Conflicts of interest: Device makers settlements

By Judith A. Waltz, JD

Editor's note: Judith Waltz is a Partner in the San Francisco offices of Foley and Lardner, LLP. She may be reached by telephone at 415/438-6412 or by e-mail at JWaltz@foley.com.

Health care providers and suppliers have long been sensitive to the government's concerns about potential conflicts of interest with physicians who are (or could be) referral sources. For example, in the government's view, a financial relationship with a particular hospital might inappropriately influence physicians to refer their patients to that hospital. Improper remuneration to physicians might, arguably, encourage them to order additional services which were not medically necessary and reasonable, or to favor a particular provider/supplier of items or services. In summary, from the government's perspective, financial relationships with, and remuneration to, physicians may improperly interfere with the physicians' medical decision making about patient care needs, and result (or could result) in increased costs to government health care programs.

The government is now turning its attention to another sector of the health care industry – medical device manufacturers – and potential conflicts of interest on the part of physician thought leaders who have relationships (usually called "arrangements" by government enforcers) with those manufacturers. Device manufacturers, like pharmaceutical companies, have long recognized that their success depends upon making their products known to physicians who will prescribe or recommend the use of their particular product, even if the physician may not be the one who ultimately purchases the product. In addition to their ability to influence current product use, physicians are also in the best position to conduct or oversee research which may expand future market share, including identifying additional clinical uses or adaptations for a product.

Recent enforcement activity by the Department of Justice (DOJ) and the Office of Inspector General of the Department of Health and Human Services (OIG) demonstrates the government's current focus on device industry arrangements with physicians which, (as in the contexts noted above) in the government's view, may skew independent medical decision making, cause a potential conflict of interest for the physisican, and represent improper remuneration constituting kickbacks. "Kickbacks to physicians are incompatible with a properly functioning health care system," said Peter Keisler, Assistant Attorney General for the DOJ's Civil Division in announcing a settlement with Medtronic Inc. last year. "They corrupt physicians' medical judgment and they cause overutilization and misallocation of vital health care resources."

In September 2007, five companies that account for nearly 95% of the lucrative market in hip and knee surgical implants entered into agreements with the DOJ to resolve allegations that they used sham consulting agreements and other tactics to induce surgeons to use their products. These agreements were alleged to have resulted in violations of the federal Anti-kickback Statute, a criminal prohibition against improperly offering or providing remuneration with the intent to induce referrals or future business. In a new twist, four of the manufacturers entered into Deferred Prosecution Agreements (DPAs), which allows them to avoid prosecution if they follow new compliance procedures under federal monitoring for 18 months. (The fifth manufacturer entered into a Non-Prosecution Agreement, under which it agreed to implement all the measures required of the other four manufacturers, including the 18 months of federal monitoring.) These four manufacturers also paid a total of $311 million in penalties, which released them from civil liability, but the fifth did not enter into a civil settlement. As part of the DPAs, the device manufacturers are required to prominently feature on their respective Web sites the name, city, and state of residence for each of the manufacturer's consultants (defined to include physicians), along with the payments made to each consultant, both in cash and in-kind.

Each of the four orthopedic device manufacturers that entered into a DPA also entered into a Corporate Integrity Agreement (CIA) with the OIG to avoid the potential for exclusion from the federal health care programs. (Again, the fifth manufacturer did not enter into a civil settlement, and consequently received no releases for civil liability or from the OIG.) CIAs provide the industry with guidance as to the operational monitoring which the OIG would like, or expect, to see from similarly situated entities. For example, the September 2007 CIA with Smith & Nephew, Inc. requires the creation of a database for all its arrangements (including those with physicians) with eight required categories of information, including the methodology for

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determining compensation. This CIA also requires tracking of all remuneration to and from parties to these arrangements.

Device manufacturer enforcement actions have obviously been lucrative for the federal government. In 2006, Medtronic Inc. agreed to pay the United States $40 million to settle civil allegations that its Medtronic Sofamor Danek division (MSD) paid kickbacks to doctors to induce them to use MSD's spinal products, according to a press release issued by DOJ. DOJ contended that these kickbacks violated the Anti-kickback Statute and the False Claims Act. Medtronic also entered into a CIA as part of the resolution. This investigation was the result of a *qui tam* filing. News reports indicate that several other investigations of device manufacturer arrangements with physicians are currently in progress.

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There are other indications that exposing and limiting physician relationships with device and pharmaceutical manufacturers will be a leading goal for the government in the coming year. In January 2008, a press release issued by the U.S. Attorney's Office for the Eastern District of Arkansas announced the guilty plea of Dr. Patrick Chan, of Searcy, Arkansas. Chan, a neurosurgeon, pleaded guilty to soliciting and receiving kickbacks from a sales representative for several medical companies that supplied surgical equipment and devices that Chan utilized. As of this writing, he has not yet been sentenced. Also according to the DOJ press release, in a related matter, a settlement agreement was finalized in a *qui tam* lawsuit that was filed against Chan which alleged that Chan violated the False Claims Act by accepting kickbacks from medical device manufacturers and by submitting or causing to be submitted related claims for payment from the Medicaid and Medicare programs. Pursuant to the terms of the *qui tam* settlement agreement, Chan agreed to pay $1.5 million, of which $350,000 will be paid to the relator.

In September 2007, Senators Charles Grassley and Charles Schumer introduced legislation (the "Physician Payments Sunshine Act") which would require manufacturers of pharmaceuticals and medical devices with annual revenues of more than $100 million to disclose the amount of money given to physicians (including dinners, vacations, and consulting fees). Several states already have similar mandates. Like the DPA requirements discussed above, which require the manufacturers to report physician arrangements on their Web sites, these laws promote transparency and, presumably, will discourage excessive or inappropriate relationships.

As a result of the increasing scrutiny of these manufacturer-physician arrangements, it seems clear that providers, suppliers, and especially physician groups must consider establishing policies and procedures which set parameters for physician relationships with product manufacturers and distributors. This consideration is recommended even in situations where the physicians are not employed by, or contracted with, the provider or supplier, although obviously the risks are greater when physicians are employees (when their acts in the course of performing their jobs can be ascribed to the employer). If the products are inappropriately used by the provider or supplier as a result of the physician's conflict of interest (e.g., for medically unnecessary procedures, or for procedures with unnecessary associated costs), there is an attendant risk that the government will focus on the entity which submits the claim for reimbursement to a federal health care program – i.e., the provider or supplier. With increasing government expectations for providers and suppliers to provide and be measured on quality patient care, the margins for error have become increasingly narrow with respect to any factors which may skew medical decision making as a result of non-medical reasons, such as a physician conflict of interest.

Best practices

Health care providers and suppliers may consider using best practices to avoid the enforcement trap, including, but are not limited to:

- Identifying potential risk areas to the provider or supplier that result from physician arrangements with product manufacturers.
- Establishing policies and procedures which will, at a minimum, require disclosure of a potential conflict of interest and, in appropriate circumstances, may require the physician's recusal from some decision making. Remember that some physician relationships with product manufacturers may be necessary for, or advantageous to, both the physician and the provider or supplier (e.g., product training).
- Reviewing codes of ethics (or conduct)

and similar guidance published by trade associations such as AdvaMed, Pharmaceutical Research and Manufacturers of America (PhRMA), National Emergency Medicine Association (NEMA), the American Medical Association (AMA), and others, which provide basic guidance on industry contacts with physicians. The OIG's Compliance Program Guidance for Pharmaceutical Manufacturers may also provide analogous guidance for device manufacturers, and by extension, the providers and suppliers who use their products. These documents are addressed to the product manufacturers (or, in the case of the AMA, the physicians themselves), but should be reviewed for applicability in the provider and supplier environment, because they are likely to be considered "industry standard" for physician relationships. Many large academic medical centers have already implemented policies and procedures for industry contacts with their physicians, which may serve as models for those looking to adopt their own policies and procedures.

As applicable, reviewing existing arrangements between product manufacturers and physicians, including, but not limited to, the following, for compliance with applicable laws, regulations, and available guidance:

Vendor-sponsored product training and education

Support for third-party educational conferences

Sales and promotional meetings with physician participation

Consulting arrangements

Gifts, paid entertainment, recreation, and meals

Charitable donations

Research grants

Providers and suppliers should also examine their own relationships with product manufacturers and their representatives, which represent the potential for more direct conflicts of interest.

Conclusion

Device manufacturers, following pharmaceutical manufacturers who in turn followed direct health care providers (such as hospitals and nursing facilities), are now the subject of increased government enforcement activity. An initial enforcement focus is the manufacturers' relationships with physician thought leaders. Due care must be taken to assure compliance with all laws and regulations regarding all such arrangements.