

OIG Advisory Opinion Restricts Relationships between Sleep Labs and CPAP Suppliers

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On June 21, 2011, the Office of the Inspector General of the U.S. Department of Health and Human Services (the “OIG”) issued Advisory Opinion No. 11-08. The Opinion reviewed existing and proposed contracts between a sleep lab and a CPAP supplier, and concluded that both the existing arrangement and the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose sanctions on the parties. This unfavorable ruling demonstrates the high level of concern that the OIG has about financial dealings between Sleep Labs and DME suppliers.

The ruling request was submitted by a CPAP supplier. The supplier was seeking a favorable ruling that both its existing contracts with sleep labs, and its proposed new contracts, would be in compliance with the anti-kickback statute. When the OIG issues an unfavorable ruling, this does not automatically mean a violation of law has occurred, but it is a very significant warning sign about the legality of a proposed or existing business practice.

The Existing Arrangement

The CPAP Supplier entered into contracts with several sleep labs that were enrolled with Medicare as independent diagnostic testing facilities (“IDTFs”). Some of the labs had physician owners, but some did not. Under each contract, the IDTF would perform services relating to CPAP set up and patient education, services that normally the CPAP Supplier would have to perform. For each patient receiving set up services by the sleep lab, the CPAP Supplier would pay the lab a fee.

The Supplier also would consign CPAP machines and supplies to the lab, so that the sleep lab could deliver devices to the patient. Patients would be provided free choice of CPAP suppliers, and would be given a list of suppliers in the area. Significantly, the set up and education services were not provided to Medicare or Medicaid patients, only to self pay and privately insured patients.

The Proposed Arrangement

The proposed arrangement was similar to the existing arrangement, except that it would apply to all patients, including Medicare and Medicaid patients, and that the fee would be a fixed annual fee, not a per case fee.

The OIG’s Rulings

The OIG declined to protect either arrangement with a favorable advisory ruling, and warned that sanctions might apply to either arrangement. **Very significantly, the OIG refused to**

protect the existing arrangement that did not apply to Medicare or Medicare patients. The OIG stated:

The Existing Arrangement covers services provided to non-Federally insured patients only. Thus, as a threshold matter, we must address whether the “carve out” of Federal business is dispositive of the question of whether the Existing Arrangement implicates the anti-kickback statute. It is not. The OIG has a long-standing concern about arrangements pursuant to which parties “carve out” Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate and may violate the anti-kickback statute by disguising remuneration for Federal business through the payment of amounts purportedly related to non-Federal business. Here, IDTFs participating in the Existing Arrangement may still influence referrals of Federal health care program beneficiaries to the Requestor for DME. Thus, we cannot conclude that there would be no nexus between the Requestor’s payments to the IDTF for services provided to non-Federal patients and referrals to the Requestor of Federally insured patients.

Further, the OIG criticized both arrangements because both involved a fee paid by the CPAP supplier to an entity, the sleep lab, that had direct patient contact, and in some cases, physician ownership. The OIG stated:

. . . we have long been concerned about aggressive marketing by DME suppliers, including those marketing activities that involve personal contact with Federal health care program beneficiaries. In-person sales pitches or “informational” sessions can be extremely coercive, particularly when such activities are targeted at senior citizens, Medicaid beneficiaries, and other particularly vulnerable patients. These marketing activities are highly susceptible to fraud and abuse, as they can lead to overutilization, increased costs to the Federal health care programs and beneficiaries, inappropriate medical choices, and adverse effects on the quality of care patients receive. Arrangements that closely tie DME suppliers to IDTF staff members, physicians with financial interests in the IDTFs who are in a position to prescribe, and patients—such as the Requestor’s Arrangements—are particularly susceptible to problematic marketing schemes. The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as “white coat” marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services—especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

The Arrangements contain hallmarks of these potentially problematic arrangements. Specifically, they involve direct payments to IDTFs that can closely tie the Requestor to

IDTF staff members and, in some instances, to physicians with financial interests in the IDTF who are in a position to prescribe. That connection effectively allows the Requestor [the DME supplier] to obtain in-person contacts with patients—including Federal health care program beneficiaries—through health care professionals who are in a position of trust. Those contacts could occur before a patient selects a DME supplier, resulting in an increased risk that the IDTF staff members and, in some instances, physicians with financial interests in the IDTF, could inappropriately influence a beneficiary’s selection of the Requestor as his or her DME supplier. Further, the Arrangements have the potential to influence the decisions of physicians with financial interests in the IDTFs to prescribe the CPAP in the first place.

For these and other reasons (including the fact that neither arrangement clearly fit within an anti-kickback safe harbor), the OIG declined to protect either arrangement.

What Does it Mean?

This ruling has several important aspects. The OIG makes it clear that the mere fact that a contract excludes federal program business will not insulate it from scrutiny, if there are other referral relationships between the parties that include Medicare or Medicaid. This is not a new position on the part of OIG, but it is often overlooked. On the other hand, if the set up fees paid for non-Medicare patients truly are no greater than fair market value, it would be hard to argue that they contain a “hidden premium” for Medicare referrals. The OIG’s stance reflects either great conservatism, a failure to believe that the set up fees are truly consistent with fair value, or both.

It also is telling that the OIG classified both proposals as “white coat marketing” schemes, when marketing was not at all part of either agreement. This might reflect a general concern about conflict of interest or bias by treating physicians, but also, perhaps, betrays some cynicism about the need for sleep labs to educate patients and to promote CPAP compliance.

Clearly, the ruling will chill the creation of new financial arrangements between sleep labs and DME suppliers. However, there may be other consequences as well.

CPAP has a significant failure rate and many patients do not comply with their prescribed therapy. Sleep physicians, sleep labs and CPAP suppliers are seeking new ways to work together to improve the efficacy of CPAP treatment and improve patient compliance.

The approach taken by the DME supplier was to involve the sleep lab directly in the patient compliance process by delegating set up and patient education to the lab. While this might make sense from a clinical perspective, the OIG sees it only as a marketing program, possibly intended to move CPAP referrals from one supplier to another, or worse, to create a financial incentive for doctors to prescribe CPAP in the first place.

The OIG has ruled against set up contracts between sleep labs and CPAP suppliers. However, the trend in sleep medicine is to create stronger linkages among sleep physicians, sleep labs and CPAP suppliers. Clearly, better approaches to integrating diagnosis, management and treatment

are needed, and more work needs to be done educating the government on the clinical value of these relationships.