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CLIENT ADVISORY

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"Carving-Out" Medicare Patients Is Not Enough to Assuage Anti-Kickback Concerns Under New OIG Opinion

On June 13, 2013, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") released a new Advisory Opinion (OIG Advisory Opinion No. 13-03) reiterating its long-standing concerns about arrangements whereby parties attempt to "carve-out" Medicare and/or Medicaid beneficiaries in order to avoid potential concerns under the Federal Anti-Kickback Statute (the "Kickback Statute"). In frank terms, the OIG opined that such a "carve-out" is not dispositive of the question of whether an otherwise questionable proposed arrangement implicates the Kickback Statute. Instead, such arrangements may violate the Kickback Statute "by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business."

In the Opinion, the OIG considered an arrangement proposed by a "Parent Laboratory" operating as an independent clinical laboratory that would establish a new legal entity (the "Management Company") to contract with physician groups (the "Physician Groups"). The Physician Groups would in turn set up their own clinical laboratories with the assistance of the Management Company. The Management Company would also provide the Physician Groups with facility space and laboratory management and support. The Management Company would offer to lease the Physician Groups personnel, equipment, and licenses for use of the Parent Laboratory's proprietary methods of operation. The Physician Groups would, however, own and operate the Physician Group laboratories for CLIA compliance and would be responsible for the laboratories' data collection, quality review process, and billing. In requesting the Advisory Opinion, the Parent Laboratory certified that the Physician Groups would provide testing in their laboratories only for patients who are not Federal health care program beneficiaries and that Physician Groups would send Federal health care program beneficiary specimens to other laboratories, including possibly the Parent Laboratory. The Parent Laboratory also certified that it would not require, pressure, or induce the Physician Groups to refer any testing to the Parent Laboratory or any other laboratory owned by or affiliated with the Parent Laboratory.

These efforts to "carve-out" federal health care program beneficiaries and ensure against improper referrals were not enough for the OIG to conclude that the arrangement would not implicate or potentially violate the Kickback Statute. The OIG noted a number of issues with the proposed arrangement, including that "the Parent Laboratory would offer the Physician Groups remuneration in the form of the potentially lucrative opportunity to expand into the clinical laboratory business with little or no risk." Additionally, while the proposed arrangement "carved-out" federal health care program beneficiaries, "participation in the proposed arrangement may increase the likelihood that physicians will order services from the Parent Laboratory for Federal health care program beneficiaries" for reasons of convenience, commitment to the Parent Laboratory, or potentially to obtain better pricing on private pay services.

Because of the potential for such remuneration, the OIG stated that it could not "conclude that there would be no nexus between the potential profits the Physician Groups may generate from the private pay clinical laboratory business, on the one hand, and orders of the Parent Laboratory's services for Federally insured patients, on the other." Further, the OIG had concerns that the financial incentives derived from the private pay laboratory business were likely

to impact the physician's decision-making regarding all patients, including Federal health care program beneficiaries, which could result in the overutilization of laboratory services and increase costs to the Federal health care programs.

The OIG opinion puts providers on notice that an arrangement that attempts to "carve-out" Medicare and Medicaid beneficiaries may receive increased scrutiny because such arrangements may be used to attempt to protect "otherwise questionable financial arrangements." Therefore, the "carve-out" is not dispositive of whether an arrangement implicates the Kickback Statute. Instead, an arrangement with a "carve-out" provision may still implicate the Kickback Statute if it has the potential to remunerate a provider by offering an opportunity for increased profits or referrals. In this case, the "carve-out" did not protect against the OIG's concerns regarding the Physician Groups opportunity to expand into the laboratory business with little or no risk, as well as the potential to impact physician decision making regarding which laboratory to utilize for Federal health care program beneficiaries.

If you have any questions related to OIG Advisory Opinion No. 13-03 or the Kickback Statute in general please contact Mary Malone (mmalone@hdjn.com), Clay Landa (clanda@hdjn.com), or Harold Han (hhan@hdjn.com). They can be reached by phone at (866) 967-9604. Additional information about Hancock, Daniel, Johnson & Nagle, P.C., is available on the firm's website at www.hdjn.com.