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**Update on Extension of Stark Exception and Anti-Kickback
Safe Harbor EHR Regulations**
By Steven Fox*

With 11 days remaining in 2013, it is time for health care organizations to consider the status of two companion regulations, one from the Centers for Medicare & Medicaid Services (CMS) and one from the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG) addressing the subsidized donation of electronic health record software (EHRs), information technology, and training services to health care providers. OIG published a safe harbor to protect certain arrangements from the reach of the Anti-Kickback Statute if they met specified criteria. The Final Rule for this safe harbor was published on August 8, 2006,¹ and it is scheduled to sunset on December 31.² Similarly, CMS published a Final Rule to protect essentially the same arrangements from the application of the Stark Laws on August 8, 2006³; that rule is scheduled to sunset on December 31.⁴

On April 10, CMS and OIG each issued a notice of proposed rulemaking (NPRM). Each NPRM proposed, among other things, updating certain aspects of the exception and safe harbor and, more importantly, extending the sunset date from December 31, 2013 to December 31, 2016. The public comment period on these proposed rules ended on June 10. Presumably, both agencies then reviewed the comments and finalized the proposed regulations. Before final regulations may be issued,

the proposed regulations must be reviewed and approved by the Office of Management and Budget (OMB). The two sets of regulations were received by OMB on November 6 (from OIG) and November 7 (from CMS).

If final regulations extending the sunset date are not issued by December 31, then as of January 1, 2014, health care organizations immediately must discontinue all subsidized donations of EHRs not otherwise protected under a separate regulation. Besides creating a huge bookkeeping nightmare, this gap would have a significant financial impact on thousands of health care providers who are currently benefiting from the subsidies.

In speaking (off the record) with a number of senior officials at HHS, CMS, the Office of the National Coordinator for Health Information Technology (ONC), OIG, and OMB, it became evident that both CMS and OIG are well aware of the significant problems and disruptions that will arise if the final regulations are not issued before the end of the year. Accordingly, the agencies are encouraging OMB to complete its review as soon as possible. These conversations also revealed that CMS and OIG would like to avoid, if at all possible, having a gap in the coverage of the regulations, as such a gap would create complex bookkeeping issues for physicians and hospitals, but the agencies acknowledge that "the ball is in OMB's court."

Email communication with OMB about the status of the two sets of regulations resulted in the following response:

To address your question, I can say on background that it is the Office of Information and Regulatory Affairs's longstanding policy not to comment on rules under review; under Executive Order 12866, OIRA has 90 days to review rules, which can be extended. Updated information on the status of these rules can be monitored at: www.reginfo.gov and information about meetings held on specific rules (as covered by EO 12866) here: http://www.whitehouse.gov/omb/oira_meetings/. To learn more information about OIRA see: http://www.whitehouse.gov/omb/inforeg_default.

In the meantime, given the uncertainty whether the sunset date for these regulations will actually be extended, organizations would be wise to decide how to plan for this potential gap in the regulations. The prudent course of action may be to assume the worst, i.e., that the regulations will expire. Whether an organization decides to send notices to all physicians who are currently receiving subsidies is a business decision that will depend, in part, on the contractual provisions in place between the organization and the receiving physicians. However, it is essential that each organization providing such subsidies beyond December 31 be prepared to modify its arrangements to assure that no subsidies are paid after December 31 unless the sunset date is extended or another

regulatory protection is in place.

**We would like to thank Steven J. Fox (Post & Schell PC, Washington, DC), for authoring this email alert.*

¹ 71 FR 45110.

² 42 CFR 1001.952(y)(13).

³ 71 FR 45140.

⁴ See 42 CFR 411.357(w)(13).

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