

conduct or policies and procedures. A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response.

H. Responding to Detected Problems and Developing Corrective Action Initiatives

Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. Detected but uncorrected misconduct can endanger the reputation and legal status of the company. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and, if so, take decisive steps to correct the problem.¹⁹ The exact nature and level of thoroughness of the investigation will vary according to the circumstances, but the review should be detailed enough to identify the root cause of the problem. As appropriate, the investigation may include a corrective action plan, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Reporting

Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the company should promptly report the existence of misconduct to the appropriate federal and state authorities²⁰ within a reasonable period, but not more than 60 days,²¹ after determining that there is credible

evidence of a violation.²² Prompt voluntary reporting will demonstrate the pharmaceutical manufacturer's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion), if the reporting company becomes the subject of an OIG investigation.²³

When reporting to the government, a pharmaceutical manufacturer should provide all information relevant to the alleged violation of applicable federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable federal health care programs or their beneficiaries.

III. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs, it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization. This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. The essential elements outlined in this compliance guidance can be adapted to the unique environment of each manufacturer. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

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Endnotes

1. The term "Federal health care programs," as defined in 42 U.S.C. 1320a-

7b(f), includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government or any state health plan (e.g., Medicaid or a program receiving funds from block grants for social services or child health services). In this document, the term "federal health care program requirements" refers to the statutes, regulations and other rules governing Medicare, Medicaid, and all other federal health care programs.

2. See 66 FR 31246 (June 11, 2001), "Notice for Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry."

3. See 67 FR 62057 (October 3, 2002), "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers."

4. 42 U.S.C. 1320a-7b(b).

5. In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products.

6. In addition, pharmaceutical manufacturers should be mindful that many states have fraud and abuse statutes—including false claims, anti-kickback and other statutes—that are not addressed in this guidance.

7. The False Claims Act (31 U.S.C. 3729-33) prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program.

8. The 340B Program, contained as part of the Public Health Services Act and codified at 42 U.S.C. 256b, is administered by the Health Resources and Services Administration (HRSA).

9. 42 U.S.C. 1396r-8. Average Manufacturer Price and Best Price are defined in the statute at 42 U.S.C. 1396r-8(k)(1) and 1396r-8(c)(1), respectively. CMS has provided further guidance on these terms in the National Drug Rebate Agreement and in Medicaid Program Releases available through its Web site at <http://www.hcfa.gov/medicaid/drugs/drug.mpg.htm>.

10. In this regard, pharmaceutical manufacturers should note that the exception for non-monetary compensation under the Stark law (42 U.S.C. 1395nn; 42 CFR 411.357(k)) is not a basis for protection under the anti-kickback statute.

11. CME programs with no industry sponsorship, financing, or affiliation should not raise anti-kickback concerns, although tuition payments by manufacturers (or their representatives) for persons in a position to influence referrals (e.g., physicians or medical students) may raise concerns.

12. It is also advisable to designate as a compliance officer an individual with prior experience or knowledge of compliance and