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Healthcare Industry ALERT
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OIG advisory opinion describes suspect 'under arrangements' transactions

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The Office of Inspector General of the Department of Health and Human Services recently posted an Advisory Opinion identifying certain types of "under arrangements" transactions as suspect under the Medicare Anti-Kickback Statute, which prohibits payments to induce referrals of government health program patients.

Medicare statutes and regulations authorize a hospital to bill and receive payment for services furnished by a third party "under arrangements." The patient and the Medicare program are responsible for payment to the hospital for the services furnished. The hospital is responsible for paying the third party contractor for the services, and the contractor is prohibited from seeking any payment from the hospital's patients or the Medicare program.

Coverage for therapeutic services for hospital outpatients is limited to services furnished in the hospital or a facility designated as provider-based. However, the Medicare program generally will cover diagnostic services provided under arrangements to a hospital outpatient regardless of the location in which the services are furnished. Consequently, many hospitals have arrangements with third parties to furnish diagnostic outpatient services for hospital patients "off campus," at the contractors' premises.

Advisory Opinion No. 10-14

A sleep disorder diagnostic testing facility requested the advisory opinion from the OIG. The sleep lab had no direct or indirect physician owners. It had contracted with a hospital (with which the sleep lab had no ownership interest or other contractual relationship) to provide the equipment, technology, supplies and staff necessary to operate a sleep testing facility at the hospital. The hospital owned and maintained the space. The hospital hired a medical director through a separate arrangement. The sleep lab did not provide professional interpretations for the sleep studies or marketing or external education services on behalf of the hospital.

Under the arrangement, the sleep lab provided services to the hospital pursuant to a signed, written agreement that specified all of the services to be provided and the material terms of the arrangement. The sleep lab charged the hospital a set per-test fee, which it certified as being consistent with fair market value. The hospital billed patients or third party payers for the sleep testing services. The fees payable by the hospital to the sleep lab did not vary based on the hospital's success in collecting payment for the claims it submitted, unless a claim was denied due to the sleep lab's equipment failure or technician error. The sleep lab certified that the arrangement was "in full compliance with Medicare regulations applicable to services secured by hospitals 'under arrangements.'"

The OIG advised that the arrangement could potentially generate prohibited remuneration under the Medicare anti-kickback statute if the requisite intent to induce or reward referrals of federal government health care program business. Nevertheless, the OIG indicated it would not impose sanctions in connection with the arrangement. Even though the OIG considered the "per click" fee arrangement as inherently reflective of the volume or value of services ordered and provided, the OIG determined that the arrangement lacked characteristics of a "suspect 'under arrangements' transaction." Additionally, the OIG concluded that the arrangement posed an "acceptably low risk of improperly influencing or rewarding referrals."

Characteristics of a "Suspect" Arrangement

The OIG's position is that even if a provider complies with relevant coverage and payment rules, an arrangement may still violate the anti-kickback statute. These are some examples provided by the OIG:

- A hospital pays above-market rates for the arranged-for services to influence referrals. The OIG indicated that an "under arrangements" entity might be in a position to influence referrals to the hospital if it provides marketing services, if it has an independent patient base, or if it is owned by referral sources for the hospital, such as physicians.
- An "under arrangements" entity agrees to accept below-market rates to secure referrals from a hospital, its owners, or its affiliates and affiliated Medicare providers and suppliers.
- A hospital owns an interest in an "under arrangements" entity such that the hospital receives remuneration in the form of returns on investment in exchange for referrals to the entity or its affiliates (such as an affiliate that furnishes ancillary services or equipment).

- A referral source for the hospital, such as a physician or physician group, owns an interest in the "under arrangements" entity.
- The "under arrangements" transaction includes the furnishing of items or services ancillary or additional to the services being furnished "under arrangements" or includes the furnishing of items and services to patients who are not hospital inpatients or outpatients (e.g., patients who have been discharged from the hospital).

The OIG indicated that this list is illustrative, not exhaustive, of the potential risks of "under arrangements" transactions.

The OIG's Analysis

The OIG focused on four factors in determining that the proposed arrangement posed a low risk of fraud and abuse in connection with the Anti-Kickback Statute.

1. The sleep studies were ordered and interpreted by physicians without a direct or indirect financial interest in the sleep lab and who thus did not stand to gain from referrals to the sleep lab. Similarly, the hospital had no direct or indirect ownership interest in the sleep lab "that might otherwise create the potential for self-dealing in the awarding of the 'under arrangements' contract or an undue incentive to generate sleep testing referrals."
2. The sleep lab certified that the per-test fee was arrived at through arm's length negotiations, was consistent with fair market value and, taken individually and not in the aggregate, did not take into account the volume or value of referrals or other business generated between the parties. "Arm's-length, fair market value fees for reasonable services actually rendered that do not individually take the volume or value of referrals into account . . . are less likely to be remuneration to induce referrals."
3. The sleep lab charged and collected the fee, regardless of whether the hospital ultimately received reimbursement from the patient or any third-party payer, including federal health care programs. The OIG indicated that the arrangement did not operate as a reimbursement guarantee, conferring financial benefit on the hospital by immunizing it against collection risk.
4. The hospital assumed business risk and contributed substantially to furnishing sleep testing services for which it billed, including providing necessary space, equipment, a medical director, and administrative services.

The OIG stated that the arrangement, taken as a whole, "is readily distinguishable from an arrangement in which one provider supplies little more than a billing number and a captive stream of referrals, while another provider that is already in the same line of business furnishes the bulk of the services through a management or similar contract, such as might happen in a 'turnkey' arrangement."

Evaluating Your Risk

Last year's change to the definition of "entity" under the Stark regulations has already resulted in the demise of a number of "under arrangements" transactions between hospitals and physician-owned contractors. Still, significant numbers of such transactions remain, either under the "rural provider" exception to the Stark law or where physicians do not refer federal government health care program patients to the "under arrangements" entity. With this Advisory Opinion, the OIG has clearly indicated that it disfavors many practices that may be common within the industry.

If you have any questions about "under arrangements" transactions or would like assistance in reviewing or evaluating your compliance risk regarding "under arrangements" transactions or other healthcare transactions, please do not hesitate to contact any of the healthcare industry lawyers listed below:

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