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OIG PUBLISHES NEW FRAUD ALERT REGARDING PHYSICIAN COMPENSATION ARRANGEMENTS

The Office of Inspector General (OIG) recently published a fraud alert (Fraud Alert) regarding physician compensation arrangements for medical directorships and outlined certain elements of such arrangements that may violate the anti-kickback statute (AKS). The Fraud Alert serves as a reminder to entities and physicians that compensation arrangements for administrative services, including medical directorships, must reflect the fair market value for bona fide services actually provided by physicians.

The AKS prohibits knowingly and willfully exchanging any remuneration to induce a party to refer or reward the referral of an individual for goods or services payable by a federal health care program. An otherwise legitimate compensation arrangement may violate the AKS if even one purpose of the arrangement is to reward a physician for the volume or value of referrals of federal health care program business. Arrangements between health care providers and entities are typically designed to comply with regulatory safe harbors that provide immunity from violations of the AKS for narrowly defined arrangements. Generally, agreements for medical director or other administrative services are drafted to satisfy the requirements of the personal services and management contract safe harbor, which requires, in part, that the compensation to be paid is set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for Medicare, Medicaid, or other federal health care program beneficiaries.

The Fraud Alert includes a brief description of physician arrangements for medical directorships and office staff compensation that were the subject of 12 settlements entered into by OIG with such physicians. OIG alleged that the compensation paid to the physicians pursuant to the medical directorship arrangements took into account the volume or value of referrals, was in excess of fair market value, and was provided for services not actually rendered by the physicians. As a result, OIG alleged that the compensation was paid in violation of the AKS. The settlements also resolved claims that some of the physicians entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff, relieving the physicians of a financial burden. OIG alleged

that this also constituted prohibited remuneration under the AKS.

The Fraud Alert states that, because OIG determined that the physicians were "an integral part of the scheme," they were subject to monetary penalties. OIG's imposition of monetary penalties against the physicians involved in the arrangements serves as a warning for physicians to ensure that all administrative services arrangements comply with all of the requirements of a safe harbor to the AKS. Violations of the AKS may result in criminal, civil, and administrative sanctions, including financial penalties and exclusion from participation in federal health care programs, for both parties to an arrangement.

OIG ISSUES FAVORABLE ADVISORY OPINION REGARDING PATIENT FINANCIAL ASSISTANCE FUNDS

The Office of Inspector General (OIG) recently issued a favorable advisory opinion (Advisory Opinion) to a nonprofit, tax-exempt charitable organization (Requestor) regarding its proposed arrangement (Arrangement) to provide financial assistance to individuals with chronic diseases receiving health care services from the Requestor. OIG concluded that, while the Arrangement could potentially generate prohibited remuneration under the federal anti-kickback statute (AKS), it would not impose civil monetary penalties or administrative sanctions on the Requestor because the Arrangement presents only a minimal risk of fraud and abuse.

The Arrangement

Under the Arrangement, the Requestor would utilize donor contributions to establish multiple disease funds to provide financial assistance to individuals undergoing treatment for various chronic diseases. The financial assistance would reduce or eliminate cost-sharing obligations for prescription drugs or devices, health insurance premiums, and incidental expenses (such as travel expenses and ongoing testing). Eligibility determinations for the financial assistance would be based on federal poverty guidelines, and assistance would be provided on a first-come, first-served basis to the extent of available funding. Applicants would be required to select a health care provider or supplier, and would have a treatment plan in place prior to applying for assistance, and would be free to change physicians, pharmacies, treatment regimens, and health insurance at all times. Assistance would be available for all devices and drugs, including generic or bioequivalent drugs, covered by Medicare or the patient's primary insurer in the approved course of treatment for the specific chronic disease. The Requestor would not consider the identity of the applicant's provider, supplier, the particular drugs or devices, the referring party, or any donor that may have contributed to the particular disease fund in making the eligibility determination. Information about available assistance would be provided to patients through physicians, pharmacies, equipment suppliers, and product manufacturers.

The Requestor would seek donations from corporations and individuals, and donors would have the opportunity to earmark their donation for a disease-specific fund or to leave the donation unrestricted. Donors and related parties would not directly or indirectly influence the identification or delineation of disease funds. No assistance fund would be limited to particular drugs or devices or those manufactured or marketed by particular entities.

Donors and their family members, officers, directors, employees, and other affiliated persons, as well as former directors, officers, or employees of a donor, who maintain an ongoing relationship with the donor would be ineligible to serve on the Requestor's board of directors and would not be in a position to exercise any direct or indirect control over the Arrangement. Directors, officers, employees, and their immediate family members of the third-party entities making eligibility determinations and processing claims would also be prohibited from serving on the Requester's board of directors or as a senior manager of the Requestor. The Requestor would provide de-identified, aggregate data to donors but would not provide donors with any data to enable them to look for correlations between the amount or frequency of their donations and resulting usage of their services or supplies by patients. The Requestor

would not provide patients with any information regarding donors and would not provide donors with any information regarding other donors.

OIG Findings

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.

In analyzing the Arrangement and the risk of violating the AKS, OIG focused on several safeguards that minimize the risk that donor contributions provided under the Arrangement might influence patient referrals by the Requestor: (1) no donor would be in a position to exert control over the Requestor or the Arrangement; (2) applicants would have to choose a provider and have a treatment plan in place prior to applying for assistance and would be free to change providers, treatment plans, and/or insurance while participating in the Arrangement, and the Requestor would not recommend providers, drugs, or devices; (3) the de-identified, aggregate data provided to donors by the Requestor would not enable a donor to correlate the amount or frequency of its donations with the amount or frequency of patient use of its drugs, devices, or services; and (4) though donors would be able to earmark donations to particular disease funds, they would not be able to directly or indirectly influence the identification or delineation of disease funds, thereby limiting the risk that a donor could direct funds to its own products.

OIG also concluded that assistance payments pose a minimal risk of influencing a federal health care program beneficiary's selection of a provider, supplier, or particular product or service because the Requestor's determination of whether an applicant qualifies for assistance would be based solely on financial need, without consideration of the identity of the applicant's provider, supplier, drugs or devices needed, any referring party, or any donor, and all financially needy patients would be eligible for assistance on a first-come, first-served basis to the extent of available funding.

Conclusion

As OIG noted, the Advisory Opinion is consistent with previously issued guidance, including Special Advisory Bulletins regarding patient assistance programs in which OIG advised that cost-sharing subsidies provided by bona fide independent charities, in most cases, do not raise concerns under the AKS, even if the subject charities receive contributions from donors whose products are supported by such subsidies. Although the Advisory Opinion is limited to the Requestor and the specific facts of the Arrangement, organizations contemplating a patient assistance program may want to carefully review OIG's interpretation of the AKS as set forth in the Advisory Opinion.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

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