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Open Letter Limits Self-Disclosure of Stark Violations

On March 24, 2009, the OIG issued an open letter narrowing the scope of the Self Disclosure Protocol designed to help resolve matters giving rise to civil monetary penalty liability under both Stark laws and the anti-kickback statute. The open letter stated, "OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation."

The OIG explained that its refinement was part of an ongoing effort to evaluate and prioritize its work and focus the self disclosure protocol on kickbacks intended to induce or reward a physician's referrals. The OIG advised that it is narrowing the scope of the self disclosure protocol would allow it to better allocate its resources, but warned providers "not to draw any inferences about the Government's approach to enforcement of the physician self referral law [Stark]."

The OIG also established a minimum settlement of \$50,000 for kickback related submissions accepted into the SDP. Despite the new minimum settlement amount, the OIG stated that it "will continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice, stated in the 2006 open letter [announcing the self-disclosure protocol], of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred."

Providers should be aware of these refinements when considering whether to self-disclose. This important decision is best made at the board level in accordance with fiduciary duties and with the advice of legal counsel. Despite the new minimum settlement amount, there may still be advantages to self-disclosure in the appropriate circumstances such as avoiding onerous corporate

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integrity agreements and/or certification of compliance agreements, and a reduction in potential Civil Monetary Penalties.

Please contact Linda Batten at lmb@kgrlaw.com or Mark Colucci at mjc@kgrlaw.com for more information on OIG's self disclosure protocol.

Internet Health Records May be Prone to Inaccuracies

Beth Israel Deaconess Medical Center acknowledged this month that it was "a mistake" to send insurance claims data to Google Health to summarize patients' medical histories. It has now discontinued the practice.

Google Health is a web portal that allows individuals to keep records of their medications, allergies, and illnesses in a single file that is easily accessible over the Internet. However, the claims data, such as diagnosis and procedure codes, is prone to inaccuracies, particularly for patients with complex health problems.

A 59-year-old kidney cancer survivor recently tried to move his Beth Israel records into his Google Health file. However, the list of conditions in his new Google record included serious diagnoses that he had never received from his doctors, as well as incorrect and missing dates.

Such inaccuracies could lead to medical errors by doctors using the bad information. Beth Israel acknowledged this problem and has taken action to remedy the issue. It will now send to Google Health information on patient medical problems from clinical records rather than from claims data. Nonetheless, Google Health has stated that it will continue to let each of its partners determine the best way to send patient records to Google, but it will work with its partners to improve the quality of the information.

Healthcare providers should be aware of potential issues with new internet health record sites and when using such web sites, and verify that the information provided for the online patient health record is accurate. Failure to do so could easily lead to negligence claims.

For more information please contact Linda M. Batten at lmb@kgrlaw.com or Mark J. Colucci at mjc@kgrlaw.com.

Sale of Practice Assets and Employment by

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Purchaser Passes OIG Muster

The OIG recently advised that it found no prohibited remuneration in the employment arrangement between a mental health counselor (the "Practitioner") who accepted employment from the outpatient mental health services company (the "Requestor") that purchased the real estate in which her practice was located (the "Building"). OIG Advisory Opinion 09-02 provides some implicit guidance to providers who sell their practices and then work for the buyer. However, the OIG declined to expressly address the relationship between revenue received from a practice sale and employment compensation.

The Requestor agreed to purchase the Building on the condition that the Practitioner serve as Requestor's clinic director in the Building. The employment contract and purchase agreement were entered into concurrently. As an employee, Practitioner agreed to be compensated based upon services she personally performed and total clinic revenue. The Requestor certified to the OIG that it paid market value for the Building and that the purchase price did not include payment for referrals.

In considering whether the employment arrangement violated the Anti-Kickback Statute ("AKS") the OIG determined that the AKS employee exception and safe harbor were satisfied. Under AKS it is a criminal offense to knowingly and willfully offer, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. "Remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. AKS has been interpreted to cover even those arrangements in which only one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.

However, AKS clearly excludes from its reach employment compensation to bona fide employees for covered services and the relevant safe harbor regulation, 42 CFR s 1001.952(i), excludes from "remuneration" amounts paid by employers to bona fide employees. The OIG concluded Practitioner's compensation for services personally performed and total clinic revenue met those thresholds.

The OIG noted that whether Practitioner was a "bona fide" employee was outside the scope of the opinion, and it passed on the opportunity to consider the impact of the purchase of the Building and price paid for the Building on the potential for referrals in violation of

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AKS. While combining an asset purchase and employment agreement is not a *per se* violation of the AKS, the asset purchase can be a complicating factor, particularly when Stark law referral prohibitions are considered. In such instances care should be taken to ensure that assets, excluding patient lists and items for which providers are prohibited from accepting consideration, are purchased at fair market value and that the purchase price is paid, if at all possible, within one year.

For more information, please contact Mark Colucci at mjc@kgrlaw.com or Linda Batten at lmb@kgrlaw.com.