update

Staying Ahead
with Saul Ewing

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Life Sciences Law

Benchmark Compliance Program Guidance For Pharmaceutical Manufacturers Released By OIG

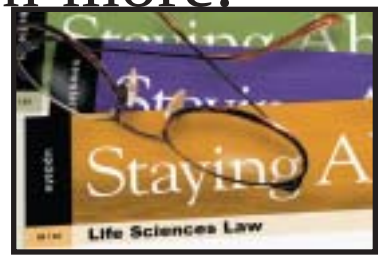
What happened?

The "Compliance Program Guidance for Pharmaceutical Manufacturers" was released this Spring by the Office of Inspector General for the U.S. Department of Health and Human Services as a voluntary initiative for this sector of the life sciences industry.

What does it mean?

To help them reduce their risk of engaging in unlawful conduct, the OIG has provided companies that develop, manufacture, market and sell pharmaceutical drugs or biological products (collectively, "Manufacturers") a structure of the important considerations for an effective compliance program.

Learn more.



Turn page to learn more about voluntary compliance criteria and other aspects of "Compliance Program Guidance for Pharmaceutical Manufacturers".

The new OIG Compliance Guidance includes the **seven elements** the OIG believes are important for any effective compliance program. These are the same recommendations that have been included in previous OIG guidance documents for different industries. More importantly, the OIG identified three **specific risk areas** for Manufacturers. They are: (1) the integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with drug sample regulations. A brief description of each is below.

1) Integrity of Data Used to Establish Government Reimbursement

According to the Compliance Guidance, a Manufacturer's reported prices must accurately reflect all price concessions that have been offered to purchasers, including cash discounts, rebates, up-front payments, goods in kind, and free or reduced-price services because these prices are often used to establish pharmaceutical reimbursement rates.

2) Kickbacks and Other Illegal Remuneration

The Compliance Guidance recommends that each Manufacturer evaluate its financial relationships with persons and entities in a position to generate federal health care business. Manufacturers should consider the following issues:

- Could the arrangement interfere with clinical decision-making?
- Could the arrangement increase costs to federal health care programs, beneficiaries, or enrollees?
- Could the arrangement increase the risk of overutilization or inappropriate utilization?
- Could the arrangement raise patient safety or quality of care concerns?

The Compliance Guidance notes the potential risks that arise out of a Manufacturer's relationship with three groups — (1) purchasers, (2) health care professionals, and (3) sales agents. Manufacturers should be especially cognizant of these relationships.

3) Drug Samples

The Compliance Guidance reiterates that drug samples should not be billed to federal health care programs, and recommends that Manufacturers ensure compliance with the Prescription Drug Marketing Act of 1987.

The Compliance Officer and Committee

The OIG believes the designation of a compliance officer, supported by a committee, with authority to implement a Manufacturer's compliance program, is critical to its success.

Reporting Instances of Potential Misconduct

The Compliance Guidance advises that if a Manufacturer discovers evidence of misconduct, and, after reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the Manufacturer should report that misconduct to appropriate federal and state authorities within sixty (60) days of concluding there is credible evidence of a violation. This recommendation has generated widespread debate and should be carefully considered by a Manufacturer.

Next Steps

Manufacturers' corporate activities are getting more attention in the media. The Compliance Guidance should be used as a tool to help Manufacturers develop and/or refine their compliance programs to help ensure adherence to the law and good corporate practices.

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