

Analysis & Perspective

Fraud and Abuse

Implementing the HHS Office of Inspector General's Final Compliance Guidance for Pharmaceutical Manufacturers

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On April 28 of this year, the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) released its 11th health care related guidance, the "Compliance Program Guidance for Pharmaceutical Manufacturers."¹ The OIG has periodically released voluntary compliance guidance to encourage health care entities to institute internal controls to identify, prevent, and mitigate the potential for fraud and abuse, and ensure compliance with applicable laws and requirements relevant to federal health care programs.

The OIG had released a draft version of the guidance on Sept. 30, 2002, and solicited comments through Dec. 2, 2002. While many elements of the draft guidance remain, the OIG has made clarifications, and has included examples and discussion of particular areas of risk as well as strategies to follow to best adhere to the guidance.

The final guidance seeks to meet the goal of reducing fraud and abuse, enhancing health care provider operational functions, improving the quality of health care services, and reducing the cost of health care. While the OIG states that the final guidance "is not a compliance program," it is clear that those health care entities who fall under one of the OIG guidance elements should use the guidance as a model for ongoing compliance programs and corporate leadership and should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. This article will deal with the OIG's suggestions on how to best structure implementation of the guidance, and will address certain challenges that may arise during a company's implementation efforts.

The final guidance identifies three major potential risk areas for pharmaceutical manufacturers: integrity of data used by state and federal governments to estab-

¹ The guidance was published in the *Federal Register* May 5 (69 Fed. Reg. 23831), and is available on the Web at <http://www.oig.hhs.gov/fraud/complianceguidance.html>.

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lish payment; kickbacks and other illegal remuneration; and compliance with laws regulating drug samples.

While pharmaceutical manufacturers are different from other health care entities that have been subject to OIG guidance in that pharmaceutical manufacturers do not directly submit claims to the federal government, the essential required elements of past OIG guidance have remained the same. The pharmaceutical manufacturer should make a formal commitment through its board of directors or other governing body, to incorporate the following seven elements:

- Implementing policies and procedures,
- Designating a Compliance Office and Compliance Committee,
- Conducting training,
- Developing effective lines of communication,
- Conducting internal auditing and monitoring,
- Enforcing standards through well-publicized disciplinary guidelines, and
- Responding promptly to detected problems and undertaking corrective action.

Pharmaceutical manufacturers will have to implement these seven elements with respect to the specific risk areas identified by the OIG. Those specific risk areas and recommendations include:

- Using the Pharmaceutical Research and Manufacturers of America Code as the minimum standards with which to comply. The OIG has stated that compliance with the Code will substantially reduce the risk of fraud and abuse and will demonstrate a good faith effort to comply with federal health care program requirements.
- Separating education and research-funding activities from marketing activities.
- Avoiding improper influence over formulary committee deliberations, including lump sum payments for inclusion in a formulary or for exclusive formulary status.
- Carefully reviewing discounts or rebates offered based upon the movement of market share ("switching arrangements").
- Reviewing the integrity of data furnished to federal health care programs to avoid knowingly manipulating the average wholesale price (AWP) of a drug to induce customers to purchase its products. This includes the review of any discounts, price concessions, or benefits.
- Carefully reviewing payments for detailing.

In order to address these and other concerns of the OIG, pharmaceutical manufacturers must structure their compliance programs around the seven suggested elements. Specifically, pharmaceutical manufacturers should take the following steps:

Implement Policies and Procedures

The OIG guidance suggests that pharmaceutical manufacturers document their practices in written policies and procedures. These policies and procedures should be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers. The creation of policies and procedures will require the compliance officer to identify and delegate the development of these policies and procedures to those managers who have relevant knowledge of the specific parts of the organization in order to draft workable, effective policies and procedures.

These policies and procedures should address each of the identified special risk areas, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices, as well as other risk areas not identified by the OIG but known to the pharmaceutical manufacturer. The policies and procedures should be provided to all affected employees, and to any agents or contractors who may furnish services that impact federal health care programs. Note that if a pharmaceutical manufacturer is amending existing policies and procedures, it should assess compliance with current standards prior to implementing new policies and procedures to identify any existing problems and ensure that the new standards can be met.

Designate a Compliance Officer and Compliance Committee

The OIG guidance suggests that pharmaceutical manufacturers designate a compliance officer who will lead the compliance efforts of the organization. The OIG acknowledges in its guidance that this position may vary depending on the size and resources of the organization. For instance, a small pharmaceutical manufacturer may combine the duties of the compliance officer with another existing position, while larger organizations may wish to create a new position. In either situation, the OIG guidance recommends that the position of compliance officer be a high-level office, with access to the leadership of the organization, and be assumed by an individual who will be able to devote substantial time and attention to compliance matters.

The compliance officer should regularly report to the company's board, chief executive officer or president, and compliance committee on compliance matters, and should periodically revise the compliance program, as necessary, to respond to changes in the company's needs, identified systemic patterns of noncompliance, or other identified vulnerabilities in the compliance program.

The OIG guidance recommends that the compliance officer oversee each element of the organization's compliance program, including training, and that the position be independent and not subordinate to the general counsel, controller, or chief financial officer. In addition, the compliance officer should have sufficient resources and staff to effectuate change as necessary.

The compliance officer also must have the authority to review all information related to compliance activities, including interactions with government programs to determine compliance with federal health care program reporting and rebate requirements and to examine interactions with health care professionals.

Conduct Effective Training

Pharmaceutical manufacturers should effectively communicate their policies and procedures to all affected personnel by requiring participation in appropriate training. Training should include general educational sessions regarding federal health care programs, while specific, targeted training on issues such as the anti-kickback statute or the calculation and reporting of pricing information and payment of rebates in connection with federal health care programs should be targeted at those employees whose job requirements make such information relevant. This will present challenges to pharmaceutical manufacturers in the creation and implementation of training while identifying particular classes of employees to receive such training.

Pharmaceutical manufacturers should train all new employees soon after the commencement of their employment, and should periodically re-train or provide educational training or materials to current employees.

The OIG guidance further recommends that participation in training programs be made a condition of continued employment and failure to comply with training requirements should result in disciplinary action.

Develop Effective Lines of Communication

The OIG guidance makes it clear that in order for a compliance program to be effective, and to reduce the potential for fraud and abuse, employees must be able to ask questions and report problems. In order to encourage questions and reports, pharmaceutical manufacturers should consider the adoption of open-door policies to facilitate dialogue between supervisors and employees. In addition, pharmaceutical manufacturers should draft confidentiality and non-retaliation policies regarding complaints and distribute such policies to all affected employees.

Questions and responses should be documented and, if appropriate, shared with other staff members so that policies and procedures can be periodically updated and improved.

The OIG guidance also encourages the use of hotlines, e-mail and other forms of communication to effectuate open lines of communication. Reports should be able to be made anonymously.

Reports that may indicate violations of company policies and procedures or federal health care program requirements should be documented and investigated. Documentation should include the nature of the investigation, results of such investigation, and any action taken.

Conduct Internal Auditing and Monitoring

Pharmaceutical manufacturers should incorporate systems to monitor and audit their compliance programs. Monitoring should be an ongoing evaluation process, and should be documented by the compliance officer and provided to the pharmaceutical manufacturer's senior management and the compliance committee.

The frequency and extent of audits will vary based on resources, risk factors, and prior history of noncompliance. Such audits could include prospective systemic reviews of a pharmaceutical manufacturer's processes, protocols and practices, or retrospective reviews of actual practices.

The OIG guidance recommends regular compliance reviews by either internal or external evaluators. Their reviews should focus on those departments that have

substantive involvement with or impact on federal health care programs and on the specific risk areas identified by the OIG.

Specifically, the reviews should determine if there are policies covering risk areas specified by the OIG guidance and the pharmaceutical manufacturer, whether such policies and procedures have been implemented and communicated, and whether such policies and procedures have been followed.

Disciplinary Standards

The OIG guidance recommends that pharmaceutical manufacturers have in place clear and well-publicized disciplinary guidelines that set forth the consequences of violating the law or the pharmaceutical manufacturer's policies and procedures or code of conduct.

Discipline should be meted out in a consistent manner across the entire organization in order for the disciplinary policy to be effective. Disciplinary action for intentional and material violations should result in significant sanctions for the violator. Sanctions could range from warnings up to and including termination.

Disciplinary action also may be appropriate if an employee's failure to detect a violation is attributable to his or her negligence or reckless conduct.

Respond to Detected Offenses

The OIG guidance suggests that pharmaceutical manufacturers institute policies and procedures to adequately respond to violations of a pharmaceutical manufacturer's compliance program, failure to comply

with applicable law, or other instances of misconduct that threaten the organizations reputation or status as a participant in the health care industry.

Therefore, upon receipt of reasonable indications of suspected noncompliance with the pharmaceutical manufacturers compliance program or applicable law, the compliance officer and management should immediately investigate and determine if noncompliance has occurred, and if it has, take steps to correct the non-compliance. As appropriate, the corrective action may include a corrective action plan, reporting and repayment to the government, and/or referral to criminal and/or civil law enforcement authorities.

Where appropriate, if violations to applicable law are discovered, pharmaceutical manufacturers should report such violations to appropriate federal and/or state authorities. Such reports should be made within a reasonable period of time, but not more than 60 days after determining that there is credible evidence of a violation. Prompt reporting will exhibit good faith on the part of the pharmaceutical manufacturers and will be considered a mitigating factor by the OIG in determining administrative sanctions.

Finally, each of the elements above should focus on identifying, minimizing, and mitigating actual and potential instances of noncompliance. To that end, pharmaceutical manufacturers should take steps to understand and analyze their relationships with sales agents, and educate themselves and their sales and marketing forces on the pharmaceutical manufacturer's compliance program, and applicable law.