An Enforcement Update from USAO and OIG

Overview

OIG/DOJ Statistics
Current Trends and Examples of Recent Fraud Settlements
Areas of Increasing Government Focus

OIG Statistics FY 2016

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criminal Actions</td>
<td>765</td>
</tr>
<tr>
<td>Civil Actions</td>
<td>690</td>
</tr>
<tr>
<td>Exclusions</td>
<td>3,635</td>
</tr>
</tbody>
</table>
DOJ Statistics FY 2016

Healthcare Fraud Recoveries:
$2.5 Billion

More than 700 Qui Tams Filed

Hospitals

Kyphoplasty Cases (December 2015)
32 Hospitals in 15 states paid more than $28 million

ICD Cases (February 2016)
51 Hospitals in 15 states paid more than $23 million

Tenet (October 2016)

• $513 million to resolve civil and criminal claims
• Tenet subsidiaries, Atlanta Medical Center Inc., North Fulton Medical Center Inc., Spalding Regional Medical Center Inc. and Hilton Head Hospital, paid kickbacks to the owners and operators of prenatal care clinics serving primarily undocumented Hispanic women in return for the referral of those patients for labor and delivery medical services at Tenet hospitals
ML(2) switched order of notes to match slide
Meletta, Lisa-Beth (USATXN), 2/3/2017
Hospitals

The Estate of Dr. Kenneth Michael Rice and UMC Physicians (August 2016)
- $3.28 million settlement
- Improperly billing for "incident to" services in the Part A inpatient hospital setting

Skilled Nursing Facilities CY2015

OEI Report: The Medicare Payment system for Skilled Nursing Facilities Needs to be Reevaluated (OEI-02-13-00610, September 2015)
- Upcoding through manipulation of RUGS classification
- Switch schemes between programs and status (inp/outpt)
- Medically unnecessary therapy (PT, OT, and SLP)
  - Can result in unnecessary and unwanted end-of-life care
- Trending towards for-profit facilities
- High turn-over rate and concerns regarding caregivers
- Theft of needed pain and other medications from patients
Skilled Nursing Facilities

Rehabcare - $125 million settlement (January 2016)
- Presumptively placed patients in highest therapy reimbursement level
- Increased therapy during assessment reference periods only
- Shifted therapy among disciplines to ensure targeted reimbursement levels
- Provided high amounts of therapy at end of measurement period to reach minimum time threshold

Life Care Centers of America Inc. and its owner, Forrest L. Preston (October 2016)
- $145 million and CIA
- Billing for rehabilitation therapy services that were not reasonable, necessary, or skilled
- Upcoding to “Ultra High” RUGS rate

Daybreak Partners, LLC (October 2016)
- Paid $5.3 million and entered into a comprehensive Quality of Care CIA
- Allegations of “materially substandard” or “worthless” services
Hospice CY2015

Hospice Annual Average Paid Per Capita
(Part A-Enrolled FFS Beneficiaries) for CY 2015

National Average
Paid Per Capita: $387

Hospice OEI Report: Hospices Inappropriately Billed Medicare Over $250 Million for
General Inpatient Care (OEI-02-10-00491, March 2016)
OEI Report: Hospices Should Improve Their Election Statements and
Certifications of Terminal Illness (OEI-02-10-00492, September 2016)
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

Hospice

Community Health United Home Care, LLC (October 2015)
- $9.8 million settlement arising from a self-disclosure.
- Submitted false claims for hospice services without certifications of terminal illness.
Serenity Hospice and Palliative Care (October 2015)
- $2.2 million settlement.
- Allegations that Serenity submitted false claims to Medicare for hospice patients who were not
  eligible to be admitted.
- Serenity also entered a CIA. Founder and former president of Serenity agreed to five-year
  exclusion from federal health care programs.
OIG CMPL cases related to medically unnecessary GIP
Hospice

In September 2016, Kindred Health Care, Inc., paid a penalty of more than $3 million for failing to comply with a corporate integrity agreement. Failure to correct improper billing practices in the fourth year of the five-year agreement.

OIG made several unannounced site visits to Kindred facilities and found ongoing violations. Kindred was billing Medicare for hospice care for patients who were ineligible for hospice services or who were not eligible for the highest level and most highly paid category of service. As a result of the findings of OIG-required audits of its claims, Kindred decided to close 18 sites that it characterized as "underperforming" since March 2015.

What’s New in Hospice

Marketers touting “new” hospice benefit where you don’t have to be terminally ill (some patient co-conspirators)
- Usually housekeeping and homemaker services
- Door-to-door solicitation by sham religious entities
- Convincing brochures
- Adult daycare misrepresented as hospice
- Increasing whistleblower cases

Home Health CY2015

[Map showing Home Health CY2015 data]
Home Health
- Criminal Enterprises
- High dollar for stolen identities
- Patient co-conspirators
- Abuse, neglect, and embezzlement
- Bust-out schemes
- Social targeting and medically unnecessary

Home Health
Home Bound Healthcare Inc. (September 2016)
- Paid $6.8 million in civil settlement and entered into a 5 year CIA
- Owner admitted to paying kickbacks
- Improperly paying physicians via sham medical director agreements in violation of the Anti-Kickback Statute

Decatur County Memorial Hospital Home Health Care (March 2016)
- Self-disclosed documentation issues with home health services billed
- Paid $3.7 million to resolve liability

Ground Ambulance CY2015
- Ground Ambulance Annual Average Paid Per Capita
  (Part B-Enrolled FFS Beneficiary) for CY 2015
Ambulance

In connection with dialysis services, mental health services, and assisted living facilities
  • Kickbacks between patients and drivers
  • BLS to ALS upcoding
  • “Nearest facility”
  • Air Ambulance
  • Specialty transports

Regent Management Services (November 2015)
  • Paid $2.7 million and entered into a 5 year CIA
  • Skilled nursing facility company based in Galveston, Texas
  • Alleged impermissible “swapping” in violation of the Anti-Kickback Statute
  • First in the nation to hold accountable the medical institution as opposed to the ambulance in this kind of “swapping” arrangement

OIG FY 2016 statistics
  • Sixteen affirmative OIG Civil Monetary Penalty cases related to ambulance companies referred from OIG’s Consolidated Data Analysis Center (CDAC)
  • Total recovery: $2.9 million
  • Settlements with providers for emergency trips to inappropriate destinations
  • Example: July 2016 settlement between OIG and Courtesy Transport Services, LLC, of Northeast Florida for $362,188
Laboratories

Millennium Health - $256 million settlement (October 2015)
- Millennium billed for unnecessary urine drug tests and genetic tests, including
  for unnecessary confirmation tests on samples that produced normal results
- Free testing cups in exchange for referrals

Elite Labs - $3.75 million settlement (December 2016)
- Billed Medicare for tens of thousands of miles that were never driven by
  Elite Lab's personnel
- Exclusion agreements for Elite Lab Services, LLC (8 years), Gerard C. Dengler
  (10 years), and Suzanne Dengler (8 years)

Laboratories

OIG Advisory Opinion 15-04
- Laboratory proposed entering exclusive arrangements with physician practices
- Under these arrangements, laboratory would provide free services to patients
  whose insurance companies would not pay for services from this laboratory
- OIG found risk of AKS liability and potential for use of permissive exclusion
  authority

Genetic Testing

Now at health fairs, church socials, and farmer's markets
- Cheek swabs at the mall
- Social engineering
- Drug sensitivity testing
- Multiple unnecessary tests
- Physician-owned laboratories
Genetic Testing

G0452 Cases
- Nearly $900,000 in settlements with 24 physicians/physician practices and 1 lab
- Cases predicated on OIG CDAC data
- Ongoing

Pathway Genomics Corporation (December 2015)
- Settlement for $4 million
- Allegations of paying remuneration to physicians in exchange for referrals

Medicare Part C

Part C closely tracks Part B fraud
- Beneficiaries enrolled without knowledge
- Increase in Part C qui tams
- Risk adjustment fraud- January 2017 OIG Alert

Part D CY2015

Part D Annual Average Paid Per Capita
(Part D-Enrolled Beneficiaries) for CY 2015

National Average Paid Per Capita: $3,270
Prescription Drug Trends

- Shift from controlled drugs to highly reimbursed non-controlled
- Concern regarding specialty and orphan drugs
- Hepatitis C drugs
- Diabetic drugs pushed for weight loss
- Potentiators (anti-psychs, HIV meds, neurologics)

Pharmacy Fraud

- Phantom pharmacy has morphed to "hybrid" pharmacies (legit & illegit business)
- Audits/enforcement created a cottage industry for false invoices
- 2015 HHS-OIG Part D Portfolio and updated Data Brief
- Gray & black market driving fraud
- Significant international demand
- Increase in "mom and pop" independent pharmacies

Durable Medical Equipment (DME)

- Wheelchairs
- Custom Orthotics & Ortho Kits
- Adult Diapers
- Oxygen
- Mattresses
- Nutrition Supplies
- Prosthetics
- Diabetic Testing Strips
What’s New in DME

- Power wheelchair repairs
  - Given poor quality loaners and rentals and original never returned
  - Repairs aren’t done
  - Hidden fees such as mileage

Medicaid Trends

- Enrollment schemes with underreported income
- Daycare, aftercare, summer camp, big brother/sister programs, VBS billed as behavioral health programs
- Medicaid sober homes targeting teens

Medicaid

- MB2 Dental Solutions (January 2017)
  - Paid $8.45 million and entered into a CIA
  - Upcoding
  - Payment of kickbacks to beneficiaries and marketing firms
Individual Accountability

DOJ
• Yates Memo

OIG
• Affirmative exclusion and CMP cases
• Referrals from DOJ criminal and civil cases

Individual Liability

Ralph J. Cox III (September 2016)
• Former CEO of Tuomey Healthcare System
• $1 million settlement and four-year exclusion
• Exclusion extends to management or administrative services paid for by federal health care programs

Individual Liability

Susan Toy (September 2016)
• Owner and operator of Millennium Billing
• Submitted claims for diagnostic tests not performed by New Jersey OB/GYN practice
• $100,000 civil money penalty and five-year exclusion
Data Analytics

Data analytics play a significant role in OIG's oversight and enforcement strategy
- Effective allocation of resources
- Case type prioritization
- Investigative efficiency
- Measurable impact

OIG Revised Exclusion Criteria

Issued April 18, 2016 (Criteria for Implementing Section 1128(b)(7) Exclusion Authority, available at – http://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf)

Replaced criteria issued in 1997

Increases OIG's expectations for providers to implement robust compliance programs, promptly respond to government investigations, and self-disclose fraud

Begins with presumption that exclusion should be imposed

Provides a compliance "risk spectrum" from low to high risk based on: (1) nature and circumstances of conduct; (2) conduct during government investigation; (3) significant ameliorative efforts; and (4) history of compliance

Highest risk will result in exclusion; below highest risk, OIG may choose to impose heightened scrutiny or no further action

Risk Spectrum

Highest Risk
Exclusion

Heightened Scrutiny

Integrity Obligations

No Further Action

Release (Self-Disclosure)

Lowest Risk
OIG Affirmative Litigation

- Use exclusion remedy to protect patients
- Complement the work of the components
- Support OIG guidance and level the playing field
- Change industry behavior
- Hold individuals accountable

OIG CMP Recoveries

<table>
<thead>
<tr>
<th>Year</th>
<th>Employment of Excluded Individual</th>
<th>False Claims</th>
<th>Stark/Kickback</th>
<th>Drug Price Reporting</th>
<th>Overcharging</th>
<th>Failure to Return Overpayments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2012</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2013</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2014</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2015</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2016</td>
<td>$0.00</td>
<td>$10,000,000</td>
<td>$20,000,000</td>
<td>$30,000,000</td>
<td>$40,000,000</td>
<td>$50,000,000</td>
</tr>
</tbody>
</table>

OIG Self-Disclosures Average Time in Protocol

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>19</td>
<td>16</td>
<td>13</td>
<td>10</td>
<td>10</td>
<td>9.25</td>
<td>9.09</td>
<td>7.78</td>
<td>8.34</td>
</tr>
</tbody>
</table>
Questions?