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EHR Donation Exception and Safe Harbor Modified and Extended through 2021

On December 27, 2013, the Centers for Medicare & Medicaid Services and the Office of the Inspector General, both of the Department of Health and Human Services, issued closely coordinated rules ("Final Rules") extending the original sunset of the current Stark exception and Anti-Kickback safe harbor for certain arrangements involving the donation of electronic health records ("EHR") items and services. The rules also made several modifications to the Stark exception and Anti-Kickback safe harbor.

Pursuant to these Final Rules, hospitals and other donors may make payments of up to 85 percent of the cost of acquiring certain EHR items and services (e.g., license fees, implementation services) for a physician, or other qualified recipient, without risk of liability under the Stark Law or the Anti-Kickback Statute.

Although most of the regulations regarding the allowable structure for these arrangements have been maintained, some significant changes were made to the original rules issued in 2010:

- Laboratory companies no longer qualify as allowable donors under the Final Rules, but no further restrictions to the class of donors or recipients were made.
- The requirement that donated software include e-prescribing capabilities has been removed.

- The process by which software is “deemed” to be certified as “interoperable” under the rules has been changed. The Office of the National Coordinator (“ONC”) will now consider arrangements for donation eligible under these rules “if, on the date it is provided to the recipient, it has been certified to any edition of the electronic health record certification criteria that is identified in the then-applicable definition of the certified EHR technology.” Thus, software certified by the ONC based on the 2011 or 2014 certification editions will now qualify under the Final Rules.

The current expiration date for the original rules is December 31, 2013. The proposed rules issued earlier this year included a sunset date of 2016, but this was extended in the Final Rules to December 31, 2021, bringing the date in line with the expiration of the Medicaid EHR Incentive Program. The extension of the sunset date takes effect immediately, while the other changes to the original rule will become effective March 27, 2014.

The extension potentially allows entities with current EHR donation arrangements to extend these subsidies well beyond the original 2013 deadline, without the risk of liability under the Stark Law or Anti-Kickback Statute. Since many contracts for provision of EHR subsidies may have expired in 2013, parties should review these arrangements to consider whether extension is appropriate and to confirm their arrangements are otherwise in compliance with the Final Rules.

The Final Rules for the Stark exception can be found [here](#) and the Final Rules for the Anti-Kickback safe harbor can be found [here](#). Please contact one of the attorneys in our Health Care Practice Group if you have any questions regarding these new rules or other questions regarding compliance with health care fraud and abuse laws.

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