

Office of Inspector General Update

Twelfth Annual Pharmaceutical Regulatory and
Compliance Congress and Best Practices Forum
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Agenda for Today

- Three main topics:
 - ◆ OIG Pharma Compliance Roundtable
 - ◆ Update on OIG Activity
 - ◆ Predictions and Recommendations

OIG Pharma Compliance Roundtable

- Details are being finalized
- Planned for early 2012
- Focus on identifying compliance measures that industry has found to be effective
- Summary of meeting will be posted on OIG website

Update on OIG Activity

- Fraud Case Settlements
- OIG Administrative Actions
- OIG Reports

Update on OIG Activity

- Settlements between the United States and Drug and Device Companies
 - ◆ AWP/pricing issues
 - ◆ Off-label promotion issues
 - ◆ Kickback issues

Update on OIG Activity

■ OIG Administrative Actions

- ◆ Exclusion of Individuals, including under:
 - ◆ 42 U.S.C. § 1320a-7(a)(3)
 - ◆ 42 U.S.C. § 1320a-7(b)(1)
 - ◆ 42 U.S.C. § 1320a-7(b)(15)

Guidance about Exclusion of Individuals under 42 U.S.C. § 1320a-7(b)(15)

- **Individuals with ownership or control interest** in sanctioned entity may be excluded if they knew or should have known of conduct that led to the sanction.
- **Officers and managing employees** may be excluded solely based on their position with the sanctioned entity.
- Guidance sets forth factors to be considered

Update on OIG Activity

- **OIG Administrative Actions**
 - ◆ Enforcement actions against manufacturers for late price reporting
 - ◆ September 2010 - OIG Special Advisory Bulletin regarding CMPs for late reporting
 - ◆ Enforcement actions against doctors for kickback issues

Update on OIG Activity

OIG Reports

- ◆ Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents (May 2011)
- ◆ Replacing Average Wholesale Price: Medicaid Drug Payment Policy (June 2011)
- ◆ Medicaid Brand-Name Drugs: Rising Prices Are Offset by Manufacturer Rebates (August 2011)
- ◆ Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D (August 2011)

Predictions/Recommendations

■ OIG Work Plan

- ◆ Reviews of entities that do not enter CIAs
- ◆ Physician owned distributorship issues
- ◆ Other areas of review:
 - ◆ Part B drug issues
 - ◆ Medicaid drug rebate issues
 - ◆ Part D issues
 - ◆ FDA issues

Predictions/Recommendations

- What does the OIG Work Plan suggest for compliance?
 - ◆ Pay attention to physician owned distributorship issues
 - ◆ Pay attention to drug price reporting and calculation issues
 - ◆ Pay attention to promotional activities and drug safety issues

Predictions/Recommendations

- Continued focus on individuals
- Continued large numbers of cases alleging improper promotion (*e.g.*, for off-label, non-covered uses of products)
- Continued large numbers of cases against drug and device manufacturers

Predictions/Recommendations

- Recent CIA Trends Will Continue
 - ◆ Accountability of Board Members
 - ◆ Accountability of Managers
 - ◆ Transparency
- Recommend implementing risk assessment and mitigation programs
- Recommend creative, effective auditing

