Office of Inspector General Update

24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

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Today's Agenda

- Update on recent enforcement and other activity of OIG
- Update on recent OIG reports and future work
- Compliance lessons and suggestions

Recent Resolutions

- This year's resolutions involved a variety of issues, including:
  - Kickback issues
  - Violations of FDA requirements
  - Violations of drug price reporting requirements

False Claims Act Matters

- Kickback-related FCA settlements with drug and device companies
  - J&J and its DePuy subsidiaries ($9.75 million)
  - OraPharma, Inc. ($100,000)

False Claims Act Matters

- Kickback-related FCA settlements with physicians
  - Speaker program issues
  - Edward Lubin, M.D.
  - Charles Nevels, M.D.

Other Resolutions

- Resolutions with medical device companies
  - Advanced Bionics LLC ($12.6 million FCA resolution)
  - Jet Medical Inc. and related companies ($745,000 criminal/civil resolution)

Other Resolutions

- $10 Million global resolution with medical device company
  - Non-prosecution agreement and FCA settlement with STIMWAVE LLC, indictment of former CEO

Other Resolutions

- Drug price reporting CMP cases
  - B. Braun Medical Inc. ($200,000)
  - Sagent Pharmaceuticals ($175,000)

Other OIG Activities

- Update on OIG's Guidance Modernization Initiative
  - Goal is to improve publicly available resources
  - Request for Information, stakeholder meetings
  - Updating Compliance Program Guidance documents

OIG Reports

Report Relating to Drug Utilization

- "Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist" Sept. 2023 (OEI-05-22-00140)

OIG Reports

Reports Relating to Average Sales Price

- "CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data to Ensure Accurate Part B Drug Payments" January 2023 (OEI-03-21-00390)
- "Manufacturers May Need Additional Guidance to Ensure Consistent Average Sales Price Calculations" January 2023 (OEI-BL-21-00330)

OIG Reports

Reports Relating to Average Sales Price

- "Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements" March 2023 (OEI-BL-23-00010)

OIG Reports

Reports on Medicare Drug Payments

- "Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices" August 2023 (OEI-03-23-00120)
- "Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2023" August 2023 (OEI-03-23-00100)
  - We also published results for the fourth, third, and second quarters of 2022.

OIG Reports

Reports on the Medicaid Drug Rebate Program

- Reviews of States' collection of Medicaid rebates for physician-administered drugs, including drugs dispensed to enrollees of Medicaid managed care organizations
  - Continuing reviews of individual states (Mississippi, Alabama, Kentucky, Florida)

OIG Reports

Work relating to the Inflation Reduction Act

- "Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs" Feb. 2023 (OEI-BL-23-00170)

OIG Reports

Work Relating to Opioids

- Identify opportunities to improve the efficiency and effectiveness of HHS programs
- Identify and hold accountable those engaged in fraud
- Empower and collaborate with partners through data sharing and education
- https://oig.hhs.gov/reports-and-publications/featured-topics/opioids/

OIG Work Plan

Current Work Plan Items

- Noncovered Versions of Part B Drugs
- Medicare Payments for Stelara
- Nationwide Review of the Administration and Oversight of Physician-Administered Drugs
- Review of the FDA's Accelerated Approval Pathway

Lessons/Suggestions

Continue to Monitor Kickback Risks

- Risks associated with HCP/customer relationships (E.g., speaker programs, provision of free equipment)
- Don't forget Open Payments reporting obligations

Lessons/Suggestions

Consider FDA-Related Risks

- Ensure compliance with FDA requirements
  - Approval/clearance requirements
  - Affirmative reporting obligations
- Ensure that submissions to the FDA are accurate, complete, not misleading

Lessons/Suggestions

Consider Medicare/Medicaid Program Risks

- Comply with drug price reporting obligations
  - ASP, AMP, Best Price
- Ensure the payment of appropriate rebates (including inflation-based rebates)
- Be mindful of coverage criteria under the programs

Lessons/Suggestions

- Individual accountability is critical
- Compliance programs should be tailored to address your organization's specific risk areas
- Compliance programs need to continue evolving to address emerging risks

In Closing . . .

Thank You

Questions?