

# Office of Inspector General Update

Pharmaceutical Regulatory and Compliance Congress  
and Best Practices Forum  
November 12, 2009

Mary E. Riordan, Senior Counsel  
Office of Counsel to the Inspector General  
[www.hhs.oig.gov](http://www.hhs.oig.gov)

# Agenda for Today

- Three main topics:
  - ◆ Environmental Scan
  - ◆ Work of Law Enforcement and the OIG in Drug and Device Area
  - ◆ Trends and Predictions

# Environmental Scan

- Scrutiny of, and concern about, certain industry practices
- Externally-driven change is likely
- Proactive changes by the industry

# Environmental Scan

## ■ Recommendations:

- ◆ Establish an effective compliance program
- ◆ Prepare for transparency
- ◆ Identify/address conflict of interest issues

# Environmental Scan

## ■ Recommendations:

- ◆ Identify/address research-related issues
  - ◆ Conflict of interest issues
  - ◆ Disclosure issues
- ◆ Don't forget state activity

# OIG Enforcement Work

- Fraud Investigations/Settlements
  - ◆ AWP and Pricing Allegations
  - ◆ Medicaid Drug Rebate Allegations
  - ◆ Kickback Allegations
  - ◆ Off-label Promotion Allegations

# OIG Enforcement Work

- Fraud Investigations/Settlements
  - ◆ Cases against Medical Device Manufacturers
  - ◆ Cases against Individuals

# OIG Review Work

- **OIG Work Plan – Fiscal Year 2010**
  - ◆ Medicare Part B Drug-Related Work
    - ◆ Drug Price Comparisons
    - ◆ Submission of Average Sales Prices (ASPs)
    - ◆ Targeted Drug Payment Work

# OIG Review Work

## ■ OIG Work Plan – Fiscal Year 2010

### ◆ Medicaid Drug-Related Work

- ◆ Average Manufacturer Price (AMP) submissions
- ◆ Calculation of AMP
- ◆ Medicaid payments for drugs not approved for use by children
- ◆ Medicaid payments for unapproved drugs

# OIG Review Work

- **OIG Work Plan – Fiscal Year 2010**
  - ◆ Medicaid Drug-Related Work
    - ◆ Rebates for Authorized Generics
    - ◆ Rebates for Physician-Administered Drugs
    - ◆ Additional Rebate Review
    - ◆ Use of AMP in Medicaid Reimbursement

# OIG Review Work

- **OIG Work Plan – Fiscal Year 2010**
  - ◆ Medicare Part D Work
    - ◆ Pharmaceutical Manufacturer Rebates
    - ◆ Alternative Calculation of Part D Rebates
    - ◆ Less-than-Effective and Terminated Drugs in Medicare Part D Claims

# OIG Review Work

- **OIG Work Plan – Fiscal Year 2010**
  - ◆ Use of Data Safety Monitoring Boards in Clinical Trials
  - ◆ Use of Foreign Clinical Trials to Support NDAs and BLAs
  - ◆ FDA's Oversight of Investigational New Drug Applications

# Trends and Predictions

- Increasing Numbers of Actions against Device Companies
  - ◆ Pending criminal actions
  - ◆ Exclusion implications

# Trends and Predictions

- Increasing Numbers of Actions against Individuals
  - ◆ Law enforcement scrutiny of responsible individuals
  - ◆ Administrative actions – including exclusions – against industry executives
  - ◆ Administrative actions against physicians and other kickback recipients

# Trends and Predications

## ■ Trends in CIA Provisions

- ◆ Increasing accountability of individuals
  - ◆ More involvement and personal accountability of members of Boards of Directors
  - ◆ Certifications by top managers, including those in key functional areas

# Trends and Predications

- Trends in CIA Provisions
  - ◆ Transparency-related provisions
    - ◆ Notification of hcps about settlements
    - ◆ Requirements to post information about payments to physicians

# Trends and Predications

## ■ Trends in CIA Provisions

- ◆ Increased flexibility and coverage of audit requirements
  - ◆ Additional Items reviews
  - ◆ Increased internal auditing - - both of field and headquarters activity
  - ◆ IRO focus on expanded types of activities

# Trends and Predictions

## ■ Trends in CIA Provisions

- ◆ Risk assessment and review process
  - ◆ Proactive identification of potential risks
  - ◆ Implementation of risk mitigation plan
  - ◆ Outside Reviewer assessment

# Trends and Predictions

## ■ Potential Outcomes?

- ◆ Better compliance
- ◆ Enhanced public trust
- ◆ Better public health
- ◆ Business advantages
  - ◆ Fewer settlements
  - ◆ Lower expenditures

