

CMS and OIG Propose Changes to the Electronic Health
Records Exception and Safe Harbor



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On April 10, 2013, the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services Office of Inspector General ("OIG") published parallel proposed rules revising, respectively, the Stark exception and Anti-Kickback safe harbor concerning electronic health record ("EHR") items and services. Highlights of the proposed rules include:

Sunset Provision. The EHR exception and safe harbor are scheduled to sunset on December 31, 2013. The proposed rules seek to extend the sunset provision to December 31, 2016.

Deeming Provision. The EHR exception and safe harbor specify that the donated software must be interoperable at the time it is provided to the physician. Currently, for purposes of meeting this condition, software is deemed interoperable if a certifying body recognized by the Secretary of Health and Human Services has certified the software no more than 12 months prior to the date it is provided to the physician. The proposed rules eliminate the 12-month certification window. Any software will be deemed certified if, on the date it is provided to the recipient, it has been certified to any edition of the EHR certification criteria that is identified in the then applicable definition of Certified EHR Technology in 45 C.F.R. part 170. In addition, the proposed rules place the Office of the National Coordinator for Health Information Technology, instead of the Secretary of Health and Human Services, in charge of recognizing bodies able to certify the interoperability of EHR systems.

Electronic Prescribing Provision. The current EHR rules require the donated software to contain e-prescribing capability. The proposed rules seek to eliminate this condition because sufficient alternative policy drivers exist to support the adoption of e-prescribing capabilities.

Additional Proposals and Considerations.

- *Protected Donors.* The EHR exception and safe harbor are currently available to a broad class of donors. The proposed rules seek to limit the availability of the EHR exception and safe harbor to cover only the original MMA-mandated donors: hospitals, group practices, Part D plan sponsors and Medicare Advantage organizations. In the alternative, the rules propose to exclude certain suppliers associated with a high risk of fraud and abuse in this context including laboratories, DME suppliers and independent home health agencies.
- *Data Lock-In and Exchange.* Due to the concern of using the EHR exception and safe harbor to lock-in referrals, the proposed rules request comments on new or modified conditions that could be added to the rules to achieve the goals of: (a) preventing data and referral lock-ins, and (b) encouraging the free exchange of data.
- *Covered Technology.* The proposed rules seek comments on whether the regulatory text should be modified to explicitly reflect the items and services that fall within the scope of covered technology. The agencies consider the current regulatory text, when read in light of the preamble discussion, sufficiently clear but seek input from the public regarding this issue.

CMS and OIG are accepting comments on the proposed rules through June 10, 2013. If you have any questions regarding these proposed rules, please contact your Thompson Coburn attorney, or any of the attorneys in our Health Care practice.

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