

Office of Inspector General Update

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

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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

