HEALTH LAW360

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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Physician Arrangements Get Device Makers In Trouble

Friday, Jan 25, 2008 --- Device makers, like pharmaceutical manufacturers, 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.

In addition to their ability to influence current product use, physicians also are in the best position to conduct or oversee research that may expand future market share, including identifying additional clinical uses or adaptations for a product — some of which may not yet be approved by the U.S. Food and Drug Administration (FDA).

With respect to many devices, physicians may not be the actual purchaser of the product; rather, a hospital or surgery center, or even a group purchasing organization, may be the actual purchaser for use in facility procedures. Nonetheless, physicians often serve as thought leaders who can directly and indirectly influence product selection by the actual purchaser.

Recent enforcement activity by the United States Department of Justice (DOJ) and the Health and Human Services Office of Inspector (OIG) demonstrates the government's commitment to limiting manufacturer contacts with physicians that may skew independent medical decision making.

The federal Anti-Kickback Statute (AKS) is a criminal prohibition against improper remunerations (broadly defined to include virtually anything of value) to referral sources.

In addition, enforcement activity may be premised upon the federal Civil False Claims Act (FCA), even though device manufacturers typically do not directly bill Medicare, Medicaid, and other federal health care programs and physicians may not directly purchase the product.

The requisite "link" is that the FCA can be violated if an individual or entity either submits a false claim, or causes a false claim to be submitted, seeking reimbursement from a federal health care program. "Kickbacks" may be alleged to "taint" a claim that may give rise to civil false claim liability under the FCA even if there is insufficient evidence to support the criminal intent required for an AKS violation.

The FCA also includes whistleblower provisions that allow private recoveries to, and protection against retaliation for, the whistleblower.

The government can take a variety of different approaches to resolving fraud

allegations as evidenced by the recent settlement involving five of the nation's largest orthopedic device manufacturers.

These manufacturers of artificial hips and knees were alleged to have used sham consulting agreements and other tactics to induce surgeons to use their products in violation of the AKS.

In a new twist, four of the manufacturers entered into Deferred Prosecution Agreements, which allow them to avoid prosecution if they follow new compliance procedures under federal monitoring for 18 months.

These four manufacturers also paid a total of $311 million in penalties. One manufacturer avoided criminal charges and civil penalties because it was the first company to cooperate with the federal investigation and instead accepted federal supervision for 18 months.

As part of the Deferred Prosecution Agreements, the device manufacturers are required to prominently feature on their Web site 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.

In addition, as part of a settlement with the DOJ involving a health care entity, a Corporate Integrity Agreement (CIA) often is required. This is the OIG's contract with the entity with respect to future performance, and reciprocates for the OIG's relinquishment of its option to exclude (debar) the entity from participation in the federal health care programs.

Each of the four orthopedic device manufacturers noted above entered into a CIA. These CIAs provide the industry with guidance as to the operational monitoring 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 of its arrangements, including those with physicians, with eight required categories of information, including the methodology for determining compensation.

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

Best Practices

Best practices for device manufacturers to consider to avoid the enforcement trap include, but are not limited to, the following:

Manufacturers should have an established and effective compliance program, including adequate resources to support it. Some states may require a compliance plan as a condition for doing business in the state (e.g., California's SB 1765). Codes of Ethics (or Conduct) and similar guidance published by trade associations such as the Advanced Medical Technology

Association (AdvaMed), PhRMA, the National Electrical Manufacturers Association (NEMA), the American Medical Association, and others, provide basic guidance on contacts with physicians, and should be considered to represent the "industry standard."

Manufacturers should critically review all existing arrangements with physicians including, but not limited to, the following:

— 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

— Preceptorship agreements

Policies and procedures should be designed — and followed — for approval of future arrangements with physicians. It is particularly important to document all terms of such arrangements, including the services to be provided (and proof that they were provided) and the methodology for compensation. "Safe harbors" specified in the regulations may provide protection against AKS allegations if all requisite conditions are met.

Sales and marketing staff must be trained on the risks associated with basic marketing practices that may be fully acceptable — or even considered key strategies — in non-health care lines of business.

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 such arrangements.

--By Judith A. Waltz and Lena Robins, Foley & Lardner LLP

Judith A. Waltz is a partner with Foley in San Francisco, co-chair of the firm's life sciences industry team and former vice chair of the health care industry team. Lena Robins is senior counsel in the health care and life sciences

industry teams in Washington, D.C.

