Government's Draft Guidelines on Drugs Are Murky At Best

by Stephen Barlas

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The federal government's drug industry fraud bloodhound—no, not James Sheehan, the U.S. attorney in Philadelphia—has drafted some guidelines on how pharmacy benefit managers (PBMs) might stay on the right side of the law. The Office of the Inspector General (OIG) at the Department of Health and Human Services is the one that does the initial sniffing out of potential defrauding of Medicare and Medicaid and then sends evidence on to the U.S. Department of Justice for potential enforcement action by U.S. attorneys. The OIG is the bloodhound; Mr. Sheehan is just one of its puppies, albeit a feisty one.

The pharmaceutical marketing draft language put out by the OIG at the end of September contains a good bit of ambiguous verbiage, bearing on sections of the anti-kickback law that Mr. Sheehan has used in his reputed cases against Medco Health Solutions and AdvancePCS. It is a good thing that the OIG is at least making an effort to specify when rebates offered by drug companies to PBMs, often for switching patients to drugs with the rebates attached, stray into illegal arrangements. Although Attorney Sheehan's two cases have generated a lot of heat, they have produced little light. Very little about those two cases has been made public. We know that the practice of drug companies paying rebates to PBMs in order to encourage switching to certain drugs is an issue of concern; beyond that, not much else is known.

Thus, there is a void out there; ostensibly, this is where the OIG comes in. It is not surprising that it has taken Attorney Sheehan four years to build a case against PBMs, although we don't know at this point whether he has succeeded. Drug companies do not sell their products directly to Medicare and Medicaid; they work through third parties, sometimes PBMs, sometimes physicians. In contrast, hospitals bill Medicare and Medicaid directly. The annual reports of the Health Care Fraud and Abuse Control Program, run jointly by the Justice Department and the OIG, show, for the past few years, all sorts of enforcement actions against hospitals and home health agencies. However, there has been only one significant fine against a drug company—and none against a PBM. That is because making cases against drug companies and PBMs is difficult to do.

Now factor in the murkiness of the law. Even though the OIG's drafted guidelines try to clear that up, the language is going to have to be improved considerably by the time these guidelines become final, if they are to be helpful to anyone.

PBMs are mentioned in a number of sections. In the section on discounts offered by drug companies, the guidelines currently caution drug companies to examine "whether they are providing a valuable tangible benefit with the intent to induce or reward referrals" when they give a PBM "free or below market rate goods or services." The guidelines then suggest—they *only* suggest, they do not state—that inducements are fine as long as they are made to all PBMs (and other purchasers) and not only to high-volume purchasers. No definition of "high-volume" is provided.

Next, the guidelines say that the inducement is "problematic" if it relieves the PBM of an expense that the PBM itself otherwise would have had to pay for. No examples of the types of "expenses" that *could be* problematic are presented.

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Given the publicity accorded the switching issue by Sheehan, one would expect PBMs to read the admonitions in the OIG guidelines very carefully. Again, though, the guidelines are notable for the gray areas they contain. They start off by saying that switching "may be permissible in certain managed care arrangements" and that manufacturers should review those arrangements "very carefully."

The same applies for "indirect" switching, which includes payments to PBMs "for contacting patients or their physicians to encourage them to change a prescription from another product to the company's product, and discounts or rebates based on movement of market share."

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