Legal Backgrounder

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RESEARCH GRANTS AND FRAUD LAWS: THE NEED TO SEPARATE SALES AND SCIENCE

by

David Hoffmeister

Federal law makes it illegal for medical device and pharmaceutical companies to offer or give anything of value in exchange for purchasing any product or service that is reimbursed by the Federal government (*e.g.,* under (or by) Medicare/Medicaid). It is also unlawful for the companies' customers — primarily physicians, hospitals and health care institutions — to either solicit such items of value from their vendors or to receive them when they are offered. Thus, the law applies directly to both the vendor companies and to their health care customers. This "Medicare/Medicaid Anti-Kickback Law" is broadly enforced on the civil side by the Office of Inspector General ("OIG") and on the criminal side by the Department of Justice. Significantly, penalties for violations of the anti-kickback law are severe, consisting not only of substantial criminal fines and up to five years in prison and civil fines, but also exclusion from participation in Medicare, Medicaid, and other federally-funded health care programs.

Several "safe harbors" are contained in the statutes' implementing regulations. However, only those who structure their business arrangements to satisfy *all* the criteria of a safe harbor will be protected from liability and prosecution.

Where a business practice does not qualify for a safe harbor, the OIG will examine the practice to determine whether it involves "remuneration"[1] and, if so, whether the arrangement appears to involve the sort of abuse the law was designed to combat. In determining whether to institute enforcement action, the OIG will look at a variety of factors, including:

- The potential for adverse consequences to competition by freezing competing suppliers out of the marketplace;
- The potential for increased charges or reported costs for items or services paid for by Medicare or Medicaid; and

[1]Remuneration includes the transfer of anything of value, directly or indirectly, in cash or in kind.

David Hoffmeister is a partner with the law firm Wilson Sonsini Goodrich & Rosati, where he leads the firm's Drug and Device Regulatory and Healthcare Law practice within the Life Sciences Group.

- Possible encouragement of overutilization of the Medicare/Medicaid system.

No one factor is dispositive, and given the interpretation of the law to date, the OIG has virtually unlimited discretion in selecting cases for enforcement. However, evidence of the parties' illegal intent is required for prosecution. Additionally, Federal courts and administrative bodies considering the law in the context of actual enforcement cases have established several important interpretive principles, including the following:

1. The law is violated *if even one of the purposes* of a payment (as opposed to its primary or sole purpose) is: (a) to induce a decision to order, purchase, or recommend an item or service; (b) in exchange for the ordering, purchasing or recommending an item or service; or (c) the referral of patients;

2. No actual payment by a Federal health care program is necessary as long as the challenged remuneration is for an item or service that *could be paid for* by a Federal health care program;

3. The fact that a particular arrangement is common in the health care industry is not a defense to a violation of the law;

4. A payment or other benefit may violate the law when the amount is sufficient to influence the customers' reason or judgment;

5. The mere potential for increased costs to, or a payment to be made by, a Federal health care program, may be enough to violate the law;

6. Illegal intent and violation of the law may be found even if there is no proof of an actual agreement to order, purchase or recommend the purchase of medical items, services or referrals; and

7. Intent may be inferred from the circumstances of the case.

Research Grants and Sales Transactions. Recently, significant attention has been given to the OIG's application of the anti-kickback law to the marketing practices of medical device and pharmaceutical companies. In particular, the OIG on numerous occasions has expressed concern that many "research studies" funded by grants from manufacturers are actually designed to provide "remuneration" to physicians and health care institutions who purchase the manufacturer's products, and to reward them for their purchases.[2] The OIG is especially skeptical of unrestricted research grants given in close proximity to a purchasing decision. Even if research grant money is actually used to benefit patient care, such grants can be interpreted as an inducement to the customer to purchase the manufacturer's product, in violation of the law. Also, large grants given to an institution at the time of purchase, which permit the institution to defray operating expenses, are an obvious target for close scrutiny by the OIG. Enforcement officials often find it difficult to believe that manufacturers make such grants out of disinterested generosity or for the well-being of the health care customer. In these cases, it is easy for the OIG to conclude that payments for "research" might in fact be intended to induce (or might have the effect of inducing) customers to purchase the manufacturer's product, thereby giving the manufacturer an unfair advantage over its competitors.

[2] *See* Office of Inspector General, Promotion of Prescription Drugs through Payments and Gifts (Aug. 1991); *see also* Special Fraud Alert on Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,372 (Dec. 19, 1994) (grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit deemed suspect).

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Because of the significant consequences that arise from violations of the anti-kickback law for both vendors and their health care-related customers,[3] it is important for all medical device and pharmaceutical companies to establish and implement standard operating procedures that prohibit the discussion and use of research grant money in the context of sales transactions; any research grants offered to these customers must be completely separate from the sale of a product or service.

Payments for Legitimate Research and Other Services. In general, there are a large number of common arrangements in the medical device and drug industries, pursuant to which persons in a position to purchase products and services might also be hired to perform services for the manufacturer. Most obviously, physicians — who use or prescribe the company's products — are often hired to carry out research for the company. Moreover, doctors and others are paid for serving as consultants and members of scientific or medical advisory boards, for participating in focus groups, and for speaking and writing on behalf of the company. It is also common in the medical device industry for physicians to serve as trainers, demonstrating techniques for appropriate use of medical devices. All of these practices raise issues under the anti-kickback law when the person being paid — whether a physician, pharmacist, hospital purchasing agent, or other — is in a position to influence the purchase of the manufacturer's products.

The OIG has acknowledged that it is not necessarily unlawful for manufacturers to pay physicians or health care institutions to perform legitimate and needed services, even if they also may be in a position to prescribe, recommend, or purchase the manufacturer's products. Because of the possibility that when legitimate services actually are provided, the structure or amount of compensation is such as to provide an inducement to refer, and the possibility that some such service arrangements may be "shams" (paying for services that are not needed or are not actually provided), payments to individuals and health care institutions who are in a position to make purchasing decisions or refer patients are assured of protection from liability only when they satisfy the criteria for the personal services safe harbor. This safe harbor requires, among other things, that the aggregate amount of compensation: (a) be set in advance; (b) represents fair market value; (c) does not vary in accordance with the volume or value of business generated between the parties; and further that (d) for part-time arrangements, the cost and intervals of service be specified in advance in a written agreement.

The Need for Internal Guidelines. In the area of research studies, including clinical research, and grants given to physicians and health care institutions to conduct research, internal company guidelines must be established and implemented. Doing this should help medical device and pharmaceutical companies provide a sound framework for showing that a research grant represents a legitimate activity, unrelated to inducing the purchase or prescribing of its products, and should help to reduce the likelihood of OIG scrutiny. The following guidelines should be considered.

First, the company must actually evaluate the research and determine its goals and purposes. The goal of the customer's proposed research should also be an important goal for the company and, to the extent possible, the research goals should be predetermined by the company. The company's research goals should not include providing the investigator personal experience with the device or product. Importantly, a research grant should not be given in exchange for or as part of an agreement to purchase the company's products, and the sales force should not be the impetus for the submission or approval of research proposals.

The company must also consider the research study's design, implementation, and scientific merit. An evaluation of a research proposal should include a search of other ongoing scientific research to determine whether the proposed research is redundant or will advance scientific knowledge. Research grant

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[3] As mentioned above, the law imposes penalties for violations of the anti-kickback law that not only consist of substantial criminal fines and up to five years in prison, but also civil fines, and the potential exclusion from participation in Medicare, Medicaid, and other federally-funded health care programs. In September, 1998, the OIG began to exercise its exclusionary authority against any individual or entity that directly or *indirectly* provides or supplies items or services reimbursable under Medicare or Medicaid. Importantly, this means that the OIG may seek to preclude Medicare and Medicaid payments for any products of a manufacturer that the OIG believes has violated the anti-kickback law.

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proposals should be evaluated by an independent group within the company that has no tie to particular marketing or sales goals. In addition, a researcher's credentials should be reviewed to ensure the individual or individuals are qualified to carry out the research. Where significant numbers of doctors and patients are involved, the numbers should not be excessive and should also be justifiable scientifically. In addition, the medical device or pharmaceutical company should monitor research studies actively, to ensure both the quality of the research, and that the company is actually receiving fair value (*e.g.*, payments should be stopped where the researcher fails to perform).

Finally, the company must consider the research agreement itself. The company's agreement with the researcher or health care institution should track the standards set out in the personal services safe harbor. In most cases, there should be a signed agreement with a term of not less than one year, specifying the services to be provided, setting out the schedule for provision of the services, and the compensation to be paid. Compensation should be fair market value and unrelated to the volume or value of business that may be generated between the company and the customer.

The amount of funding should be reasonable in light of the work being performed, and not redundant of any work normally performed in the scope of the researcher's practice. To the extent that work is to be performed by others (*e.g.*, nurse or technician), compensation should be based on the expenses connected with that individual's work on the project, not on the value of the researcher's time.

The above guidance is supported by the Office of Inspector General in its April, 2003 Final Compliance Program Guidance for Pharmaceutical Manufacturers. Specifically, under the heading *Educational and Research Funding* section, the OIG states:

> "Payments for research services should be fair market value for legitimate, reasonable and necessary services. Research contracts that originate through the sales or marketing functions — or that are offered to physicians in connection with sales contracts — are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer's science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products."

Conclusion. Providing physicians and health care institutions with research grants is a standard practice for many medical device and pharmaceutical companies. However, when research grants are provided in conjunction with a sales transaction significant questions arise as to whether the grant is for legitimate research or simply an inducement to purchase the company's products. The Medicare/Medicaid Anti-Kickback Law not only prohibits medical device and pharmaceutical companies from offering anything of value in exchange for purchasing any product or service that is reimbursed by the government, it also prohibits their customers from asking for or receiving the items of value in this context. Thus, companies that link valuable research grant money to sales transactions not only risk liability for themselves, they also expose their customers to severe penalties, including exclusion from participation in Medicare, Medicaid, and other federally-funded health care programs.

Companies must be diligent in clearly separating the two transactions, and written procedures for evaluating and awarding research grants are essential. Failure to recognize the need to separate the two transactions can be costly to all parties involved.

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