OIG Approves Investment Structure of Physician-Owned Medical Device Company



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On August 7, 2025, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued favorable advisory opinion No. 25-09 for an arrangement involving a medical device company partially owned by physicians, including the creator of the medical devices. Specifically, the advisory opinion analyzed whether remuneration to the physician owners was prohibited under the Anti-Kickback Statute (AKS) and the civil monetary penalty law (CMPL). The physicians, in the aggregate, own approximately 35% of the company, and may order or purchase the company's devices or recommend that a hospital order and purchase the company's devices. No other owners of the company are in a position to make or influence referrals to the company.

The OIG re-iterated its long-standing position that arrangements involving physicians who own a medical device company and are in a position to make referrals to, and receive profits distributions from, that company are inherently suspect under the AKS. However, under the unique facts presented, the arrangement is protected by the small entity investment safe harbor of the AKS because the arrangement satisfies all the required elements of the safe harbor:

• No more than 40% of investment interests are held by referral sources;

• Investment terms for investors in a position to make referrals to the company are the same as investors who are not in a position to make referrals to the entity;

• Investment terms are not related to referrals or generation of business;

• Investors are not required to make referrals or generate business for the company;

• There is no difference in marketing or furnishing the company's devices to investors and non-investors;

• No more than 40% of the company's gross revenue is from referrals or business generated from investors;

• No loans or loan guarantees were provided by the company or any investor to another investor to acquire their investment interests in the company;

• Payment to an investor for their investment interest is directly proportional to the amount of the capital investment of that investor.

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