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HHS, OIG, and CMS Issue Final Rule Revising the Stark Law and Anti–Kickback Act EHR Safe Harbor

On December 27, 2013, the Department of Health and Human Services ("HHS"), the Office of Inspector General ("OIG"), and the Centers for Medicare and Medicaid Services ("CMS") issued final rules revising the Stark Law, 42 C.F.R. § 411.357(w) and the Anti-Kickback Act safe harbor, 42 C.F.R. § 1001.952(y). The Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b, address, *inter alia*, physician conflicts of interest by effectively prohibiting physicians from referring services to other entities, such as hospitals, where the two have a financial relationship. As an exception, donation of electronic health records ("EHR") is permissible as long as parties strictly adhere to the statutory language. The Stark Law and the Anti-Kickback Act safe harbors were established originally in 2006, but were set to expire on December 31, 2013. In the recently issued Final Rules, available at http://federalregister.gov/a/2013-30923 and http://federalregister.gov/a/2013-30924, the OIG and CMS seek to amend regulations protecting arrangements involving the donation of EHR software, which includes related information technology and training services. This article describes several of the key provisions implemented by the Final Rule, but practitioners should be aware that it does not provide an exhaustive review of all the provisions. The Final Rule went into effect on March 27, 2014 and expires December 31, 2021. Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202-01, 79,202 (Dec. 27, 2013) [hereinafter Medicare Programs].

Updates to Donation Rules Originally Published in 2006

Congress has required the Secretary of Health and Human Services ("Secretary") to promulgate regulations setting forth "safe harbors" to the anti-kickback statute. These rules were meant to be evolving to accommodate the changes in practices and technology of the healthcare industry. As a result, OIG originally published safe harbor rules in 2006 that were scheduled to sunset on December 31, 2013. It was therefore necessary to revise them to reflect changes in the industry since 2006.

The most recent changes include: (1) an update of the provision under which EHR software is deemed interoperable; (2) removal of the requirement of electronic prescribing capability from the safe harbor; (3) extension of the sunset date, which is the date by which the safe harbor period is set to expire; (4) a limit to the scope of protected donors to exclude laboratory companies; and (5) clarification of the condition that prohibits a donor from taking action to limit or restrict use, compatibility, or interoperability of the donated items or services. *Id*. This column provides a brief explanation of each of these changes.

Updated Provision under which EHS Software Is Deemed Interoperable

The agencies proposed two modifications to the "deeming provision" in 42 C.F.R. § 1001.952(y)(2) to reflect and to coordinate with recent developments in the Office of the National Coordinator for Health Information Technology ("ONC") certification program. Under 42 C.F.R. § 1001.952(y)(2), EHR safe harbor requires that donated software must be "interoperable," as defined in the note to 42 C.F.R. § 1001.952(y). Currently, software may be deemed interoperable if the software has been certified by a Secretary-approved body no more than 12 months prior to the date that the software is provided to the recipient.

The Final Rule seeks to revise 42 C.F.R. §1001.952(y)(2) to "state that software is deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170." Medicare Programs, 78 Fed. Reg. at 79,204. The agencies concluded that ONC's expertise allows it to determine the relevant criteria and standards, and therefore the linking was appropriate. 78 Fed. Reg. at 79,204–79,205.

Removal from Safe Harbor of Requirement Related to Electronic Prescribing Capability

Prior to the Final Rule, software must have "contain[ed] electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided." 42 C.F.R. §1001.952(y)(10). The agencies have determined that there is currently enough support for adoption of electronic prescribing technology such that the current rule has become unnecessary. The Final Rule, therefore, eliminates the requirement that EHR software contain electronic prescribing capability to qualify for protection under the safe harbor at 42 C.F.R. §1001.952(y). Medicare Programs, 78 Fed. Reg. at 79,206.

Extension of the Safe Harbor Date to December 31, 2021

Originally, the proposed extension of the sunset date of the safe harbor period was December 31, 2016. But, in response to comments, the sunset date in the Final Rule was extended to December 31, 2021. Although many comments suggested that the safe harbor be permanent, the agencies disagreed out of concern that a permanent extension would create the risk of inappropriate donations of EHRs. A compromise was reached with an extended date to strike a balance between encouraging the adoption of interoperable EHRs with the risks of misuse. Medicare Programs, 78 Fed. Reg. at 79,206–79,207.

Exclusion of Laboratory Companies as Protected Donors

Although broad safe harbor protection is an important part of furthering the underlying public policy goal of promoting EHRs, the agencies expressed concern regarding misuse of EHRs. There have been many comments to suggest that donations in return for referrals have been a consistent problem as related to laboratory companies. As such, the Final Rule removes laboratory companies from the scope of protected donors under the safe harbor. Medicare Programs, 78 Fed. Reg. at 79,208–79,209.

Clarification of Prohibition against a Donor Taking Action to Limit or Restrict the Use, Compatibility, or Interoperability of Items or Services

In some cases, parties may appear to meet the conditions of the safe harbor, but, in fact, do not because of "data and referral lock-in." Data or referral lock-in occurs when software becomes effectively proprietary, creating prohibitive costs for non-donor providers and suppliers who cannot afford to connect to it. This is a problem because it has the same effect as altering the interoperability of software, albeit through different means. Although the Final Rule does not seek to adopt new requirements or modifications, the agencies expressed limited clarification to better reflect their intent. In essence, each potential violation requires a case-by-case evaluation to determine whether an arrangement between parties is of the prohibited type. Medicare Programs, 78 Fed. Reg. at 79,213.

There are a number of examples of the type of arrangements that would be incompatible with the exception. As a general statement of their intent, the agencies noted that "donations of items or services that have limited or restricted interoperability due to action taken by the donor or by any person on the donor's behalf (which could include the recipient acting on the donor's behalf) would fail to meet the condition at 42 CFR 1001.952(y)(3)." Medicare Programs, 78 Fed. Reg. at 79,213. This type of arrangement would include, for example, any agreement to inhibit competitors from interfacing or any agreement to create high interface fees to competitors. The agencies intend to consider "any action taken to achieve such a result [as] evidence of intent to violate the anti-kickback statute." *Id.*

Conclusion

The Final Rule reflects the agencies' continued recognition of the importance of encouraging the adoption of EHRs. These changes, however, present critical challenges and issues for current donation arrangements. First, labs and lab donation recipients had to terminate donation agreements to comply with the Final Rule before it became effective on March 27, 2014. Second, current donations, which may be protected, are entitled to continue provided they adhere to the new changes. Third, because agencies continue to be highly concerned about improper motives, parties may need to continually evaluate the nature of the donation agreement. Healthcare institutions and providers who engage in programs for donation of electronic health records should take note of the Final Rule to ensure proper compliance.

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