

OIG Issues Final Compliance Program Guidance for Pharmaceutical Manufacturers

The Office of Inspector General (OIG) of the Department of Health and Human Services released on April 28, 2003 the final Compliance Program Guidance for Pharmaceutical Manufacturers (Guidance). The OIG received over 140 responses to its initial draft of this Guidance that was released for comment on September 30, 2002. This Guidance is intended to assist pharmaceutical manufacturers in establishing internal controls to ensure compliance with applicable laws and requirements. This Guidance specifically applies to companies that develop, manufacture, market and sell pharmaceutical drugs or biological products. However, the OIG indicates that the compliance program elements and potential risk areas addressed in this 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.



WHAT ARE THE SIGNIFICANT DIFFERENCES BETWEEN THE OIG'S DRAFT AND FINAL GUIDANCE?

The following passages highlight some of the key differences between the OIG's draft and final Guidance:

- The OIG revised its stance on the PhRMA Code from the draft Guidance, which suggested that the PhRMA Code merely represented "a good starting point for compliance purposes" and "minimum standards." The final Guidance more positively states that compliance with the PhRMA Code "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."
- The OIG recommends that manufacturers separate their educational and research funding activities from their sales and marketing operations. This new recommendation, which appears at several points in the final Guidance, has the potential to significantly change or influence the way that many manufacturers are currently handling educational and research grants.



- The OIG clarified that all arrangements with potential referral sources (e.g., health care entities or professionals who can refer or generate federal health care business) are not *per se* illegal. To identify arrangements or practices that may present significant potential for abuse, the OIG recommends that manufacturers apply a two-prong test: (1) “identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly;” and (2) “determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program.” In addition, the final Guidance provides a list of illustrative questions that manufacturers should ask when identifying problematic arrangements.
- The OIG added a new section that discusses formularies and states that the development of a formulary is not likely to raise significant anti-kickback issues. However, the OIG indicates that some practices appear to have the potential for abuse, including: improper influence over formulary committee deliberations; any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM’s customers’ purchases; and lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status.
- The discussion of “switching” remains the same except for a noticeable deletion of the discussion of “discounts or rebates based on movement of market

share,” which was referenced in the draft Guidance as an example of arrangements that should be carefully reviewed.

- The OIG states that payments for detailing are “highly susceptible to fraud and abuse and should strongly be discouraged.”
- Although the Average Wholesale Price (AWP) section remains essentially the same from the draft Guidance, the OIG clarifies in the final Guidance that: “it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the ‘spread’ to induce customers to purchase its product.”

WHICH AREAS FROM THE OIG’S DRAFT GUIDANCE REMAIN THE SAME AND MAY BE OF PARTICULAR INTEREST TO MANUFACTURERS?

While the OIG incorporated significant changes in its final Guidance, as noted above, several areas in the final Guidance remained unchanged from the draft Guidance and may be of particular interest to manufacturers, including the following OIG recommendations:

- A manufacturer’s compliance function (e.g., compliance officer) should not be subordinate to the pharmaceutical manufacturer’s general counsel, comptroller, or similar financial officer.
- Manufacturers should provide compliance policies and procedures to any agents or contractors who may furnish services that may have an impact on the federal health care programs.
- Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the applicable safe harbors to the anti-kickback statute.
- Employees should be required to have a minimum number of compliance-educational hours per year, as appropriate, as part of their employment responsibilities.

- A manufacturer’s supervisors can serve as a “first line of communications” in responding to employees’ concerns, although the OIG encourages hotlines to maintain open lines of communication.
- A compliance officer should carefully consider whether the manufacturer should hire or do business with individuals or entities that have been sanctioned (e.g., excluded from the federal health care programs) by the OIG.
- A manufacturer should “promptly report the existence of misconduct to the appropriate federal and state authorities within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a violation.”

ARE THERE ANY NEW SUGGESTIONS RELATED TO THE SEVEN ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM?

This final Guidance generally follows the OIG’s customary Guidance on the seven elements of an effective compliance program, which is based on insight offered in the Federal Sentencing Guidelines issued by the U.S. Sentencing Commission in 1991:

1. Implementing written policies and procedures,
2. Designating a Compliance Officer and Compliance Committee,
3. Conducting effective training and education,
4. Developing effective lines of communication,
5. Conducting internal monitoring and auditing,
6. Enforcing standards through well-publicized disciplinary guidelines, and
7. Responding promptly to detected problems and undertaking corrective action.

With respect to the seven elements, the final Guidance offers no major changes from the draft Guidance.



ARE YOU REQUIRED TO FOLLOW THE OIG COMPLIANCE PROGRAM GUIDANCE?

The Guidance presents voluntary suggestions on how manufacturers can establish internal controls and prevent fraudulent activities. Adherence to the Guidance is not mandatory. The Guidance is not a regulation, nor is it a requirement for participation in Federal health care programs. Furthermore, the contents of the Guidance should not be viewed as an exclusive discussion of the advisable elements of a compliance program. The applicability of the recommendations and guidelines provided in the Guidance depends on the circumstances of each particular manufacturer, including the size, resources, and corporate structure of the organization. However, OIG Compliance Program Guidances have provided the basis for creating *de facto* industry standards and manufacturers should seriously consider the final Guidance when developing, implementing, or assessing their compliance programs.



WHAT SHOULD YOU DO NOW?

The OIG's Guidance will provide assistance to manufacturers in the development and implementation of their compliance programs. For those manufacturers that already have existing compliance programs, this Guidance may serve as a benchmark against which to measure ongoing compliance practices. At the very least, this Guidance should prompt manufacturers to evaluate whether:

- Existing written policies and procedures reflect the underlying objectives of the OIG's recommendations in the Guidance,
- Actual practices conform to company policies and procedures, and
- Company practices comply with applicable laws and requirements when there are no pre-existing written policies and procedures.

We encourage you to carefully review the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. You can find the final Guidance and other related information posted on the OIG's website at: <http://www.oig.hhs.gov/fraud/complianceguidance.html>



FOR MORE INFORMATION PLEASE CONTACT:

Brent Saunders

Partner, Global Pharmaceutical and Health Sciences Group
brenton.saunders@us.pwcglobal.com
973-236-4682

Tony Farino

Partner, Global Pharmaceutical and Health Sciences Group
anthony.farino@us.pwcglobal.com
312-298-2631

Michael Shaw

Director, Global Pharmaceutical and Health Sciences Group
michael.l.shaw@us.pwcglobal.com
202-414-1552

Michael Swiatocha

Director, Global Pharmaceutical and Health Sciences Group
michael.p.swiatocha@us.pwcglobal.com
973-236-4541

MAILING ADDRESS:

PricewaterhouseCoopers LLP, 400 Campus Drive, Florham Park, NJ 07932

WWW.PWC.COM/PHARMA/

Pharmaceutical Industry Alert is published by PricewaterhouseCoopers' Global Pharmaceutical Industry Group. The information published in this Alert is intended to provide an overview of regulatory compliance matters facing the pharmaceutical and healthcare products industry. Please contact a qualified professional advisor to address your specific questions. In helping our clients to perform as market leaders, we draw on the full knowledge and skills of the firm's professionals in 142 countries.

© 2003 PricewaterhouseCoopers LLP. "PricewaterhouseCoopers" refers to PricewaterhouseCoopers LLP, a Delaware limited liability partnership or, as the context requires, the network of member firms of PricewaterhouseCoopers International Limited, each of which is a separate and independent legal entity.