PHARMA AUDIOCONFERENCE

An Analysis of the HHS OIG Draft Compliance Program Guidance for the Pharmaceutical Industry

Overview of Draft CPG

Michael P. Swiatocha

October 22, 2002

Agenda for Audioconference

- Introductions
- Overview of OIG Draft Compliance Program Guidance for the Pharmaceutical Industry – Michael Swiatocha
- Review of Key Structural Issues – Bert Weinstein
- Review of Identified Risk Areas – Panel Discussion
- Questions from the Audience

Background

Draft Compliance Program Guidance (CPG) for the Pharmaceutical Industry

- **Agency – Office of Inspector General (OIG), Health and Human Services**
- **June 11, 2001 – OIG published a solicitation notice seeking information and recommendations**
- **OIG received 8 comments**
- **Draft CPG published as Federal Register Notice on October 3, 2002**
- **Comment period – 60 days after publication of FR Notice**
- **http://oig.hhs.gov/fraud/complianceguidance.html**

Background

Goals of the Compliance Program Guidance Initiative at OIG

- **Effort to engage the health care community in preventing and reducing fraud and abuse in Federal health care programs**
- **Enhance health care provider operations**
- **Improve the quality of health care services**
- **Reduce the cost of health care**
- **Encourage use of internal controls to efficiently monitor adherence to statutes, regulations and program requirements**

Background

Goals of the Compliance Program Guidance Initiative at OIG (Continued)

- **Other CPGs issued by OIG**
  - **Hospitals, nursing facilities, home health, and hospices**
  - **Clinical laboratories**
  - **Durable medical equipment suppliers**
  - **Medicare+Choice organizations**
  - **Individual and small group physician practices**
  - **Ambulance suppliers (draft)**

Overview of CPG

Key Terms and Definitions

- **Federal health care programs include 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 U.S. government or any state health plan**
- **Federal health care program requirements are the statutes, regulations and other rules governing Medicare, Medicaid, and all other Federal health care programs**
- **Federal and state authorities include the OIG, Criminal and Civil Divisions of DOJ, U.S. Attorney, FDA, FTC, DEA, FBI and other investigative arms for the agencies administering affected Federal and state health care programs**

Overview of CPG

- **CPGs are not regulations, nor requirements for participation in Federal or state health care programs**
- **Intended to assist pharmaceutical companies that develop, manufacture, market and sell drugs and biologics for use in Medicare, Medicaid and other Federal health care programs**
- **CPGs offer guidelines and principles to consider when developing and implementing an effective compliance program**
  - **Compliance program structural issues**
  - **Specific risk areas identified through investigative efforts**
- **Words to remember about CPGs – voluntary, not binding, illustrative, minimum and benchmarks**

Overview of CPG

Tangible and Intangible Benefits to Pharmaceutical Manufacturers from Compliance Programs

- **Fulfill legal observations and reduce risks from unlawful conduct**
- **Demonstrate commitment to honest and responsible corporate behavior**
- **Prevent, identify, and correct inappropriate behavior**
- **Establish lines of communication**
- **Minimize financial loss from penalties**

Overview of CPG

Additional sources of information

- **Other CPGs**
- **OIG Advisory Opinions (42 CFR 1008)**
- **Federal Anti-Kickback statute safe harbor regulations (42 CFR 1001.952)**
- **Fraud Alerts**
- **http://oig.hhs.gov**
- **PhRMA Code on Interactions with Healthcare Professionals**
- **http://www.phrma.org**
- **Michael.p.swiatocha@us.pwcglobal.com (973-236-4541)**