

"I'm from the government, and I'm here to help..."

By Mary Ann Porucznik

"Enforcement goes in waves," says OIG chief counsel

"I'm so envious of the tools you use. Walking around the exhibit floor, I wanted to be an orthopaedic surgeon—and I'll bet you wish I were one, too!"

That remark from Lewis Morris, JD, chief counsel for the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), spurred laughter from the audience of more than 850 orthopaedic surgeons and industry representatives who gathered in the Gateway Ballroom during the 2008 Annual Meeting. But for most of the rest of his presentation, there was grim silence.



Lewis Morris, JD

As part of a panel examining the evolving situation regarding relationships between orthopaedic surgeons and industry, Mr. Morris provided the government's perspective. Pointing out that he was not a member of either the Department of Justice or the Centers for Medicare and Medicaid Services and thus had no role in either regulations or reimbursement, Mr. Morris focused on the

current enforcement environment, potential areas of risk, and compliance resources.

“There is a problem”

The scenarios Mr. Morris outlined in OIG’s three areas of enforcement—criminal, civil, and administrative—were not pretty. For example, under the antikickback statute (criminal enforcement), any payments from a manufacturer that might be construed as inducement for a physician to recommend an item or service are suspect. Penalties can be severe, including jail and criminal fines, as well as exclusion from all government programs.

Under the False Claims Act, he noted, it’s illegal to submit a claim or statement to Medicare or Medicaid knowing that it’s false or fraudulent. In addition, the government doesn’t need to prove specific intent to defraud. “Recklessness equals liability,” he said.

Penalties under the False Claims Act include payments of up to three times the government’s outlay for the investigation, plus a \$5,500 to \$11,000 per claim penalty. If the case was initiated by a whistle-blower, that individual gets 30 percent of the total penalty payments—a substantial sum in many cases. “Whistle-blowers may themselves have dirty hands,” said Mr. Morris, “but that won’t prevent them from getting a handsome reward.”

The administrative version of the False Claims Act is the Civil Monetary Penalties Act, under which penalties are even more onerous, amounting to three times the amount claimed, plus up to \$10,000 per item or service. If kickbacks are involved, an additional penalty equal to three times the amount of the kickback, plus \$50,000, may be assessed.

Members of the audience may have felt caught in a vortex as Mr. Morris explained that under the Civil Monetary Penalties aspect of the False Claims Act, cases are not heard by a jury but by an administrative judge who is an employee of the HHS. Hearsay is admissible, and a conviction isn’t needed to exclude the individual from participating in any government programs, not just Medicare and Medicaid.

Under the proposed Physician Payments Sunshine Act (S. 2029), manufacturers of pharmaceutical drugs, medical devices, and biologics would be required to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel, and other means. The name of the physician, the nature of the payment or economic benefit, and the basis for the payment would be part of an annual report to HHS and would be published on the Internet. The law would apply to all manufacturers with \$100 million or more in annual gross revenues.

Risk areas

Mr. Morris identified the following five risk areas for physicians: gifts and gratuities, educational funding, research funding, royalty agreements, and consulting contracts. “Wining and dining” physicians and their guests or staff could be very problematic because these activities could be seen as influencing medical decision making ([Fig. 1](#)). Patient perceptions of the influence of these activities vary greatly from physician perceptions.

Research and education funding by industry may have legitimate benefits, but several problems also exist. In no way should this funding be dependent on referrals, and manufacturers should have no control over content. Royalty and consulting contracts should be based on the fair market value of the physician’s actual and meaningful contribution. Documentation of physician work effort is key to upholding these agreements.

You can be proactive

Mr. Morris encouraged audience members to be proactive if they identify a problem. "Come to us and we can work together to resolve the situation collaboratively and fairly," he urged. "You will have to return any payments made to you, and you will have to pay a penalty, but the final costs will be much lower than if you don't self-disclose."

He also outlined the following five steps that physicians could follow to minimize their legal risk:

- Adhere to professional guidelines, such as the AAOS Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest.
- Establish a compliance program for your practice.
- Use the "Fair Market Value" test to judge whether payments are excessive.
- Use the "Washington Post" test—if you wouldn't want the arrangement to appear in your local paper, don't do it.
- "If it seems too good to be true, it probably is."

"What you do in caring for patients is remarkable and essential," said Mr. Morris. "The challenge is managing the conflict of interest that might exist."

On that point, at least, there was unanimous agreement.

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