Office of Inspector General Update

Thirteenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
November 5, 2012

Gregory E. Demske, Chief Counsel
Mary E. Riordan, Senior Counsel
Office of Counsel to the Inspector General

Agenda for Today

- Three main topics:
  - Report on Pharmaceutical Compliance Roundtable
  - Update on OIG Activity
  - Predictions and Recommendations

OIG Pharmaceutical Compliance Roundtable

- Held on February 23, 2012
- 23 companies and the OIG participated
- Report available on OIG website

  www.oig.hhs.gov

OIG Pharmaceutical Compliance Roundtable

- Discussion Topics Included:
  - CIA implementation challenges
  - Compliance program structure and oversight
  - Identifying and monitoring risk areas
  - Policies, procedures, and training activities
  - Compliance after the CIA ends

Update on OIG Activity

- Fraud Case Settlements
- OIG Administrative Actions
- OIG Reports

Update on OIG Activity

- Recent settlements with drug and device companies addressed:
  - Off-label and improper promotion practices
  - Kickback issues
  - AWP/pricing issues

Update on OIG Activity

- Noteworthy Trends in Recent CIAs
  - Focus on interactions with government payors
  - Focus on centralized risk assessment programs
  - Focus on financial incentives for individuals
    - Executives
    - Sales Force

Update on OIG Activity

- OIG Administrative Actions
  - Exclusion actions against individuals
    - Former executives of Synthes, Inc.
    - Former executives of Purdue Frederick

Update on OIG Activity

- OIG Administrative Actions
  - Civil monetary penalty (CMP) actions against manufacturers for late price reporting
    - $230,000 CMP against Sandoz, Inc.
    - 2010 Special Advisory Bulletin

Update on OIG Activity

- OIG Reports
  - Analyzing Changes to Medicaid Federal Upper Limit Amounts, OEI-03-11-00650 (October 2012)
  - Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2010, OEI-03-11-00410 (November 2011)
  - States Collection of Medicaid Rebates for Drugs Paid Through Medicaid Managed Care Organizations, OEI-03-11-00480 (September 2012)
  - Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications, OEI-07-08-00152 (November 2011)
  - Scientific Disagreements Regarding Medical Device Regulatory Decisions OEI-01-10-00470 (June 2012)

Predictions/Recommendations

OIG Work Plan for FY 2013

- Numerous proposed studies in a variety of areas:
  - Part B drug issues
  - Part D issues
  - Medicaid drug rebate issues
  - FDA issues

Predictions/Recommendations

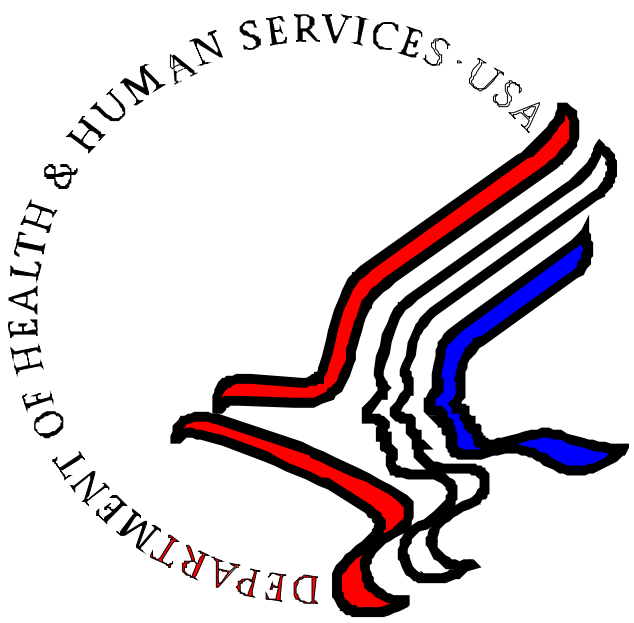
- What does the new OIG Work Plan suggest for compliance?
  - Pay attention to drug price calculation and reporting issues
  - Pay attention to promotional activities, including the use of coupons
  - Pay attention to rebate practices (under Medicaid and with Part D sponsors)

Predictions/Recommendations

- Continued focus on promotional practices, including on less-traditional issues
- Increasing focus on research and publication activities
- Scrutiny of payments to physicians
- Continued focus on individuals

Predictions/Recommendations

- Implement centralized risk assessment and mitigation programs
- Maintain effective and flexible auditing practices
- Evaluate incentives for individuals and ways to increase accountability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