HCCA Kansas City Regional Conference
Chair Update – Year in Review

Brian Bewley
Polsinelli PC
bbewley@polsinelli.com

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
- eClinical Works 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

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 Rosenstein 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)](chart)

<table>
<thead>
<tr>
<th>Type of Behavior</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hospitals and Health Systems</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Post-Acute Care</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Diagnostic Services</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>DME</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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>
</tr>
</thead>
<tbody>
<tr>
<td>AKS &amp; Stark</td>
<td>$8.5M</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>AKS, Stark, &amp; medically unnecessary services</td>
<td>$16.5M</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Billing for services in violation of coverage requirements</td>
<td>-</td>
<td>-</td>
<td>$12M</td>
</tr>
<tr>
<td>False cost reports</td>
<td>-</td>
<td>$13.9M</td>
<td>-</td>
</tr>
<tr>
<td>Improper donations to government for Medicaid</td>
<td>-</td>
<td>$75.6M</td>
<td>-</td>
</tr>
<tr>
<td>Medically unnecessary services</td>
<td>$14.7M</td>
<td>$45M</td>
<td>$27.6M</td>
</tr>
<tr>
<td>Stark</td>
<td>$85M</td>
<td>$216.2M</td>
<td>-</td>
</tr>
<tr>
<td>Stark &amp; medically unnecessary services</td>
<td>$40.9M</td>
<td>$35M</td>
<td>-</td>
</tr>
<tr>
<td>Stark &amp; upcoding</td>
<td>$98.2M</td>
<td>$48M</td>
<td>-</td>
</tr>
<tr>
<td>Upcoding</td>
<td>$35M</td>
<td>$48M</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$320.8M</td>
<td>$455.1M</td>
<td>$50.6M</td>
</tr>
</tbody>
</table>

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

### Post-Acute Care

<table>
<thead>
<tr>
<th>Type of Behavior</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>AKS</td>
<td>-</td>
<td>$17M</td>
<td>$1.8M</td>
</tr>
<tr>
<td>Billing for services by an excluded provider</td>
<td>-</td>
<td>$6.5M</td>
<td>-</td>
</tr>
<tr>
<td>Billing for services w/o appropriate certification</td>
<td>-</td>
<td>$5.6M</td>
<td>-</td>
</tr>
<tr>
<td>Deficient services</td>
<td>$750K</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Medically unnecessary services</td>
<td>$1.9M</td>
<td>$12M</td>
<td>$17.9M</td>
</tr>
<tr>
<td>Medically unnecessary services &amp; upcoding</td>
<td>$25M</td>
<td>$4.7M</td>
<td>-</td>
</tr>
<tr>
<td>Medically unnecessary and deficient services &amp; upcoding</td>
<td>-</td>
<td>$38M</td>
<td>-</td>
</tr>
<tr>
<td>Stark</td>
<td>-</td>
<td>$150M</td>
<td>-</td>
</tr>
<tr>
<td>Stake &amp; medically unnecessary services</td>
<td>$110M</td>
<td>$48M</td>
<td>-</td>
</tr>
<tr>
<td>Upcoding</td>
<td>$10M</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$179.7M</td>
<td>$101.8M</td>
<td>$174.8M</td>
</tr>
</tbody>
</table>

Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report
RECENT ACTIVITY AND DEVELOPMENTS

The Office of Inspector General

OIG-HHS

- 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 SNF
- OIG will audit electronic medical record incentive payments for compliance with meaningful use requirements
- OIG will audit home health agency providers
- Medicare Compliance Reviews - RERARE
  - Process
  - Transparency
  - Reports
  - Appeals

OIG-HHS

- 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