

New Notices of Proposed Rulemaking Address Electronic Health Records

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SUMMARY

The Centers for Medicare and Medicaid and the Office of Inspector General have published two (2) Notices of Proposed Rulemaking extending the sunset period for permitted donations of electronic health records under the Stark Law and Anti-Kickback Statute. Comments from all interested parties are due no later than June 10, 2013.

On April 10, 2013, the Centers for Medicare and Medicaid (“CMS”) and the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) published companion Notices of Proposed Rulemaking [78 Fed. Reg. 21308, 21314 (Apr. 10, 2013)] (each, a “Proposed Rule”).

The Proposed Rules specifically address electronic health records. The OIG Proposed Rule would revise an existing safe harbor under the federal Anti-Kickback Statute (“AKS”), and the HHS Proposed Rule would modify an existing exception under the so-called Stark Law.

There are three (3) primary purposes for the OIG and HHS Proposed Rules:

- extend the sunset date for the electronic health record safe harbor and the exception from December 31, 2013 to at least December 31, 2016;
- remove the requirement related to electronic prescribing capability from the safe harbor and the exception; and
- update the provisions under which electronic health records software is deemed interoperable to maintain consistency with the Office of the National Coordinator for Health Information Technology’s (“ONC”) electronic health record certification program.

In August 2006, OIG and CMS published simultaneous final rules that created a safe harbor under the AKS and an exception under the Stark Law, respectively, to protect donations of electronic health records software and related information technology and training. Under both 2006 final rules, the electronic health records technology was required to be interoperable and have electronic prescribing functionality. Both the exception and the safe harbor were set to expire on December 31, 2013.

Under each Proposed Rule, the exception and the safe harbor will be extended until at least December 31, 2016, and possibly longer. In the commentary to the Proposed Rules, OIG and CMS note that December 31, 2016 was chosen because it corresponds with the last year in which a provider may receive a payment under the Medicare electronic health record incentive program and the last year a

provider can initiate participation in the Medicaid electronic health record incentive program. OIG and CMS are seeking comments on further extending the exception and the safe harbor, possibly until December 31, 2021, when the Medicaid electronic health record incentive program expires.

The Proposed Rules also align the interoperability requirements for electronic health records technology covered by the Stark Law exception and the AKS safe harbor with the requirements issued by ONC under the HITECH Act. If the Proposed Rules are adopted as is, electronic health records technology will be considered "interoperable" if it has been certified as "Certified EHR Technology" under the then-current standards established by ONC.

Finally, the Proposed Rules remove the requirement that covered electronic health records technology include electronic prescribing capabilities, although in practice this will likely have little impact since e-prescribing is a critical measure of meaningful use under the Medicare and Medicaid incentive programs.

As part of the commentary accompanying the Proposed Rules, OIG and CMS are soliciting comments to limit the scope of donors protected by the AKS safe harbor and the Stark Law exception. At present, all donors, including laboratories, durable medical equipment makers and suppliers of ancillary services, are protected by the exception and safe harbor. OIG and CMS are concerned about the high potential for fraud and abuse by certain types of donors, and especially misuse of electronic health record donations to secure and/or lock in referrals. In particular, OIG and CMS state that they are considering excluding laboratories from the scope of permissible donors because their donations have been the subject of complaints.

Health care providers and donors using the AKS safe harbor and/or the Stark Law exception should review each Proposed Rule carefully and consider submitting comments to OIG and CMS to protect their interests no later than June 10, 2013. While electronic health records technology is not going away, this may be the last opportunity for interested parties to provide feedback to OIG and CMS relating to the AKS safe harbor and the Stark Law exception for the foreseeable future.

Saul Ewing can, among other things, assist in providing comments to the Proposed Rules. For more information, please contact the authors or the Health practice attorney with whom you are regularly in contact.

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