

Part B Insider (Multispecialty) Coding Alert

COMPLIANCE: Don't Let Financial Ties to Manufacturers Create Legal Woes for Your Physicians

3 ways to navigate increasing transparency of prescriber-supplier relationships.

With the new healthcare reform law in place, the federal government will soon be able to take a harder look at financial relationships between physicians and companies that make drugs, biologics, medical devices, and supplies. Here's what you need to know and do to stay out of federal prosecutors' crosshairs.

The basics: The reform bill incorporates provisions of the Physician Payment Sunshine Act, which requires manufacturers to report annually to the Department of Health & Human Services how much they've tendered of value to "covered recipients," e.g., physicians and teaching hospitals.

The annual reporting requirement goes into effect on March 31, 2013 for payments made from Jan. 1 through Dec. 31, 2012. The companies have to report the date, amount, and form of payment (cash, stock, services, etc.), whatever the arrangement is -- and the product involved, says attorney **John Jones Jr.**, with Pepper Hamilton in Philadelphia. (Manufacturers don't have to report anything under \$10 unless the annual aggregate amount to a "covered recipient" surpasses \$100.)

Watch Out for Stark Violations

The primary areas where physicians could be vulnerable to prosecutions are "anti-kickback law and possibly violation of the Stark self-referral prohibition," says attorney **Wayne J. Miller** with The Compliance Group in Los Angeles.

Miller points out that "recent settlements involving large pharma and some DME suppliers ... are already resulting in action against facilities." And he expects "the next tier of enforcement involving alleged kickbacks will move to individual or group providers."

Overall, it's tough to say whether prosecutions against individual practitioners are "going to kick up," says attorney **John Oroho** with Porzio Bromberg & Newman in Morristown, N.J. But "when prosecutors see cases that are not necessarily" in an area where "intent won't be difficult to prove, I don't think they will hesitate to bring them."

3 Strategies Cover the Basics

The good news is that physicians can keep their financial dealings with manufacturers in the safety zone. Here's how:

Strategy 1: Pay close attention to how you set up financial relationships. Physicians can still do deals with manufacturers, but the arrangements "need to be set at fair market value [and] be at arm's length," Jones says. "A physician consultant has to actually perform the services" for the company, he adds. And the physician cannot get paid for referrals.

Key example: Suppose a surgeon serves as a consultant to a device maker and has a royalty arrangement for helping to engineer the device maker's implantable orthopedic device. In that case, the physician can't receive royalties on the devices used by the hospitals where he practices and implants the devices. (The doctor can, however, receive the usual third-party reimbursement for performing the surgeries.) "This applies to any product," Jones says.

"On the pharma side," Jones adds, "we have seen doctors sometimes actually become an extension of a [drug company's] sales force where they get into marketing a drug -- that's a big no-no."

On the other hand: "Just because a pharma company paid a physician \$50,000 in consulting fees in a given year would

not in and of itself be sufficient to prove that that physician" violated the anti-kickback statute, counsels attorney **Daniel Margolis**, with Pillsbury Winthrop Shaw Pittman in New York City.

Strategy 2: Take the high road with self-disclosure. Miller points out that "many doctor groups and facilities already require medical staff or member doctors to disclose arrangements with vendors as part of a conflict of interest review."

Strategy 3: Consider unwinding problematic relationships with manufacturers, advises Miller. That may be appropriate to do, especially with ones that have already been under scrutiny, he says. Also consider whether to disclose a terminated relationship to the government or payers "to the extent there may be a legal or reimbursement impact."