

cannot be properly structured to fit in a safe harbor. Nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are those areas of activity that have a potential for abuse based on historical law enforcement experience and that should receive close scrutiny from manufacturers. The discussion highlights potential risks under the anti-kickback statute arising from pharmaceutical manufacturers' relationships with three groups: purchasers (including those using formularies) and their agents; persons and entities in a position to make or influence referrals (including physicians and other health care professionals); and sales agents.

(1) Relationships with Purchasers and their Agents—(a) Discounts and Other Remuneration to Purchasers. Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Purchasers include direct purchasers (e.g., hospitals, nursing homes, pharmacies, some physicians), as well as indirect purchasers (e.g., health plans). Inducements offered to purchasers potentially implicate the anti-kickback statute if the purchased products are reimbursable to the purchasers, in whole or in part, directly or indirectly, by any of the federal health care programs. 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.

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

Discounts. Public policy favors open and legitimate price competition in

health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported. See 42 U.S.C. 1320a-7b(b)(3)(A); 42 CFR 1001.952(h). However, to qualify for the exception, the discount must be in the form of a *reduction in the price* of the good or service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (i.e., a rebate).

Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the discount safe harbor at 42 CFR 1001.952(h) (and, if relevant, the safe harbors for price reductions in the managed care context, 42 CFR 1001.952(m), (t), and (u)). In particular, manufacturers should pay attention to the discount safe harbor requirements applicable to "sellers" and "offerors" of discounts. Under the safe harbor, sellers and offerors have specific obligations that include (i) informing a customer of any discount and of the customer's reporting obligations with respect to that discount, and (ii) refraining from any action that would impede a customer's ability to comply with the safe harbor. To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the federal health care programs (e.g., whether the customer is a managed care, cost-based, or charge-based biller). Compliance with the safe harbor is determined separately for each party.

Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that

eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Educational Grants. Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.

To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are *bona fide*. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

Research Funding. Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. Prudent manufacturers will develop contracting procedures that