compliance with the Anti-Kickback Statute EHR safe harbor causes an arrangement to be immune from prosecution.¹ The Final Rules are effective March 27, 2014,

except that the change of the "sunset date" to December 31, 2021 was effective December 31, 2013.

Saul Ewing attorneys regulatory assist clients with regulatory analyses and structuring transactions, including the licensing of EHR software and negotiation of such arrangements. If you have any questions about this Client Alert or would like more information, please contact Bruce Armon or Karilynn Bayus, one of the other attorneys in the Saul Ewing Health Practice, or the attorney in the Firm with whom you are regularly in contact.

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¹ Compliance with the Anti-Kickback Statute EHR safe harbor causes an arrangement to be immune from prosecution. Failure to comply with a safe harbor under the Anti-Kickback Statute is not, however, fatal to the transaction. Rather, such an arrangement would be evaluated on a "facts and circumstances" basis.