OIG Advisory Opinion: Donation of Limited Interfaces and Related Support Services Does Not Violate Anti-Kickback Statute

On December 19, 2012, the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS) issued Advisory Opinion No. 12-20, regarding a healthcare provider's provision of free electronic interfaces to community physicians and physician practices. According to the OIG, donation of such interfaces, intended solely to permit physicians to order laboratory and diagnostic services and then obtain the results electronically, does not constitute prohibited "remuneration" for the purposes of the Anti-Kickback statute.

The OIG Advisory Opinion is certainly good news for healthcare systems facing the immense challenge of connecting its hospitals, labs, community physicians and other providers. However, it also serves as a reminder of the importance of evaluating whether an organization's efforts to connect with the health IT systems of its affiliates and partners satisfies the Stark, Anti-Kickback and other regulatory requirements. It is also essential to keep in mind that both the Stark exception and the Anti-Kickback safe harbor for EHR donations, which permit subsidies of up to 85% of the cost of the EHR, expire at the end of this year, on December 31, 2013, unless they are extended. For the latest information on whether the exception and safe harbor will be extended, please check back periodically on our Health IT Law Blog (www.healthitlawblog.com).

In addition to allowing donations of certain interfaces, the OIG Advisory Opinion permits the donation of support services necessary to maintain the interface, including software updates. There were two provisos to such donations: (i) the interface must be provided to all physicians who request it; and (ii) physicians who choose to avail themselves of the arrangement are solely responsible for all aspects of their own electronic health records system (EHR), including all necessary hardware, installation and connectivity services that would allow them to communicate with the hospital or health system.

In OIG's analysis, such interfaces do not have any independent value for the physician practices, because they are "integrally related to the offering provider's or supplier's services" and may not be used for any other purpose. The OIG noted that access to the interface is a contemporary analog to the limited-use computer described in the preamble to the 1991 safe harbor regulations, which concluded that providing such a limited-use computer (with no independent value) to access lab results could not constitute an illegal inducement under the Anti-Kickback Statute.

In May 2008, the Center for Medicare and Medicaid Services (CMS) reached substantially the same conclusion regarding donation of software interfaces for the purposes of the Stark law. In Advisory Opinion No. CMS-AO-2008-01, CMS determined that such donations would not constitute prohibited "remuneration" for the purposes of the Stark law. Neither the 2008 CMS Advisory Opinion, nor last month's Advisory Opinion from OIG addressed the question of whether a donation of such software interfaces would be allowed pursuant to a Stark exception or an Anti-Kickback statute safe harbor (e.g., for donation of electronic health records (EHR) systems). Similarly, neither Advisory Opinion extends beyond the limited scope of the proposed arrangements in their respective cases. Therefore, if a healthcare provider intends to donate software or interface technology with a wider suite of capabilities than just the ordering and reporting of test results, such planned donation requires an especially close legal review.

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