Office of Inspector General Update

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October 19, 2016
AGENDA FOR TODAY

- Update on recent enforcement activity
- Update on OIG reports and other publications
- Lessons/suggestions for consideration
ISSUES IN RECENT SETTLEMENTS

- Settlements addressed a variety of areas:
  - Kickback issues
  - Marketing and sales issues
  - Medicaid drug rebate program issues
  - Drug price reporting issues
FALSE CLAIM ACT SETTLEMENTS

- Kickback-related settlements
  - Salix Pharmaceuticals, Inc.
  - Olympus Corporation of the Americas
  - Novartis Pharmaceuticals
  - Warner Chilcott
  - Omnicare, Inc.
FALSE CLAIM ACT SETTLEMENTS

- Settlements involving sales and marketing issues
  - Acclarent, Inc.
  - Genentech Inc. and OSI Pharmaceuticals LLC
  - Paradigm Spine
  - Qualitest Pharmaceuticals

- Settlement involving Medicaid drug rebate issues
  - Wyeth/Pfizer

- Settlements involving other issues
  - Imported and compounded drugs
CIVIL MONETARY PENALTY SETTLEMENTS

- Drug Price Reporting CMP Settlements
  - Nephron Pharmaceuticals Corporation
  - Cipher Pharmaceuticals US, LLC
  - Coloplast Corp.
OIG REPORTS

- Drug pricing issues
  - “Average Manufacturer Prices Increased Faster Than Inflation for Many Generic Drugs” – December 2015 (A-06-15-00030)

- 340B program issues
  - “Part B Payment for 340B Purchased Drugs” - Nov. 2015 (OEI-12-14-00030)
  - “State Efforts to Exclude 340B drugs from Medicaid Managed Care Rebates” – June 2016 (OEI-05-14-00430)
OIG REPORTS

- Reports relating to the Medicaid Drug Rebate Program
  - Reviews of the collection of Medicaid rebates for physician-administered drugs - KS, UT, WY, SD, MT, CA

- Other issues
  “FDA Is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist - July 2016 (OEI-01-14-00390)"
OIG FY 2016 WORK PLAN

- Planned work includes
  - Medicare Part B drug pricing review
  - Reviews of price increases for Medicare Part D covered drugs
  - Medicaid drug rebate-related reviews
  - 340B drug pricing program review
NEW AND NOTEWORTHY

- April 2016 – Criteria for implementing permissive exclusion under Section 1128(b)(7) of the SSA
  - Supersedes and replaces prior 1997 notice
  - Reflects lessons learned from OIG’s experience
  - Reflects widespread development of compliance programs
  - Under the new criteria, OIG uses a risk spectrum to evaluate whether to pursue exclusion.
LESSONS/SUGGESTIONS

- Maintain a focus on kickback issues
  - A continued area of focus in cases/settlements
  - Open Payments database
  - Think broadly - payments and transfers of value
  - Risk areas from recent cases:
    - Speaker programs
    - Arrangements with specialty pharmacies
    - Equipment loans, free equipment
LESSONS/SUGGESTIONS

- Importance of individual accountability
  - Law enforcement focus on responsible individuals
  - Think about accountability in compliance
    - Certifications from Boards of Directors
    - Management certifications
    - Compliance as a component of employee evaluations
    - Disciplinary action for compliance failures
LESSONS/SUGGESTIONS

- Effective compliance programs remain the goal
  - Basic compliance program elements are expected
    - Modifications in recent CIAs
  - Compliance programs/CIAs should be tailored to address risk areas
  - Compliance program must continuously evolve
    - Importance of risk assessment and mitigation
QUESTIONS?