

clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions—or that are offered to purchasers in connection with sales contracts—are particularly suspect.

Pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. In many cases, the research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients. However, as with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.

*Other remuneration to purchasers.* As already noted, any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of remuneration in connection with a sale include, but are not limited to, "prebates" and "upfront payments," other free or reduced-price goods or services, and payments to cover the costs of "converting" from a competitor's product. Selective offers of remuneration (*i.e.*, offers made to some but not all purchasers) may increase potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated. In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value for legitimate, reasonable, and necessary services.

(b) *Formularies and Formulary Support Activities.* To help control drug costs while maintaining clinical appropriateness and quality of patient care, many purchasers of pharmaceutical products, including indirect purchasers such as health plans, have developed drug formularies to promote rational, clinically appropriate, safe, and cost-effective drug therapy. Formularies are a well-established tool for the effective management of drug benefits. The formulary development process—typically overseen by a committee of physicians, pharmacists, and other

health care professionals—determines the drugs that are covered and, if tiered benefit levels are utilized, to which tier the drugs are assigned. So long as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.

Formulary support activities, including related communications with patients and physicians to encourage compliance, are an integral and essential component of successful pharmacy benefits management. Proper utilization of a formulary maximizes the cost-effectiveness of the benefit and assures the quality and appropriateness of the drug therapy. When provided by a PBM, these services are part of the PBM's formulary and benefit management function—a service provided to its customers—and markedly different from its purchasing agent/price negotiator role. Most importantly, the benefits of these formulary support activities inure directly to the PBM and its customers through lower costs.

To date, Medicare and Medicaid involvement with outpatient drug formularies has been limited primarily to Medicaid and Medicare managed care plans. In light of the safe harbors under the anti-kickback statute for those managed care arrangements, the financial arrangements between health plans and pharmaceutical manufacturers or, where the pharmacy benefit is managed by a PBM, the arrangements among the three parties, have received relatively little scrutiny. However, as federal program expenditures for, and coverage of, outpatient pharmaceuticals increase, scrutiny under the anti-kickback statute has also increased. Several practices appear to have the potential for abuse.

• *Relationships with formulary committee members.* Given the importance of formulary placement for a manufacturer's products, unscrupulous manufacturers and sales representatives may attempt to influence committee deliberations. Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products are suspect and should be carefully scrutinized. Manufacturers should also review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.

• *Payments to PBMs.* Any rebates or other payments by drug manufacturers

to PBMs that are based on, or otherwise related to, the PBM's customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer. In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 CFR 1001.952(m), (t) and (u).

• *Formulary placement payments.* Lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.

In addition, some manufacturers provide funding for purchasers' or PBMs' formulary support activities, especially communications with physicians and patients. While the communications may indirectly benefit the manufacturer, the primary economic beneficiary is typically the formulary sponsor. In other words, the manufacturer's dollars appear to replace dollars that would or should be spent by the sponsor. To the extent the manufacturers' payments are linked to drug purchases directly or indirectly, they potentially implicate the anti-kickback statute. Among the questions that should be examined by a manufacturer in connection with these activities are: Is the funding tied to specific drugs or categories? If so, are the categories especially competitive? Is the formulary sponsor funding similar activities for other drug categories? Has funding of PBM activities increased as rebates are increasingly passed back to PBM customers?

(c) *Average Wholesale Price.* The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.