Client Alert: Covidien Settlement Confirms US DOJ's Willingness to Pursue Healthcare Kickback Cases Based on Non-Monetary Remuneration to Potential Referral Sources

Both Federal and State anti-kickback statutes applicable to referrals of patients or healthcare services prohibit kickbacks, including remuneration and compensation that is not just monetary but is anything of value provided to induce referrals. Historically, non-monetary kickback cases brought by federal and state agencies have involved free dinners, gifts, vacations, and other items that have an obvious and readily quantifiable commercial value to the referring provider. Less common are cases involving promotional opportunities, travel assistance for patients, logistical support for testing, and other free or "in-kind" services because these alleged kickbacks do not have a direct or easily calculable value to the referral source.

But providers should be aware that federal and states agencies are *increasingly willing* to pursue such non-monetary and tangential remuneration as a basis for criminal and civil liability under both criminal anti-kickback statues and civil false claims or fraud laws.

Illegal Remuneration

The broad reach of the Medicare anti-kickback statute, 42 U.S.C Section 1320a-7a, was confirmed by a recent federal False Claims Act settlement under which Covidien LP agreed to pay $17.2 million to the United States and over $2.5 million to various states (including California and Florida) to settle allegations that the company caused the submission of false claims for its ClosureFAST radiofrequency ablation catheters by providing practice and market development support to physicians as an inducement for the physicians to use such catheters. Specifically, Covidien LP's illegal remuneration to physicians allegedly consisted of "practice and market development support [including] customized marketing plans for specific vein practices; scheduling and conducting "lunch and learn" meetings and dinners with other physicians to drive referrals to specific vein practices; and providing substantial assistance to specific vein practices in connection with planning, promoting, and conducting vein screening events to cultivate new patients for those practices." *See*3/11/19 DOJ Press Release.

This settlement reflects DOJ's increasingly aggressive approach to any marketing or promotional activities of any service or item directed at specific referral sources. While Covidien LP's marketing strategy was not simply a general print and ad campaign for its product, but instead targeted specific physician practices, there is no indication in the government's press release or its pleadings that the company's educational activities or marketing assistance was overtly tied to the participating physicians' promise or commitment to use the promoted catheters.

"Causation" Evidence

Although the lack of direct evidence casually tying the alleged inducement to the physician's referrals is a substantial defense to a kickback allegation, one can assume that the DOJ was able to show that specific physicians who participated in Covidien LP's promotional and marketing activities used the catheters more than those who did not. For the DOJ, such "causation" evidence is now seen as enough, at least in the civil context with its lower burden of proof, even though the same evidence would be insufficient to establish any illegal inducement with respect to a manufacturer's entirely passive product marketing and promotional activities that are not specific to any particular physician. This reality doubtlessly factored into Covidien LP's decision to extensively cooperate with DOJ's investigation and enter into a civil settlement that did not admit FCA liability, rather than to litigate whether its promotional activities were, in fact, an "inducement" for the physicians' use of their catheters.

For manufacturers and users of healthcare devices, items and drugs, the Covidien settlements serves as a timely

reminder that any promotional and marketing assistance to specific physicians or other potential referral sources regarding a particular product raises a substantial risk of violating federal and state anti-kickback statutes and creating liability under federal and state false claims statutes when claims for the product are submitted even if the manufacturer's assistance did not require the user's promise or other commitment to use the product. In addition, this settlement was the result of whistleblower actions filed by employees of Covidien and a physician who will receive over **$3 million as a reward**, thereby underscoring the importance to healthcare manufacturers and providers of responding to internal regulatory concerns in a prompt and meaningful manner.

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