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UPDATE
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OIG Issues Advisory Opinion Permitting Podiatrist-Owned Orthotics Business

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The Office of Inspector General (OIG) issued a favorable Advisory Opinion to a podiatrist and the podiatrist's spouse (together, the Requestors) regarding a proposed limited liability company (LLC) that will enter into agreements with various manufacturers and entities (Customers) to provide industrial orthotics and services to the Customers' employees, who spend much of their workday on their feet (together, the Proposed Arrangement). The Advisory Opinion is summarized below.

OVERVIEW

The Requestors are a podiatrist, who both owns and operates a general podiatric medical clinic (Clinic), and the podiatrist's spouse, who serves as the Clinic's vice president. The Requestors' Proposed Arrangement will provide orthotics to their Customers' employees as well as the following services: foot scans and the manufacturing, delivery, fitting, and adjusting of the orthotics.

COMPONENTS OF THE PROPOSED LLC

To carry out the Proposed Arrangement, the LLC will lease a foot scanner from the Clinic. The lease will comply with all parts of the anti-kickback statute's (AKS) equipment rental safe harbor. Under the Proposed Arrangement, the services provided will be limited to those mentioned above, and the LLC will not submit any claims to a federal health care program. Additionally, under the Proposed Arrangement, the LLC will charge fair market value for each orthotic sold and for the other related services provided. Specifically, the price the LLC charges for its products and services will not be based on the number of referrals to the proposed LLC or to any other entity owned by the Requestors.

Under the Proposed Arrangement, the LLC will employ the podiatrist as well as a licensed practical nurse, who is currently employed by the Clinic. Both will be part-time employees of the LLC, working for the LLC on the days that they are not scheduled to work at the Clinic. The LLC will employ the podiatrist's spouse to serve as president to carry out the day-to-day affairs of the Proposed Arrangement. The compensation for each LLC employee will be set at fair market value and will not be based on the volume or the dollar value of referrals to the LLC or to any other entity owned by the Requestors.

The Requestors certified that some of the Customers' employees who will receive services under the Proposed Arrangement may already be patients of the Clinic. There is also the potential that, while in the process of fitting an employee of a Customer, the LLC may realize that the Customers' employee requires additional medically necessary services not provided by the LLC. In this event, the LLC will only inform a Customers' employee of the need to receive additional medically necessary services and/or treatment but not refer that person to the Clinic for such services and/or treatment.

OIG FINDINGS

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals or services reimbursable by a federal health care program. The OIG found that the Proposed Arrangement could potentially violate the AKS. Although the LLC will not be billing any of its services to a federal health care program, the Clinic does bill to federal health care programs for some of the items and services it provides. The OIG emphasized the risk of a connection between the LLC and the Clinic. Specifically, the OIG questioned whether, under the Proposed Arrangement, the LLC's relationship with its Customers has the ability to produce federal health care program referrals to the Clinic. Nonetheless, the OIG found that the Proposed Arrangement does not violate the AKS because (1) the orthotics and services provided by the LLC will be at fair market value; (2) the Requestors confirm they will not refer Customers' employees to the Clinic; and (3) the agreements with Customers will be done as an arm's-length transaction that does not consider the dollar value or the number of referrals to the LLC or to any other entity owned by the Requestors. Additionally, the OIG determined that the risk of swapping (the discounting of prices by the LLC in exchange for referrals to the Clinic) is not present under the Proposed Arrangement because the LLC will sell its products and provide its services at an arm's length from the other entities owned by the Requestors. Overall, the OIG concluded that the Proposed Arrangement presented a low risk of fraud and abuse under the AKS.

The Advisory Opinion is limited to the Requestors' Proposed Arrangement. Nonetheless, it provides guidance to other businesses that may consider entering into agreements with Customers to provide their employees with nonfederal health care program services. Such businesses may wish to consider implementing similar safeguards to those cited by the OIG and described above to prevent allegations of prohibited conduct under the AKS.

FOR MORE INFORMATION

If you have any questions about this OIG Advisory Opinion, please contact a member of Robinson & Cole's Health Law Practice Group:

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