

DISCOUNTS AS KICKBACKS FOR MEDICAL EQUIPMENT

Manufacturers of medical devices and supplies should be aware that their sales and marketing practices could potentially violate the federal Anti-Kickback Statute (the “Act”). This may include certain discounts.

Why be concerned? Penalties for violating the Act are harsh. A violation is a felony, punishable by up to five years’ imprisonment and/or \$25,000 in fines. Violators can also be liable for civil monetary penalties of up to \$50,000 per claim plus three times the illegal remuneration. Moreover, the Act is vigorously enforced. In 2003, settlements totaling more than \$700 million were reached with device manufacturers. And apparently the U.S. Department of Health and Human Services plans to accelerate its investigations of alleged fraud and abuse by medical device companies. A violation of the Act can also lead to exclusion from the Medicare and Medicaid programs.

Prohibitions. As most people know, kickbacks for referrals of Medicare or Medicaid patients are illegal. Less commonly known is that the Act also prohibits offering or paying anything of value to induce someone to purchase goods that ultimately will be paid for by Medicare or Medicaid, and this prohibition applies to both sides of the illegal remuneration, that is, to both the payor (or offeror) and the receiver.

Application to Discounts. Sales of medical devices or supplies, whether to federal healthcare program beneficiaries (i.e., patients), or to providers such as hospitals or nursing homes that participate in federal healthcare programs, may violate the Act if they involve discounts, rebates, or free goods or other incentives. Discounts, for example, almost invariably are offered to induce the purchasing, leasing, or ordering of a product, and may be regarded as illegal remuneration under the Act if the product ultimately is paid for by Medicare or Medicaid, unless the safe harbor applies.

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The regulations provide “safe harbor” protection for discounts that comply with certain requirements, which vary depending on the type of buyer. For example, if the buyer is a hospital that files cost reports as required by federal or state programs, the requirements for permissible discounts include:

- The discount must be earned on purchases of the same good bought within the same fiscal year (except where both goods are reimbursed by the same federal healthcare program using the same reimbursement methodology);
- The hospital must claim the benefit of the discount in the same or the following fiscal year;
- The hospital must fully and accurately report the discount in its cost report;
- The seller must fully and accurately report the discount on the invoice, coupon or statement submitted to the hospital, and advise the hospital of its obligations to report the discount; and
- The seller must not do anything to impede the hospital from complying with its obligations to report the discount.

Several discounting practices may be problematic under the Act, including undisclosed discounts, discounts earned across product lines, cash discounts, and free goods or supplies provided in connection with the purchase of other goods. When in doubt, consult with your attorney.

Be Proactive. Manufacturers of medical devices and supplies should familiarize themselves with the Act’s prohibitions and applicable safe harbor requirements, and review their sales practices for compliance with the law. Regular compliance training for sales forces is also encouraged.

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