You can expect the Justice Department to pay more attention to dealings between P&T committees and drug manufacturers, now that the Inspector General at the Department of Health and Human Services has just issued guidance for the pharmaceutical industry. The Inspector General laid out some general ground rules for how both parties can avoid running afoul of federal anti-kickback rules.

The Inspector General's advice is strictly that—it does not have the force of law. It isn't specific enough, anyway, to even qualify as law. But inasmuch as the Inspector General took the trouble to flash some “yellow lights” with regard to drug company interactions with P&T committees, it makes sense to run through some of the finer points of that message.

First the context. The Inspector General has issued guidelines for many sectors within the health care industry, so this yardstick for the pharmaceutical industry on how to stay on the right side of the fraud and anti-kickback laws was not stimulated by some upsurge in abuse; the pharmaceutical industry’s number simply came up. Moreover, in the past, the Justice Department has been much more concerned about hospitals, physicians, nursing homes, and home health outfits because they have had a much bigger impact on Medicare and Medicaid spending (which is where Justice’s jurisdiction comes in) than drug manufacturers do. After all, there is no Medicare outpatient drug benefit. That may continue to be the case. On the other hand, if Congress gives Medicare beneficiaries an outpatient drug benefit, private insurance companies will manage it and P&T committees will jump into the federal ring with both feet.

The Inspector General guidance, for the most part, says that as long as you do this or don’t do that, you’ll be clear of anti-kickback suspicion. The Inspector General applies this guideline to a P&T committee’s choice of drugs by saying that as long “as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.”

The guidance then goes on to bless formulary “support activities,” including related communications with patients and physicians to encourage compliance, and emphasizes that these services are “markedly different from its purchasing agent/price negotiator role.”

That is the good news. The bad news is that PBMs must be careful about how they pay for those support communications. If the funds come from a manufacturer, and the communication (for example, a letter to physicians about the efficacy of drugs within a certain class) seems to nudge the manufacturer’s product to the head of the class, there might well be anti-kickback violations.

Manufacturer payments that end up in the pocket of a P&T committee member will also raise a red flag at the Inspector General’s office, although the guidance provides few details on that score.

Another potential problem is caused when rebates that are paid by a manufacturer to a PBM are based on, or otherwise related to, purchases by customers of PBMs. Protection is available via one of the aforementioned safe harbors; payments have to be authorized in advance by the PBM’s customers, and all amounts actually paid to the PBM based on the customer’s purchases must be disclosed in writing, at least annually, to the customer.

Most major PBMs believe that they comply with federal and state law. “The guidance underscores principles that we have embraced for years, and which form a core part of our business model for making the use of prescription drugs safer and much more affordable,” says Derrell Carter, a spokesman for Express Scripts. Caremark says almost exactly the same thing.

That kind of confidence is what one would expect from solid companies. But it probably wouldn’t hurt for PBMs to go back through their policies with an Inspector General–inspired fine-tooth comb just to make sure that every hair is in place.