

Part B Insider (Multispecialty) Coding Alert

COMPLIANCE: Drugmaker Guidance Could Have Wide Reach to Physicians

If you're accepting free services or payments as an inducement to prescribe a particular drug, you could be writing a prescription for disaster.

The **HHS Office of Inspector General's** compliance guidance for pharmaceutical companies, released April 23, has important lessons for both pharmacies and other providers, experts say. The OIG casts such a broad net for fraud and abuse that the drugmaker-tailored guidance should raise red flags for providers of all stripes.

The final CPG is far more detailed than the draft version issued last October. Here are the hot spots in a nutshell:

1. **Data Integrity.** Drugmakers face False Claims Act charges and potential kickback prosecution if they report inaccurate pricing data to the government.
2. **Kickbacks.** Pharmaceutical companies' networks of business arrangements essentially form a kickback minefield, the OIG warns. Noting that business practices "that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal healthcare program business," the OIG cautions that pitfalls could be hidden in arrangements with purchasers, benefit managers, formulary committee members, group purchasing organizations, physicians, certain allied [health professionals](#) and pharmacists.

"The days of logoed golf balls are gone," says attorney **Elizabeth Carder-Thompson** with **Reed Smith Shaw & McClay** in Washington.

The guidance enumerates a wide range of potentially suspect activities, from "marketing the spread" - the manipulation of the average wholesale price to boost profits for doctors - to bogus educational grants.

Remember, "the anti-kickback law criminalizes improper remuneration, whether it is in cash or in kind, direct or indirect," says attorney **Robert Wanerman** with **Reed Smith** in Washington. "The government doesn't distinguish among these broad categories - they're all illegal." And keep in mind that "this is not a situation where there's a lack of penalties and sanctions if you're caught" breaking the rules, says **Brett Bissey**, chief compliance officer for **Deborah Heart & Lung Center** in Brown Mills, N.J.

The compliance guidance could impact providers for a few reasons, says **Ankur Goel**, a partner with **McDermott Will & Emory** in Washington. First, to the extent that it convinces pharmacies to change their pricing practices and bring down average wholesale price numbers, it could cut into providers' profits.

Second, the OIG is signaling it will subject all sorts of drug purchasing arrangements to greater scrutiny. And some of its guidance about arrangements between drugmakers and purchasers can easily apply to arrangements between pharmacies and referral sources as well, Goel says.

For example, if a pharmacy is furnishing a provider with services such as checking on patients, that could attract scrutiny.

Third, any inducement to someone who is in a position to influence the patient's choice of medications could trip the OIG's radar, Goel says. This is more likely to be a physician or health plan than a pharmacist, but there could be cases in which a pharmacy receives a better price for one medication than another and convinces a patient to use the cheaper medication.

The bottom line for physicians is that your relationships with drugmakers are fraught with perils, and enforcement on this

front may be coming to a boil. The CPG zeros in on, among other things, "switching" arrangements, under which doctors receive a fee when a patient switches medications; trumped-up consulting or advisory payments; lavish gifts of entertainment, travel, meals and recreation in connection with marketing presentations; and questionable educational and research funding.

The agency also suggests that doctors who make sales representatives pay for their time could be running big kickback risks.

And whatever you do, don't bill for free drug samples.

One way to carve out a safe space is to adhere to the code of ethics created by the Pharmaceutical Research and Manufacturers of America, Carder-Thompson says. This goes into very specific detail about relationships with other "healthcare professionals." The OIG says in its guidance that following this code won't shield you from liability, but will indicate a "good-faith effort," Carder-Thompson says.

Editor's note: The PHRMA code is at www.phrma.org.