An Enforcement Update from USAO and OIG

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Overview

- USAO v. OIG
- OIG/DOJ Statistics
- Recent Significant Fraud Settlements
- Current Trends
- On the Horizon

USAO v. OIG

- FCA v. CMP
- Remedies
- Compliance
OIG Statistics FY 2014

- Criminal Actions: 971
- Civil Actions: 533
- Exclusions: 4,017
- HHS Investigative Rec.: $4.1 Billion

DOJ Statistics FY 2013

- HCF Recoveries: $2.3 Billion
- Criminal Investigations Opened: 1,013
- Civil Investigations Opened: 1,083
- Over 700 Qui Tams Filed

Recent Significant Fraud Settlements
Cases Involving Stark Issues

Halifax Tuomey

Medically Unnecessary Cardiac Procedures

King’s Daughters Medical Center (May 2014)
$40.9 million settlement
5 year CIA

Saint Joseph London (January 2014)
$16.9 million settlement
5 year CIA

Adventist Health Systems/West and St. Helena Hospital Napa Valley (January 2015)
$2.25 million settlement

Recent Affirmative CMP and Exclusion Cases

Calloway Laboratories, Inc.
$4.6 million; 5-year CIA

CVS Pharmacy, Inc.
$1.2 million
12 Kickback cases/one scheme
$2.5 million; exclusions

Daybreak Venture LLC
$350,000
Employment of Excluded Individual

- 45

False Claims Allegation

- 15

Stark/AKS

- 6

Total over $18 million

- Employment of Excluded Individual: $7M+
- False Claims Allegation: $8M+
- Stark/AKS: $2+M

Current Fraud Trends
Medicare Part A

- Smaller hospitals being purchased to create large health systems
- Health providers
  - Old trend of health systems getting rid of providers
  - Then health systems began to employ providers at a cheaper cost
  - Newest trending towards purchase and/or association with providers and provider groups
    - Increase in kickback and Stark violations

Medicare Part A

- Continued increase in medically unnecessary diagnostic laboratory and radiology
- Concern regarding medically unnecessary orthopedic surgery and invasive cardiology
- Trending towards costly and customized oncology treatment
- Continued increase in adverse events and patient harm
Skilled Nursing Facilities

- Upcoding through manipulation of RUGS classification
- Medically unnecessary therapy (PT and OT)
  - Can result in unnecessary and unwanted end-of-life care
- Diabetics Testing Strips, Mattress Pads, and other DME schemes
- High turn-over rate and concern regarding caregivers
- Theft of needed pain and other medications from patients
  - Few integrity safeguards
  - Counterfeit and expired drugs through secondary wholesalers
Hospice

- Early or false diagnosis of terminal illness
- Continuous care in alleged crisis situation
- Unqualified providers and facilities
- Patient or family involvement in the fraud scheme
- Lucrative medical director contracts/kickbacks

What’s New in Hospice

- Marketers touting “new” hospice benefit where you don’t have to be terminally ill
  - Usually homemaker services
- New trend involving hospice with fraudulent “burial benefits”
  - Fraudsters often own hospice and funeral home
  - Misrepresent associations with religious entities
- Adult daycare misrepresented as hospice
- Switching patients between SNF and hospice
- Hospice a problem in states where no certificate of need for licensing a new hospice

Quarterly Medicare $ for HHAs, 2006-2012
Home Health

- Criminal Enterprises
- High dollar for stolen identities
- Patient co-conspirators
- Abuse, neglect, and embezzlement
- Bust-out schemes
- Social targeting and medically unnecessary

Outcomes: HHA Payment Trends

Sustained declines in Medicare payments have followed Federal enforcement and oversight action.

- Medicare payments for Home Health care increased from 2006 until 2010
- In 2009, Federal enforcement actions (initiated by the HEAT Strike Force case U.S. v. Zambrana in Miami), followed by the OIG HHA Outlier Payments report, influenced CMS to change Medicare’s HHA outlier coverage policy.
- Since 2010, Medicare payments for home health care nationally decreased by more than $1 billion per quarter (e.g., more than $4 billion annually)
  - In Miami, payments for HHAs decreased by more than $100 million per quarter since 2009
  - In Dallas and McAllen, TX, payments for HHAs decreased by $30 million per quarter since 2009
  - In Detroit, payments for HHAs decreased by $25 million per quarter since 2009

Sustained declines in Medicare payments have followed Federal enforcement and oversight action.

Quarterly Medicare $ for Part B Services, 2006-2012

- billed
- paid
Medicare Part B

- Diagnostic radiology and lab testing
- Social targeting and patient absorbs cost
- Genetic testing
- Urine drug screens
- Dermatology
  - False cancerous growth diagnosis and unnecessary minor surgery
  - Misrepresentation of cosmetic procedures

Medicare Part B

- Podiatry
  - Custom orthotics that are off-the-shelf shoe inserts
- Mass visits at SNFs, ALFs, Senior Centers
- Chiropractic Services
  - Currently seeing DC kickback/referral schemes for diagnostic labs and radiology (MRIs) and ambulatory surgery centers
  - Therapeutic massage and Manipulation Under Anesthesia (MUA)

Medicare Part B

- Ophthalmology
  - Unnecessary optical coherence tomography (OCT) testing; retinal imaging, neuroimaging, and fundus photography
- Allergy testing
  - Unnecessary or useless food allergy & pediatric testing
  - Aggressive office setting screening resulting in immunotherapy
Medicare Part B

- Sleep studies & associated CPAP machines
  - Almost 40% increase in billing over last 5 years
  - Increase in hospital outpatient and free-standing facilities
  - Primarily medically unnecessary testing and false positive diagnoses to justify CPAP machines

Medicare Part B

- Transportation Fraud:
  - In connection with dialysis services, mental health services, and assisted living facilities
  - Kickbacks
  - CMHC – Houston (Oct 2014)
  - BLS to ALS upcoding
  - “Nearest facility”
  - Air Ambulance
  - Specialty transports

Medicare Part C

- Part C closely tracks Part B fraud
  - Biggest concern is data blind spot
  - Underutilization big concern, but sophisticated schemes seem to be the problem

- Risk adjustment fraud
  - Upcode diagnoses and scores for a higher capitation rate

- Non-participating provider schemes
  - Submission of cloned provider applications, adding a new office site

- Fraud migration (DME)
Part C – Enrollment Schemes

• Cherry Picking  
  • Selecting only the healthiest patients to increase profit margin

• Lemon Dropping  
  • Selectively disenrolling sickest and/or encouraging sickest to disenroll

Part D - Prescription Drug Diversion

• Shift from controlled substances to highly reimbursable non-controlled  
  • Concern regarding specialty and orphan drugs

• Increasing number of pharmacy cases, to include secondary wholesaler schemes

• Prescription drug addiction is an epidemic, and drives a diverse range of fraud

• Enforcement actions/proceedings coordination with DEA

Specialty/Orphan Drugs

• Solvaldi (Hepatitis C)  
  $1000 a pill

• Juxtapid (Cholesterol)  
  $300,000 a year

• Farxiga (Diabetes)  
  $4000 a year

• New psoriasis drug?

• OIG tracking top blockbuster drugs
Durable Medical Equipment (DME)

- Wheelchairs
- Custom Orthotics & Ortho Kits
- Adult Diapers
- Oxygen
- Mattresses
- Nutrition Supplies
- Prosthetics
- Diabetic Testing Strips

Dentistry

- Bundling/Unbundling
- AKS – targeting low income patients
- Medically unnecessary and unperformed services

On the Horizon......
Regulations Under Review

Proposed Revisions to OIG’s Exclusion Authorities (May 9, 2014)

• Expansion of waiver authority
• New affirmative exclusion authority
• Investigational inquiries
• Obstruction of an audit
• Failure to supply payment information
• Technical Changes

Regulations Under Review

Proposed Revisions to OIG’s CMP Rules (May 12, 2014)

New Authorities

• Failure to grant timely access to OIG
• Ordering or prescribing while excluded
• Making false statements, omissions, misrepresentations in an enrollment application
• Failure to return an overpayment
• Making or using a false record or statement that is material to a false or fraudulent claim
• Medicare Advantage and Part D plan sponsor misconduct.

Regulations Under Review

Proposed Rule (October 3, 2014)

• New safe harbors
• ACA’s revised definition of remuneration
• Gainsharing CMP provision
Questions