

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

(2) Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals. Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' products, even though the persons or entities may not themselves purchase (or in the case of

GPOs or PBMs, arrange for the purchase of) those products. These remunerative relationships potentially implicate the anti-kickback statute. The following discussion focuses on relationships with physicians, but the same principles would apply when evaluating relationships with other parties in a position to influence referrals, including, without limitation, pharmacists and other health care professionals.

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (*e.g.*, physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (*i.e.*, the purposeful inducement of business).

In light of the obvious risks inherent in these arrangements, whenever possible prudent manufacturers and their agents or representatives should structure relationships with physicians to fit in an available safe harbor, such as the safe harbors for personal services and management contracts, 42 CFR 1001.952(d), or employees, 42 CFR 1001.952(i). *An arrangement must fit*

*squarely in a safe harbor to be protected.* In addition, arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances, bearing in mind the following factors, among others:

- *Nature of the relationship between the parties.* What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer? Does the manufacturer have other direct or indirect relationships with the physician or members of the physician's group?

- *Manner in which the remuneration is determined.* Does the remuneration take into account, directly or indirectly, the volume or value of business generated (*e.g.*, is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated? Is there any service provided other than referrals?

- *Value of the remuneration.* Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals?<sup>10</sup> Do fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?

- *Potential federal program impact of the remuneration.* Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?

- *Potential conflicts of interest.* Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality of care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?

These concerns are addressed in the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), adopted on April 18, 2002, which provides useful and practical advice for reviewing and structuring these relationships. (The PhRMA Code is available through PhRMA's Web site at <http://www.phrma.org>.) Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.