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Proposed Rules Would Extend and Modify the Anti-Kickback Safe Harbor and Stark Exception for Electronic Health Records

On April 9, 2013, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published complementary proposed rules that would both extend the life of, and modify in several respects, the anti-kickback safe harbor and Stark exception for electronic health record (EHR) donation programs. The safe harbor and exception allow certain entities to give non-monetary assistance, in the form of software and technical assistance and training (but not hardware), to healthcare providers to enable the providers to implement EHRs. The nearly identical safe harbor and exception were promulgated in 2006, and both are currently scheduled to expire on December 31, 2013.

CMS and OIG are specifically soliciting comments on the following aspects of the proposed rules:

- Extension of Deadline: CMS and OIG propose to extend the existing EHR safe harbor and exception through at least December 31, 2016, which is the last year that Medicare's meaningful use incentive payments will be available. CMS and OIG indicated that they are considering extending the deadline to December 31, 2021, which is the last year that Medicaid's meaningful use incentive payments will be available.
- Limiting Categories of Protected Donors to Reduce Abuse: Currently protection is afforded to any donor that provides and submits claims for healthcare items or services covered by a federal health care program. CMS and OIG noted concerns about donations from providers and suppliers of ancillary services rather than those that have a direct and primary patient care relationship. Specifically, CMS and OIG are concerned that ancillary providers are ignoring the interoperability components and are instead seeking to "lock-in" data and referrals. CMS and OIG thus requested comments on whether the rules' applicability should be limited to donors which are hospitals, physician group practices, Prescription Drug Plan sponsors, and Medicare Advantage organizations, and whether laboratories, durable medical equipment (DME) suppliers and independent home health agencies (described as presenting a high risk of fraud)

should be expressly excluded.

- Applicability to Health Information Exchanges (HIEs): CMS and OIG are soliciting comments on whether donations of services to enable the interoperable exchange of health records through other related technologies should also be protected. Although the term “HIE” is not specifically mentioned, the proposed rules contain broad language that would seem to encompass HIEs. This issue is important for hospitals as they establish HIEs and seek to connect group practices’ EHRs through their HIEs.
- Change to Certification Requirement: The current exception and safe harbor require that the donated software be interoperable when it is provided to the recipient, and software will be deemed interoperable if a certifying body recognized by HHS has certified interoperability no more than 12 months before the donation is made. This “deeming” provision is proposed to be amended in two ways. First, the Office of National Coordinator for Health Information Technology (ONC), rather than HHS, would approve deeming authorities. Second, rather than the 12-month time frame, an EHR could be deemed interoperable under any current edition of the EHR certification criteria and standards adopted by ONC.
- Removal of the Electronic Prescribing Requirement: The current exception and safe harbor require the donated software to have an electronic prescribing capability. In light of subsequently enacted federal incentives for electronic prescribing, CMS and OIG suggest that adequate incentives exist and propose deleting the e-prescribing condition under the EHR safe harbor and exception.

These proposed rules are important because, unless they are finalized prior to their current sun-setting date of December 31, 2013, many companies will need to restructure their EHR arrangements. Also of particular interest is the proposal to disallow protection for certain previously protected donor sectors (labs, DME, home health). Providers adopting HIEs also should take note and consider submitting comments seeking clarification that the protections would extend to donations of software and services to connect EHRs to their information networks.

Comments are due sixty days after publication of the proposed rules, or by June 10, 2013. CMS’s proposed rule is available [here](#) (78 Fed. Reg. 21308 (April 10, 2013)), and the OIG’s proposed rule is available [here](#) (78 Fed. Reg. 21314 (April 10, 2013)).

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