



Update from the Office of Inspector General

19th Annual Pharmaceutical And Medical Device Compliance Congress

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Agenda for Today

- Update on recent enforcement activity
- Update on recent OIG reports and future work
- Lessons/suggestions for consideration





Recent Settlements

- Settlements involved a variety of issues:
 - Kickback issues
 - Promotional issues
 - Product issues





False Claim Act Settlements

Settlements involving prescription drugs

- AmerisourceBergen Corporation
- Pfizer Inc.
- United Therapeutics Corporation





False Claims Act Settlements

Settlements involving medical devices

- Alere Inc.
- AngioDynamics, Inc.
- Allergan Inc.
- Abiomed, Inc.





2018 National Health Care Fraud Takedown

- 600+ Defendants
- 58 Federal Districts
- \$2 Billion in Medicare/Medicaid losses
- Conduct involved various types of fraud, including opioid-related activities





OIG Reports

- Reports on Drug Pricing/Reimbursement Issues
 - “Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices” August 2018 (OEI -03-18-00120)
 - “Increases in Reimbursement for Brand-Name Drugs in Part D” June 2018 (OEI-03-15-00080)





OIG Reports

- Reports Relating to the Medicaid Drug Rebate Program
 - “Potential Misclassifications Reported by Drug Manufacturers May have Led to \$1 Billion in Lost Medicaid Rebates” Dec. 2017 (OEI-03-17-00100)
 - Reviews of States’ collection of Medicaid rebates for physician-administered drugs, including drugs dispensed to enrollees of Medicaid managed care organizations
 - Reviews for: Ohio, Texas, Nebraska, Arkansas, Arizona





OIG Reports

- Reports on Other Issues
 - “Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting” August 2018 (OEI-03-15-00220)
 - “Questionable Billing for Compounded Topical Drugs in Medicare Part D” August 2018 (OEI-02-16-00440)





OIG Reports

- Reports on Opioid Issues
 - “Opioid Use in Medicare Part D Remains Concerning” June 2018 (OEI-02-18-00220)
 - “Opioids in Ohio Medicaid: Review of Extreme Use and Prescribing” July 2018 (OEI-05-18-00010)
 - “Toolkit: Using Data Analysis to Calculate Opioid Levels and Identify Patients at Risk of Misuse or Overdose” June 2018 (OEI-02-17-00560)





OIG FY 2018 Work Plan

- Ongoing work includes several items relating to the Medicaid drug rebate program:
 - Manufacturers' use of reasonable assumptions
 - FDA approval status of drugs covered under the Medicaid drug rebate program
 - Impact of authorized generics on Medicaid drug rebates





OIG FY 2018 Work Plan

- Other planned work includes:
 - Review of specialty drug coverage and reimbursement under Medicaid
 - FDA response planning for a networked medical device compromise
 - Data briefs regarding financial interests reported to the Open Payments Program





OIG FY 2018 Work Plan

- Planned opioid-related work includes:
 - Review of prescription opioid drug abuse and misuse prevention – Prescription Drug Monitoring Programs
 - Review of FDA oversight of REMS to address prescription opioid abuse
 - Review of opioid use in Indian Health Service
 - Review of States’ oversight of opioids





Lessons/Suggestions

- Think broadly about compliance risk areas – established and emerging
 - Risks under the Federal anti-kickback statute
 - Risks associated with failure to comply with FDA requirements
 - Risks associated with the Medicaid drug rebate program
 - Risks associated with HIPAA issues





Lessons/Suggestions

- Maintain a focus on kickback issues
 - Kickbacks are a continued area of focus in cases
 - Think broadly about arrangements with a variety of individuals and entities
 - Risk areas to watch:
 - Arrangements with health care providers
 - Arrangements involving patient assistance programs





Lessons/Suggestions

- High level support for and involvement with compliance is critical
 - Support for compliance
 - Financial resources
 - Less tangible support is equally important
 - All business units should be included in the organization's compliance program





Lessons/Suggestions

- Importance of individual accountability
 - Certifications from the Board of Directors
 - Management certifications
 - Compliance as a component of employee evaluations
 - Discipline/rewards relating to compliance





Lessons/Suggestions

- Other thoughts about compliance
 - Basic compliance program elements are expected
 - Meaningful monitoring is a must
 - Compliance programs should be tailored to address risk areas specific to the organization
 - Compliance programs must continuously evolve





Lessons/Suggestions

Key question: Is your compliance program effective?





Questions?

