HCCA Kansas City Regional Conference

Chair Update – Year in Review

Agenda

1. Noteworthy Settlements and Trends
2. By the Numbers – FCA Settlements
3. Office of Inspector General Activity
4. Competing Compliance Guidance – DOJ vs. OIG
NOTEWORTHY SETTLEMENTS AND ENFORCEMENT TRENDS

Recent Settlements

- Mercy Hospital - $34 mil
- Pacific Alliance Medical Center - $42 mil
- eClinical Works - $155 mil
- Hartford Dispensary (Opioid) - $627,000
Settlement Trend: Individual Participation

- **Freedom Health (MCO)** paid $32M (alleged Medicare Advantage fraud)
  - Former COO paid $750,000
- **eClinicalWorks** paid $155M (alleged AKS, meaningful use noncompliance)
  - CEO, CMO, COO jointly liable for full amount
  - Developer and 2 project managers paid $80,000
- **Family Medicine Centers** paid $1.56M (alleged unnecessary lab tests and upcoding)
  - Former CEO and largest shareholder paid $443,000
- **Ortho Specialist of Jacksonville** paid $4.5M
  - Former COO paid additional $100,000

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Settlement Trend: Individual Participation

- **Cypress Pharmaceutical and CEO Max Draughn** paid $2.8M
  - Alleged promotion of misbranded drug (manuf.)
- **Hartford Dispensary and top executive Paul McLaughlin** paid $627,000
  - Alleged medical direction noncompliance (addiction treatment nonprofit)
- **Regional Health System, former COO and 6 radiologists** paid $1.6M
  - Inadequate supervision alleged (hospital)
Settlement Trend: Individual Participation

- Integrated Medical Solutions and former President Jerry Heftler paid $2.475M
  - Alleged kickbacks (prison healthcare)
- Sightpath Medical and former CEO James Tiffany paid $12M
  - Alleged kickbacks (medical device)
- Health Concepts and COO John Gage paid $2.2M
  - Unnecessary therapy in a SNF alleged (LTC provider)
- Virginia's Fredericksburg Hospitalist Group and 14 of its shareholders paid $4.2 million
  - Upcoded E&M services alleged (physician practice)

Settlement Trend: Individual Participation

- Bostwick Lab owner pays $3.75M to settle FCA suit (company paid $6.5M)
- No. American Health (board chair to pay $1M of $28.5M settlement)
- Former CEO & Board Chair of Tuomey excluded and fined $1M
- Theranos CEO banned from owning a lab under CLIA
- Boehner v. Burwell, court upheld exclusion of a pharma executive
- Dec. 2016: Forest Park Hosp. - 21 people indicted related to payments from private pay hospital
- Feb. 2017: former CEO of a HCA hospital in Atlanta indicted (alleged AKS violations)
Settlement Trend: Individual Participation

- Trend crosses all:
  - Types of providers, individuals and positions
  - Types of alleged misconduct
  - Settlement ranges (dollar amounts)
- Unclear if trend will continue
  - April 2017: AG Sessions affirmed concept of “holding individuals accountable for corporate misconduct”
  - Sept. 2017: Deputy AG Rosenstien states that the Yates Memo is “under review” and there may be changes “in the near future”

Average of FCA Settlements by Type

Average of FCA settlements from 2014-2016 (in millions)

- Pharmaceuticals
- Hospitals and Health Systems
- Medical Devices
- Post-Acute
- Diagnostic Services
- DME

Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report
### Hospitals and Health Systems

<table>
<thead>
<tr>
<th>Type of Behavior</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tr>
<td>AKS &amp; Stark</td>
<td>$8.5M</td>
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<td>-</td>
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<td>AKS, Stark, &amp; medically unnecessary services</td>
<td>$16.5M</td>
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<tr>
<td>Billing for services in violation of coverage requirements</td>
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<td>$23M</td>
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<td>False cost reports</td>
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<td>$12.9M</td>
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<td>Improper donations to government for Medicaid</td>
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<td>$75M</td>
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<td>Medically unnecessary services</td>
<td>$36.7M</td>
<td>$20M</td>
<td>$27.6M</td>
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<td>Stark</td>
<td>$85M</td>
<td>$216.2M</td>
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<td>Stark &amp; medically unnecessary services</td>
<td>$40.9M</td>
<td>$35M</td>
<td>-</td>
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<tr>
<td>Stark &amp; upcoding</td>
<td>$98.2M</td>
<td>$48M</td>
<td>-</td>
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<tr>
<td>Upcoding</td>
<td>$35M</td>
<td>$48M</td>
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<td><strong>Total</strong></td>
<td><strong>$320.8M</strong></td>
<td><strong>$455.1M</strong></td>
<td><strong>$50.6M</strong></td>
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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

### Post-Acute Care

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<tr>
<td>AKS</td>
<td>-</td>
<td>$17M</td>
<td>$1.8M</td>
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<tr>
<td>Billing for services by an excluded provider</td>
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<td>$6.5M</td>
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<td>Billing for services w/o appropriate certification</td>
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<td>$5.6M</td>
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<td>Deficient services</td>
<td>$750K</td>
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<tr>
<td>Medically unnecessary services</td>
<td>$3.9M</td>
<td>$20M</td>
<td>$173M</td>
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<td>Medically unnecessary services &amp; upcoding</td>
<td>$25M</td>
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<td>Medically unnecessary and deficient services &amp; upcoding</td>
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<td>$38M</td>
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<tr>
<td>Stark &amp; medically unnecessary services</td>
<td>$150M</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Upcoding</td>
<td>-</td>
<td>$10M</td>
<td>-</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$179.7M</strong></td>
<td><strong>$101.8M</strong></td>
<td><strong>$174.8M</strong></td>
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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report
RECENT ACTIVITY AND DEVELOPMENTS

OIG monthly Work Plan
- Data mining and targeted audits
- Audits include: 1. Medicare payments to hospital outpatient providers for non-physician outpatient services; and 2. Part B payments for ambulance services subject to Part A SNFs;
- OIG will audit electronic medical record incentive payments for compliance with meaningful use requirements
- OIG will audit home health agency providers
  - Medicare Compliance Reviews – BEWARE
    • Process
    • Transparency
    • Reports
    • Appeals
Update to Beneficiary Inducement Provisions under the Civil Monetary Penalties Law:

- CMP prohibits offering remuneration to beneficiaries that is likely to influence selection
- ACA added an exception to permit remuneration that “poses a low risk of harm and promotes access to care

Access to Care:

- Improving a particular beneficiary, or beneficiaries, ability to obtain items and services payable under Medicare or Medicaid
  - Focuses on removing socio-economic, educational, geographic, or other barriers that could prevent patients from seeking care
  - Examples include:
    - Free child care to individuals attending smoking cessation program
- Low Risk of Harm defined:
  - unlikely to interfere with, or skew, clinical decision-making;
  - Not increasing costs to federal health care programs through overutilization;
  - Not raising patient safety concerns
OIG-HHS

- **Updates to Exclusion Authorities**
  - Expands permissive exclusion authority to individuals or entities that 1. obstruct audits; 2. furnish items or services, including those that refer for furnishing or certify the need for services, who fail to provide payment information; and 3. submit false statements or misrepresent *material* facts in enrollment applications.

- **Issues OIG Alert on patient abuses in SNFs**
DOJ’s “Evaluation of Corporate Compliance Programs”

- **Published on Feb. 8, 2017**
  - Offers 11 key subject areas DOJ may consider when conducting investigation
  - DOJ makes clear that off the shelf compliance programs are not helpful
  - DOJ’s document includes many open ended questions and doesn’t explain how responses to these questions will be weighed by DOJ

OIG/HCCA Guide

- **Published on March 27, 2017**
  - More prescriptive
  - Contains more than 400 compliance metrics
  - OIG/HCCA clearly don’t intend this to be a one size fits all approach
  - Focuses on the 7 elements
Predictions for 2017

- Aggressive administrative actions (revocation, suspension, exclusions, non-enrollment)
- Appellate courts weigh in on the FCA's materiality standard, but no consistency or clarity
- No decrease in focus on long term care, hospice and home health, AKS and financial relationships
- Government commences / continues dragnet targeting opioid and controlled substances prescriptions
- Enforcement and rhetoric by DOJ and OIG about pursuing individuals (more “exemplar” cases, more exclusion cases)

Questions or Comments?

Brian Bewley
Shareholder | Polsinelli PC
bbewley@polsinelli.com