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OIG Issues Favorable Opinion to Physician-Owned Medical Device Company

On April 20, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) issued a favorable opinion regarding an arrangement where physicians with an ownership interest in a medical device company would order products manufactured by the company for use in surgeries personally performed and recommend such products to hospitals and ambulatory surgery centers (ASCs) for purchase. The opinion is notable because over the years, OIG has identified physician investments in medical device companies as creating a strong potential for improper inducements between physician-investors, the entities and hospitals/ASCs. In 2013, the OIG issued a Special Fraud Alert in which it called physician-owned entities that derive revenue from selling or arranging for the sale of devices ordered by their physician owners "inherently suspect" under the federal anti-kickback statute. In this most recent opinion, the OIG opined that although the arrangement would generate prohibited remuneration under that statute (assuming requisite intent), it would not impose administrative sanctions because the proposed arrangement includes safeguards that mitigate the fraud and abuse risks identified in the Special Fraud Alert as follows:

- **The company is a legitimate business and does not serve as a shell company.** The company develops products sold domestically and internationally, has dozens of employees, and is responsible for the full range of operations, including design, development, testing, quality control, regulatory submissions and inventory management. The OIG also found it compelling that the innovator of the device was granted the majority interest in the company based on his product development contributions.
- **Profit distributions are determined in a way that dilutes financial incentives for physician owners to order company products.** The company does not give physician owners preferential treatment compared with non-physician owners in making profit distributions. The company makes profit distributions to all owners and in direct proportion to each owner's investment interest in the company, and it implements a "carve out" of certain revenue generated by physician owners from distributions in order to diminish the financial incentive for a physician owner to order company products.
- **Physician owners are not the sole or primary users of the product.** The percentage of orders of company product by physician owners has steadily decreased over the years. The company's sales are continuously expanding nationally and internationally with more physicians who do not have any ownership interest in the company ordering its products.
- **Ownership is not contingent on business generation.** The company does not select or retain physician investors in "suspect ways" such as by retaining the right to repurchase a physician's ownership interest or requiring a physician owner to divest his or her interest if the physician decreases referrals to the company or ceases practice. The company does not use its sales reports to encourage additional orders from physician owners and does not track physician owner referrals differently than orders from other business sources.

- **Physician owners do not condition referrals to hospitals or ASCs on purchases.** Although the physician owners use the company's products for procedures personally performed and recommend purchase of the company's products to ASCs and hospitals where they perform procedures, they do not condition referrals to such hospitals or ASCs on the purchase of company products. These hospitals and ASCs are not required to enter into an exclusive purchase or minimum purchase arrangement with the company.
- **The company and physician owners are transparent about potential conflicts of interest.** Physician owners and the company are transparent with patients, facilities and the public about their ownership interests. The company provides written notices to patients who may be treated with a company product by a physician owner that list alternative medical device companies and such patients are offered the opportunity to be treated with an alternative device. The physician owners also notify the hospitals and ASCs where they perform services of their ownership interest in the company.

The opinion may be relied upon only by the requestors and is limited to the specific facts of the proposed arrangement. However, it lends support to physician entrepreneurs and innovators seeking to invest in medical device startups and may open doors to health systems that have been reluctant to purchase devices from physician-owned manufacturers. Day Pitney lawyers are available to assist you in structuring physician investments in entities such as medical device manufacturers and evaluating the adequacy of safeguards in physician ownership arrangements.

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