OIG DEVELOPMENTS 2018
HCCA ANNUAL COMPLIANCE INSTITUTE
APRIL 16, 2018

Gary Cantrell
Deputy Inspector General for Investigations

Greg Demske
Chief Counsel
HHS Office of Inspector General

Topics

• OIG Overview
• OIG Priorities in 2018
• Current Developments
OIG by the Numbers

• HHS Budget > $1.1 Trillion
• OIG Budget = $342 Billion
• $695 Million of Oversight for each OIGer
• HCFAC ROI = 4:1

OIG – 2013-2017

• $24.4 Billion in Expected Investigative and Audit Recoveries
• 1,607 Audit and Evaluation Reports
• 4,581 Criminal Actions
• 3,221 Civil Actions
• 18,222 Exclusions
Identifying OIG Priorities

• Work Plan
• HHS Top Management and Performance Challenges
• HHS Secretary’s Priorities
• OIG Priority Outcomes

Priority Areas

• Prescription Drugs / Opioid Crisis
• Improving Care for Vulnerable Populations
  – Focus on Non-institutional settings
• Managed Care / Private Insurance
Prescription Drug Investigations

- OIG Investigative Priority
- DOJ Prescription Interdiction & Litigation Task Force
- Diversion
- Opioids
- Non-Controlled Drugs

Opioids

- OI Enforcement Efforts
- OEI Data Brief: “Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Billing”
- Upcoming: Toolkit to Identify Patients at Risk of Opioid Misuse
In 2016, Medicare Part D covered 44 million beneficiaries.

1 in 3 beneficiaries received opioids.

1 in 10 beneficiaries received opioids on a regular basis.

Continuous use of opioids increases the risk of opioid dependence.

Source: HHS analysis of Medicare Part D data, 2016
Learn More https://aspe.hhs.gov/opioidbrief

In 2016, Medicare Part D covered 44 million beneficiaries.

14.4 million received opioids

Here’s an example of a beneficiary receiving extreme amounts of opioids:

A beneficiary in NY received 62 opioid prescriptions for fentanyl and oxycodone in one year.

That’s more than 1 prescription per week.

The patient’s average daily dose was almost 35 times the level that CDC recommends avoiding.

Source: HHS analysis of Medicare Part D data, 2016
Learn More https://aspe.hhs.gov/opioidbrief
In 2016, Medicare Part D covered 44 million beneficiaries: 14.4 million received opioids.

HALF A MILLION Part D beneficiaries received HIGH AMOUNTS of opioids in 2016.

These beneficiaries received an average daily dose of opioids, equivalent to taking more than:

12 VICODIN TABLETS  OR  16 PERCOCET TABLETS

These dosages far exceed the amounts CDC recommends avoiding.

2017 NATIONAL HEALTH CARE FRAUD TAKEDOWN
2017 TAKEDOWN By The Numbers

- 412 Defendants Charged, Including
- 115 Medical Professionals
- $1.3 Billion in Losses
- 41 Federal Districts
- 30 Medicaid Fraud Control Units
- 295 Exclusion Notices
- 350 OIG Agents

Source: DOJ and HHS OIG

PILL MILLS & PRESCRIBERS
Opioid-Related Exclusions

In association with the 2017 National Health Care Fraud Takedown, the Department of Health and Human Services Office of Inspector General’s Exclusion Program issued notices to 295 individuals based on the conduct related to opioid diversion and abuse. These notices represent doctors that operate a pill mill, nurses reporting for duty impaired due to diversion from patient or employer pill stock; and pharmacists and pharmacy technicians stealing pills and other similar conduct.

Top 5 States with Exclusions

- NY: 30
- MA: 24
- TX: 23
- PA: 22
- NC: 21

Exclusions by Occupation

- Nurses: 162
- Doctors: 57
- Pharmacy Services: 37
Medicaid Fraud Control Units

- OIG Administers Grants to MFCUs
- Key OIG Partners
- 1,564 Convictions in 2016
  - 74% Fraud
  - 26% Patient Abuse or Neglect

Improving Care for Vulnerable Populations
Skilled Nursing Facilities

- Early Alert: Reporting incidents of potential abuse or neglect
- Unnecessary Therapy
  - Reliant Care Group - $8.3 million
  - Catholic Health System Inc. - $6 million
- Substandard Care
  - Health Services Management - $5 million
Home Health

- Dr. Jacques Roy
  - 35 year prison sentence
  - $268 million restitution order
- Risk Alert: Reliance on unverified patient lists
- Focus on Geographic “Hot Spots”
- OIG Industry Outreach

Hospice

- Chemed / Vitas - $75 million
- Genesis Healthcare - $52 million
- Hospice Portfolio (Upcoming)
  - Summary of evaluations/audits/investigations
  - Recommendations for protecting beneficiaries and improving program
- Trends in Hospice Deficiencies and Complaints (Upcoming)
Personal Care Services

- MFCUs: Investigation and Prosecution of Fraud and Beneficiary Abuse in Medicaid Personal Care Services
  - 38% of MFCU indictments involve PCS providers or attendants
  - Some involve guardian collusion with PCS attendant
  - Serious risk of patient abuse

Care Provided Through Private Insurers

- Medicare Advantage – 18 million beneficiaries
  - Tripled since 2004
- Medicaid MCOs
  - Most Medicaid beneficiaries
- Medicare Part D
  - 44 million beneficiaries
Managed Care Provider Fraud

- Why do we care?
  - When fraud increases, quality decreases
  - Increased costs inflate future bids
  - Fraud often affects multiple payors
  - Strong government remedies

- Region 8 Mental Services - $7 million/CIA
  - Preschool day-treatment program – services not provided or unqualified providers

Medicaid Managed Care

- Requirement of Effective Compliance Program (42 CFR 438.608(a)(1))
  - Applies to Plans and Subcontractors
  - System and Dedicated Staff
  - Routine Monitoring and Auditing
  - Prompt Response to / Investigation of Compliance Issues
  - Correction and Cooperation
Managed Care Organizations

- Access to Providers, Network Adequacy, and Access to Services
- Encounter Data
- Risk Adjustment Data
- United HealthGroup, Inc. (litigation ongoing)

Current Developments

- Bipartisan Budget Act of 2018
- Investigative Resources
- Data Analytics
- Drug Pricing
- Health IT
- Industry Guidance / CIAs
- Administrative Enforcement
Bipartisan Budget Act of 2018

- AKS Exception for ACO Beneficiary Incentives
- Telehealth Technologies Exception to BI CMP
- Increased Fines / Penalties
  - AKS criminal penalty now 100K / 10 years prison
  - CMPs in 1128A of SSA increased (mostly doubled)
    - Sets new basis for annual inflation adjustments

---

Bipartisan Budget Act of 2018

- Implements an OIG audit recommendation
- Hospital discharges to hospice care will be post-acute care transfers and subject to pay adjustments
- CBO scored savings: $4.9 billion over 10 years
Identifying Risk Areas

- Data Analytics
- Hotline, Qui Tams, Tips
- Audits and Evaluations
- Investigations

Drug Pricing

- Mylan, Inc.
  - Misclassified Epipen as a generic drug for Medicaid rebate purposes
  - Settled FCA case for $465 million
  - CIA
Health IT

- Audit: $729M paid to providers that did not meet meaningful use requirements.
- eClinicalWorks and 3 senior executives paid $155 million in FCA settlement.
  - Software Issues
  - Did not comply with meaningful use standards
- Information Blocking CMP
New Models

- Fraud Waivers for CMS New Payment Models
  - Anti-Kickback Statute
  - CMP for Beneficiary Inducements
- Medicare Diabetes Prevention Program
  - Beneficiary Incentives
  - Streamlined Waiver
  - Effective April 1, 2018

Advisory Opinion 17-01

- Level I trauma center with rural/underserved patients to provide free lodging at modest hotel.
- First ad op on access to care/low risk of harm exception to BI CMP.
Advisory Opinion 17-03

• Pharmaceutical company to offer “spoilage policy” to replace sensitive drugs spoiled by environmental factors.
• Similar to warranty.

Advisory Opinion 17-09

• Neurosurgeons gainsharing arrangement for designated surgeries.
• First gainsharing ad op since statute amended.
Ad Op 06-04 Rescinded

- Patient Assistance Program
- Certified to independence from pharmaceutical company donors
- OIG determined PAP failed to comply with material certifications

Corporate Integrity Agreements

- United Therapeutics Corporation
  - CIA addresses donations to PAPs
- Freedom Health Inc. - MCO
  - Risk adjustment data
  - Provider network information
- Luitpold Pharmaceuticals (Daiichi Sankyo)
  - $1.2 million CMP for reported kickbacks
Goals of OIG Administrative Enforcement

- Use exclusion to protect patients
- Amplify OIG priorities/guidance
- Level the playing field
- Change industry behavior
- Hold individuals accountable

OIG Administrative Enforcement

- OIG Administrative Litigation Unit
  - Created 3 years ago
- Civil Money Penalties and Affirmative Exclusion
CMP Project Examples

- Ambulances
- Pelvic Floor Therapy
- Urine Drug Testing
- Blood Labs
- Millennium Physicians

AnMed EMTALA

- Allegations: Failure screen or stabilize psychiatric patients
- Hospital had psychiatrists on call and available psychiatric beds.
- 35 individuals were in the ED for up to 38 days.
- $1.25 million
- Largest EMTALA
60-Day Overpayment Rule

• Upon receiving credible evidence of an overpayment, must:
  – exercise reasonable diligence to investigate the potential overpayment
  – quantify overpayment over 6-year period
  – report and return any overpayments within 60-days of identification
    » Violations enforceable under FCA and CMP

60-Day Overpayment Rule

• OIG audits can trigger 60-day rule obligations
  – OIG recommends that providers look at potential similar overpayments outside of audit period.
  – Auditee is responsible to look at similar claims within 6-year lookback period.
Self-Disclosure Protocol

• Over 1200 matters for over $600 million
• Over $35 million in 2017
• Benefits
  – Faster Resolution
  – Less Disruption
  – Lower Payment
  – Exclusion Release