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## OIG Warns That Arrangements Between CPAP Suppliers and Sleep Labs Pose F&A Risks

By: [Alan J. Arville](#)

In Advisory Opinion 11-08, the OIG took an unfavorable view of both an existing and a proposed arrangement where the requestor, a durable medical equipment (DME) supplier of continuous positive airway pressure equipment and supplies (CPAP), would contract with sleep labs enrolled with Medicare as independent diagnostic testing facilities (IDTFs) to provide CPAP set-up and patient education services on behalf of the DME Supplier. In its July 14, 2011, ruling, the OIG expressed concern that payments to potential referral sources for such services could potentially generate prohibited remuneration under the federal antikickback statute.

### Existing Arrangement

Pursuant to the existing arrangement, when a patient of a contracted IDTF selects the DME supplier to provide the CPAP, an IDTF staff member provides CPAP set-up and patient education services to the patient on behalf of the DME supplier. Some of the IDTFs are owned by physicians in a position to prescribe CPAPs. Notably, the IDTF performs such services only for non-Federal Health Care Program (FHCP) beneficiaries. The DME supplier certified that the amounts paid to the IDTF are consistent with fair market value. The IDTF may cancel its contract at any time, but the DME supplier may terminate the contract only for breach or for cause.

In addition, the DME supplier consigns CPAP supplies to the IDTFs, but the IDTFs are permitted to stock competing DME supplier products, and are neither required nor prohibited from endorsing the DME supplier to patients. In all cases the IDTFs inform patients of their right to choose a different DME supplier than the DME supplier, and provide patients with a written list of local DME suppliers.

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## Proposed Arrangement

The proposed arrangement differed from the existing arrangement in the following manner:

1. The proposed arrangement would apply to all patients, including FHCP beneficiaries;
2. The fee paid to an IDTF would be a flat monthly or flat annual fee;
3. Although the flat fee would not be altered, the DME supplier would have the right to terminate the contract if the DME supplier was not satisfied with the number of patients receiving the services; and
4. The DME supplier could not certify that the flat fee would reflect the fair market value of the services rendered.

## OIG Analysis

The OIG determined that neither arrangement satisfied the personal services and management contracts safe harbor, in part, because the arrangements did not satisfy the condition that for periodic, sporadic, or part-time services, the agreements must specify the exact schedule, precise length, and exact charge for the intervals. In the absence of safe harbor protection, the OIG analyzed the facts and circumstances of the particular arrangements, and, citing the following concerns, concluded that both arrangements could potentially violate the antikickback statute:

- *“Swapping” Concerns.* In refusing to issue a favorable opinion with respect to the existing arrangement that only applied to non-FHCP beneficiaries, the OIG cited its long-standing concern that arrangements that “carve out” FHCP beneficiaries implicate and may violate the antikickback statute by disguising remuneration for federal business through the payment of amounts purportedly related to non-federal business.
- *Fair Market Value.* Since the IDTFs’ staff (which sometimes include physicians with a financial interest in the IDTF) are in a position to influence FHCP beneficiaries, the OIG expressed a general concern that the arrangements may result in payments that are above market rates (as

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is potentially the case with the proposed arrangement), or payments that may be consistent with fair market value but may otherwise reflect the volume or value of past or expected referrals (as is the case with the existing arrangement).

- *White Coat Marketing.* The OIG stated that the arrangements contain hallmarks of potentially problematic white coat marketing schemes. “White coat” marketing refers to the involvement of a physician or other health care professional in marketing activity and is closely scrutinized because physicians and other health care professionals are in a position of public trust and may exert undue influence when recommending health care-related items or services. The OIG expressed concern that patients who receive in-person sales pitches or “informational” sessions from the IDTF’s staff may have difficulty distinguishing between professional medical advice and a commercial sales pitch.
- *Direct Payments to IDTFs.* The OIG stated that the direct payments to the IDTFs pursuant to the arrangements connect the DME supplier with the IDTF staff members who are in a position to prescribe. According to the OIG, such connection could inappropriately influence a beneficiary’s selection of the DME supplier as his or her DME supplier.
- *Consignment Issue.* Although the DME supplier certified that it would not make separate payments for rental space and consignment services, the OIG determined that at least some portion of the fee would likely be attributable to the consignment component, which raises fraud and abuse risk.

## Implications and Outlook

The unfavorable ruling in Advisory Opinion 11-08 likely reflects the OIGs cynicism about the real purpose of the payments. The requestor no doubt asserted that the payments were fair market value for legitimate services and, despite the fact that the DME supplier stated that marketing or otherwise endorsing the DME supplier was not part of the arrangement, the OIG seems concerned that such an arrangement between a CPAP supplier and a sleep lab that had direct patient contact, and in some cases, physician ownership, was actually a marketing program.

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Although the OIG's ruling represents a significant warning about the legality of such CPAP set-up services arrangements, it does not rule out the possibility that such an arrangement could be structured in a manner compliant with the antikickback statute. For instance, if a CPAP supplier did not have personnel that could assist with CPAP set-up in a patient's geographical area, there may be a legitimate business need to engage a sleep lab to provide such service for a fee that reflects fair market value. DME suppliers and potential referral sources should take heed of the OIG's ruling, however, and take steps to ensure that their services arrangement will withstand government scrutiny.

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