OIG RELEASES PHYSICIAN-OWNED ENTITY SPECIAL FRAUD ALERT

EXECUTIVE SUMMARY

On March 26, 2013, the Office of Inspector General ("OIG") released a special fraud alert ("Alert") regarding physician-owned distributorships ("PODs"). PODs are entities that sell, or arrange for the sale of, implantable medical devices that may be used by the physician-owners or others for procedures on patients in hospitals and ambulatory surgery centers ("ASCs"). The PODs then receive revenues from the sale of these devices. The Alert focuses on the characteristics of PODs that the OIG believes pose the greatest risks of fraud and abuse and dangers to patient safety. For a full copy of the Alert, click here.

OIG REAFFIRMS LONGSTANDING GUIDANCE ON PODS

Over the years, the OIG has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, as well as specific guidance on physician investments in medical device manufacturers and distributors. This Alert is intended to reaffirm the OIG's belief that such arrangements have a strong potential for improper inducements between and among the physician investors, the entities, device vendors and device purchases and, as such, should be closely scrutinized under the fraud and abuse laws.

PHYSICIAN-OWNED DISTRIBUTORSHIPS

Physicians that profit from investments in an entity for which they generate business may find themselves in violation of the Anti-Kickback Statute ("AKS") for receiving illegal remuneration. The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a federal health care program. Further, penalties for violating the AKS include a felony conviction and fines of up to $25,000. More importantly, the Department of Health and Human Services may also exclude individuals or entities that violate the AKS from the Medicare and Medicaid programs.

Federal courts and the OIG have typically taken the position that, if even one purpose of the POD arrangement is to induce referrals, the AKS is violated. The OIG has identified several features that cause arrangements to be highly scrutinized:

- Choosing investors that are in a position to generate business for the entity;
- Requiring investors to relinquish their ownership interests if they leave the practice area; and
- Distributing significantly high returns on the investment, particularly when the level of risk is low.

According to the OIG, if a POD possesses any of these features, it will likely raise AKS concerns, such as corruption of medical judgment, overutilization, increased costs to the federal health care programs and beneficiaries and unfair competition. These features have the effect of creating financial incentives for POD owners to perform more procedures than may be medically necessary and to use POD devices instead of other similar devices.

Further, the OIG has expressed particular concern with implantable medical devices because the exact item is often decided based upon physician preference rather than being controlled by the hospital or ASC where the procedure is performed. The OIG has also stated that an ownership disclosure notice provided to patients does not alleviate its concerns because this does not provide adequate assurance against fraud and abuse.

The intent of the parties is necessary to determine if a violation of the AKS has occurred. The OIG has identified several characteristics that may show a POD's intent including, but not limited to, the following:

- The components of the POD's legal structure;
- The POD's operational safeguards; and
- The actual conduct of the investors, management entities, suppliers and customers during the implementation phase and ongoing operations.

Ultimately, the Alert suggests the OIG will be highly skeptical of PODs when the physician-owners are few in number and/or alter their medical practices to perform more surgeries with their own devices. The Alert also offers additional characteristics of PODs that the OIG considers suspect and may trigger heightened scrutiny. This focus on PODs and physician relationships with device and pharmaceutical manufacturers in general appears to be a reflection of the OIG's continued emphasis on transparency to protect the sanctity of medical decision making.

PRACTICAL TAKEAWAYS

Some hospitals have adopted policies against doing business with PODs, while others are open to PODs but place limits on them. Given the regulatory landscape, when a hospital or ASC contemplates purchasing a product or device from a POD, it should evaluate the arrangement and implement steps to limit the risk associated with entering into this type of arrangement. Thus, when assessing the OIG's concerns in the Alert, hospitals and ASCs should consider:

- Requesting information about the legal structure of the POD and determining if any physician-investors are part of the hospital's medical staff;
- Assessing whether any physician-owners condition their referrals to hospital or ASC;
- Confirming POD conducts product evaluations, maintains or manages sufficient inventory and employs personnel necessary for operations;
- If applicable, confirming whether the physician-investor has disclosed a conflict of interest due to its ownership interest in the POD;
- Performing a supply chain analysis of the cost and quality of the product in the same manner any nonphysician-owned vendor would be analyzed; and
- Performing an independent fair market value assessment to ensure that pricing of the products sold through the POD are consistent with other similar products on the market.

If you have any questions about PODs, please contact:

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