In the dog-eat-dog world of medical goods suppliers, suppliers sometimes approach providers with "creative" compensation arrangements. Some suppliers, for example, offer to compensate the provider for services purchased from the provider’s staff. These arrangements give the vendor preferred status and allows their representatives to have regular contact with prescribers and their staff (often bearing pizza or doughnuts).

The compensation may violate the Anti-kickback Statute (the AKS), exposing both parties to potential criminal liability. The AKS makes it a crime to pay or receive remuneration at least one purpose of which is to induce referrals or ordering of items and services payable under Medicare.

The AKS has “safe harbors” that insulate certain financial arrangements from enforcement. To comply with the safe harbors, suppliers generally try to demonstrate that the price paid is fair market value for provider services. Another defensive approach is to exclude all federal program beneficiaries (Medicare, TRICARE, Medicaid) from the compensation scheme. The logic is that if the federal programs are not impacted by the arrangement, the participants will not be exposed under the AKS.

However, in light of two OIG Advisory Opinions issued this summer, providers should be especially cautious about such arrangements, and ask their purchasing and compliance staff to examine them closely.

Advisory Opinion 11-08

In the first opinion, the OIG rejected a DME supplier’s proposal to compensate independent diagnostic testing facilities (IDTFs) (which are often owned by physicians) for the services of their staff in helping patients select, fit, and learn to use a CPAP machine and supplies. This equipment is prescribed for individuals who suffer from sleep apnea, which is often diagnosed after an overnight sleep study in an IDTF.

Medicare requires enrolled DME providers to educate beneficiaries about the care and use of equipment when they deliver it. Many providers and DME suppliers agree that a patient gets more personalized attention when the selection, fitting and education process takes place at the point of treatment rather than in the home. This may promote better patient compliance. In this case, the IDTF’s patients were given a list of possible DME suppliers, but were also advised that the items were kept on site and that the IDTF staff was available to advise and fit the equipment.

Exclusion of Government Payors Does Not Protect Scheme

The DME supplier was not providing compensation for services to patients covered by a federal health care program, and certified to the OIG that what it was paying the provider was fair market value (FMV). The DME supplier asked the OIG to approve: (1) inclusion of federal program patients in the compensation scheme; (2) payment of a fixed monthly fee to the provider (which could not be certified as FMV because of the unpredictable number of patients receiving staff services); and (3) allowing the DME supplier to terminate the arrangement if it was dissatisfied with the numbers of patients receiving services.

1 OIG Advisory Opinions 11-08 (June 14, 2011) and 11-11 (July 28, 2011)

2 Such patients were assisted by provider staff in the same way, but the DME supplier made no payments to the provider.
The OIG refused to approve the proposal and also rejected the existing arrangements, even though no payments were made for federal program patients. The OIG restated its longstanding concern that such arrangements simply conceal unlawful kickbacks:

“Such arrangements implicate and may violate the AKS 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 added that even existing arrangements would not qualify for protection under the safe harbor for personal services arrangements “because they do not meet all of the safe harbor’s conditions, including 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.” 42 C.F.R. § 1001.952(d)(3).

The OIG noted that these deals give suppliers the opportunity to make in-person contact with patients, physicians, and staff, possibly resulting in the provider doing “white coat marketing” on behalf of a supplier. The OIG warned: “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”.

Advisory Opinion 11-11
The second opinion concerns the proposed use of separate companies to provide the same service, one for federal program beneficiaries and one for other patients. The medical supply/DME company requesting the opinion provides both items payable under Medicare Part B (Covered Items) and items that must be bought by the skilled nursing facility (Non-covered Items). In a bid to become a nursing home’s exclusive provider of Covered Items (for which the supplier bills Medicare), the supplier proposed two models. Under one, the company would furnish Non-covered Items below its cost, acknowledging that the Medicare reimbursement from Covered Items would more than offset any losses it would incur. The alternative proposal was identical except that a new company would be formed solely to furnish Non-covered Items, and the companies would submit a joint bid.

The OIG rejected both arrangements, noting that:

“Prices offered to a skilled nursing facility that are below the supplier’s total costs of providing the items and services - as in the facts presented here - give rise to an inference that the supplier and the SNF may be “swapping” the below-cost rates on business for which the SNF bears the business risk (i.e., the Non-Covered Items) in exchange for the profitable non-discounted federal business (i.e., the Covered items), from which the supplier can recoup losses incurred on the below-cost business, potentially through overutilization or abusive billing practices.”

Turning to the “separate company” proposal, the OIG emphasized that the substance and not the form of the arrangement governs under the AKS, and that this proposal carried the same risk of improper “swapping”.

Conclusion - No Free Lunch
It is tempting for providers to enter into arrangements where vendors pay for office consignment space, for staff training, restocking, fitting, or patient education, but these arrangements present real compliance issues. Offers of free supplies, equipment or services by the vendor should generally be declined. Even agreements for rebates based on volume purchasing need careful scrutiny to be sure they don’t implicate the AKS. It is a lot cleaner to negotiate a lower price, faster delivery or better service than to allow anything resembling “remuneration” into the arrangement. Such deals may simply not be worth the risk, and usually need legal review. These Advisory Opinions reaffirm that excluding federal program patients or creating separate companies and rates will not save inducement arrangements from possible enforcement activity.

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