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HEALTH CARE ALERT

Department of Health and Human Services Advisory Opinion Adverse To Arrangement Involving Electronic Health Records For Labs

By James Schuster, Partner

The federal government, through the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG), has just released a federal health care fraud and abuse advisory opinion that requires health care providers, laboratories and electronic health record and related software and technology (EHR) providers to take into account their business dealings with one another.

HHS OIG Advisory Opinion No. 14-03, dated April 1, 2014, but not released until April 8, 2014, calls into question, as suspect for fraud and abuse under the anti-kickback statute, situations in which a physician or other health care provider transmits a blood or other lab test through an EHR and that test is, in turn, carried out by a clinical laboratory that has an arrangement with the EHR vendor to pay the EHR vendor a per-order fee for each test received.

Under the federal Anti-Kickback Statute, at 42 USC § 1320a-7b, it is a crime to knowingly and willfully offer, pay, solicit, or receive remuneration or reward referrals of items or services that are reimbursable by Medicare, Medicaid and other federal health care programs.

Under the proposed arrangement in the advisory opinion, a physician would make an order using the EHR vendor's EHR service and the laboratory in question would be an "in-network" laboratory. The laboratory would then, in turn, pay a per-order fee to the EHR vendor. However, if the physician would decide to order the test to be carried out by a "non-network" laboratory, the physician would be required to pay the EHR vendor a fee of up to one dollar per transmission.

The Inspector General concluded that this arrangement was suspect for generating remuneration in contravention of the federal Anti-Kickback Statute. It noted that it could impose sanctions on health care providers utilizing such an arrangement.

Electronic transmission of medical data, including laboratory testing and orders, is increasingly common. Some laboratories will collaborate with cloud-based EHR service vendors in order to allow physicians to order tests and receive their results directly through the EHR vendor's EHR service. While such a situation would obviously provide a more streamlined and efficient avenue for physicians, it is also ripe for abuse.

The HHS OIG advisory opinion identifies yet another fraud and abuse risk concerning physician, laboratory and other health care provider use and dealings with EHR systems and providers. Given the HHS OIG's analysis and rational for its conclusions, federal government, *qui tam* relators, and others may well seek to rely on this advisory opinion in other EHR contexts to support claims of fraud, abuse and false claims against health care providers.

Although health care providers participating or obtaining reimbursement under Medicare, Medicaid and other federal health care programs are directly subject to the federal Anti-Kickback Statute and other fraud and abuse laws, EHR vendors do not face reciprocal exposure. Health care providers

cannot assume, therefore, that EHR vendor and their contracts and agreements are attentive to health care provider compliance requirements and risks.

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