HEALTH CARE

Legal News Alert℠

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Testimony Confirms OIG's Ongoing Focus on Vendor Relationships With Physicians

Testimony of the Office of Inspector General's (OIG) Assistant Inspector General for Legal Affairs before the Senate's Special Committee on Aging on February 27, 2008, explained the OIG's views of the risks associated with industry-physician financial relationships. The testimony also describes OIG's recent enforcement actions and outreach efforts to promote compliance as well as its views of ways to mitigate these risks, including increased transparency. The testimony reflects and confirms the OIG's continued focus on physician-industry relationships and demonstrates a need to revise compliance programs to address such relationships.

OIG's Assistant Inspector General for Legal Affairs, Gregory E. Demske, testified before the Senate Committee on Aging at a hearing held on February 27, 2008, about the OIG's views with respect to financial relationships that exist between physicians and the medical device industry. Sen. Herb Kohl, the chair of the committee, and Sen. Charles Grassley sponsored the Physician Payments Sunshine Act, which would create a national database of payments and gifts to physicians. The hearing also included testimony from a clinical professor who heads the Association for Ethics in Spine Surgery, three representatives from device manufacturers, and a representative from Advamed, a trade organization for medical device manufacturers.

Although OIG's testimony focused on the medical device sector, it is clear that much of the OIG's observations and recommendations also are applicable to other health care sectors with physician interactions such as pharmaceutical manufacturers and suppliers.

Among the OIG's concerns with such relationships are the potential for industry-induced bias resulting in:

- Risks to patients (treatment decisions that are not based solely on patient-care interests)
- Risks to health care programs (increased costs and unfair competition)
- Risks to scientific research (corrupting research independence and the standards of scientific integrity)

The testimony acknowledged that industry-physician relationships can, in many circumstances, advance medical science and benefit patients. Additionally, the testimony noted that device companies can

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legitimately compensate physicians for their actual time and intellectual contributions to product innovations and training in the appropriate use of devices.

The OIG is concerned by the significant risk that such payments may improperly influence medical decision-making. According to the OIG, its investigations have determined that in some cases, industry payments to physicians are not payments for legitimate services, but rather are "kickbacks" designed to influence medical decision-making. These kickbacks often take the guise of consulting contracts, royalty agreements, or gifts. An additional source of concern for the OIG is an apparent growing trend toward physician ownership of medical device manufacturers and related businesses.

The OIG's recommendations for actions to mitigate the risks from these financial relationships include review of the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, which the OIG explicitly states also is useful for medical device manufacturers. The OIG also recommends subjecting physician-industry relationships to reporting requirements and greater transparency. Some existing state laws already require pharmaceutical companies to report payments to physicians. The OIG also expressed support for steps outlined in recent settlements with several orthopedic device manufacturers that require companies to post the names of physicians receiving payments and the amounts paid on company Web sites. In addition, the OIG noted the policies of a number of academic medical centers and health systems to address the conflicts of interest that are created by accepting gifts from the pharmaceutical and medical device industries.

The testimony also summarized recent enforcement activity, including several specific examples of situations identified as involving improper payments to physicians for little or no work. Among the options for federal enforcers are the False Claims Act (FCA), which includes whistleblower provisions; the Anti-kickback Statute; and the Civil Monetary Penalties Law (CMPL). As noted in the testimony, it is the OIG's view that the CMPL may provide the most direct remedy (as compared to the FCA) to address a kickback scheme regardless of whether any of the parties to the scheme actually submit claims. Thus, the CMPL is particularly effective, in the OIG's view, in cases in which a device manufacturer is paying a physician to induce the physician to recommend the manufacturer's device for use in a hospital procedure. In such cases, the claim is submitted by the hospital, which is not a party to the alleged kickback. CMPL penalties for kickback cases include monetary penalties of up to $50,000 for each act, assessments of up to three times the amount of the remuneration, and exclusion from participation in federal health care programs.

Conclusion

Industry-physician financial relationships are a high-enforcement priority for the OIG. All parties to such relationships must take steps to ensure documentation of the justifications for and the reasonableness of such arrangements. In addition, health care providers and suppliers whose reimbursement claims may reflect the influences of such arrangements are advised to act diligently to mitigate attendant risks. Full transcripts of the testimony may be found at http://aging.senate.gov/hearing_detail.cfm?id=293677&.