Government’s Draft Guidelines on Drugs Are Murky At Best

by Stephen Barlas

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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.

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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