Two recent Federal Court decisions in cases brought by whistleblowers reveal the Courts’ willingness to apply an expansive interpretation of the Stark and Anti-Kickback Statutes. These decisions signal a more stringent enforcement environment and show the necessity of assuring arrangements are compliant. To overlook compliance is to risk catastrophic penalties. Fortunately, as outlined in this Client Alert, there are compliance steps you can take.

THE DECISIONS

_U.S. ex rel Fry v. The Health Alliance of Greater Cincinnati, et al._ is an action, under the False Claims Act, being brought against a hospital and a dominant cardiology group at the hospital by a competing cardiologist and joined by the government. It is alleged that the hospital assigned time in the hospital’s heart station in proportion to the volume of referrals of cardiac procedures made by cardiologists to the hospital. The hospital and cardiology group moved to dismiss the action, asserting, among other arguments, that the Anti-Kickback Statute did not apply because scheduling does not amount to remuneration within the meaning of Anti-Kickback Statute. They maintained that remuneration is meant to include only cash or in-kind benefits. In its decision rejecting a motion to dismiss, _the District Court held that an opportunity to bill and earn money may constitute illegal remuneration under the Anti-Kickback Statute._ While the Court’s decision is less surprising where facts may be proved establishing that the hospital’s scheduling policy was designed for the purpose of inducing referrals, the Court’s determination that an opportunity to earn money may constitute illegal remuneration under the Anti-Kickback Statute highlights the broad reach of the Statute and how it may be unexpectedly implicated.

_United States ex rel. Ted D. Kosenske, M.D. v. Carlisle HMA, Inc., et al._ is an action, under the False Claims Act, brought against a hospital by a former anesthesia group physician. In this case, an anesthesia group, which had an exclusive anesthesia services agreement with the hospital to provide all anesthesia services required by the hospital’s patients at the hospital, also provided pain management services to patients at a hospital-owned outpatient ambulatory surgery center and pain clinic (the “Pain Clinic”). The hospital did not charge the anesthesia group rent for space and equipment, or a fee for support personnel it provided to the anesthesia group at the Pain Clinic. The exclusive anesthesia services agreement between the hospital and the group had not been amended to specifically address pain management services at the Pain Clinic. The Court stated that in pain management a physician in an outpatient facility is in a position to generate business for a hospital, and the government’s concern is remuneration flowing from the hospital to these physicians in order to somehow induce the physicians to provide business for the hospital.
The Court held that the hospital’s provision of space, equipment and support personnel without charge constituted “remuneration” for purposes of Stark and established a “compensation arrangement” and a “financial arrangement” between the anesthesia group and the hospital as those terms are defined under the Stark law. Because Stark prohibits a physician who has a financial relationship with an entity from making a referral to the entity for the furnishing of designated health services (in this case hospital services) for which payment may be made under Medicare or Medicaid, and the entity that provides the services pursuant to such improper referral is prohibited from submitting a claim for or otherwise billing for the services, an exception to the law’s broad prohibition must apply. The Court also held that the arrangement did not meet the law’s “personal services exception” because: (i) there was no written contract addressing the arrangement at the Pain Clinic; and (ii) “there were no arm’s length negotiations that could vouch for the fair match of service and compensation,” i.e., there was no fair market value exchange.

**COMPLIANCE LESSONS**

- Make sure all arrangements where a party is in a position to refer or otherwise generate business are documented by a written agreement.
- Make sure the written agreements set forth in detail all service and compensation terms.
- Make sure existing agreements are updated to address any change in circumstances. Establish a policy of reviewing existing agreements to confirm they have not become stale or outdated.
- Document, at the time the agreement is entered into, that the agreement’s compensation or remuneration constitutes fair market value. Utilize an independent valuation expert to review the arrangement and confirm and document whether the compensation arrangement or remuneration reflects fair market value and the arrangement is commercially reasonable.
- Be aware that “remuneration,” as defined under the health laws, can be found to exist even in the absence of money being exchanged.
- Determine at the outset whether a party to the arrangement is in a position to refer or otherwise generate business. In the *Kosenske* case, the anesthesia group did not begin to do pain management at the Pain Clinic until approximately six years after it had entered into the exclusive hospital contract. The group may never have considered the fact that it became in a position to refer or otherwise generate business to the hospital.
- Have all arrangements reviewed by health law counsel in advance in order to identify what health laws are implicated, whether an exception applies and what must be done in order to meet each element of an exception.

If you would like additional information about the issues addressed in this CLIENT ALERT, please contact:

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