



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

3

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

5

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)

6

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)

7

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
- *Bohner 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)

8

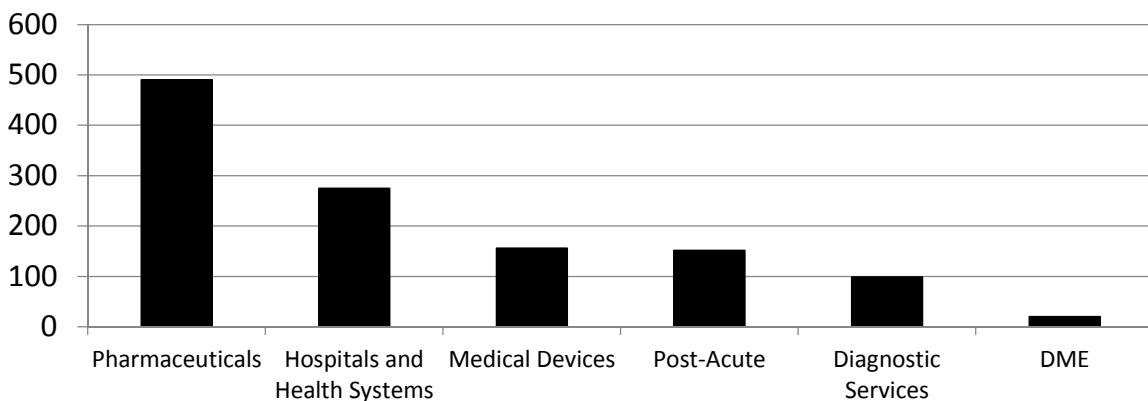
Settlement Trend: Individual Participation

- 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”

9

Average of FCA Settlements by Type

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



10

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

Hospitals and Health Systems

Type of Behavior	2014	2015	2016
AKS & Stark	\$8.5M	-	-
AKS, Stark, & medically unnecessary services	\$16.5M	-	-
Billing for services in violation of coverage requirements	-	-	\$23M
False cost reports	-	\$12.9M	-
Improper donations to government for Medicaid	-	\$75M	-
Medically unnecessary services	\$36.7M	\$20M	\$27.6M
Stark	\$85M	\$216.2M	-
Stark & medically unnecessary services	\$40.9M	\$35M	-
Stark & upcoding	\$98.2M	\$48M	-
Upcoding	\$35M	\$48M	-
Total	\$320.8M	\$455.1M	\$50.6M

11

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

Post-Acute Care

Type of Behavior	2014	2015	2016
AKS	-	\$17M	\$1.8M
Billing for services by an excluded provider	-	\$6.5M	-
Billing for services w/o appropriate certification	-	\$5.6M	-
Deficient services	\$750K	-	-
Medically unnecessary services	\$3.9M	\$20M	\$173M
Medically unnecessary services & upcoding	\$25M	\$4.7M	-
Medically unnecessary and deficient services & upcoding	-	\$38M	-
Stark & medically unnecessary services	\$150M	-	-
Upcoding	-	\$10M	-
Total	\$179.7M	\$101.8M	\$174.8M


12

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



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The Office of Inspector General
RECENT ACTIVITY AND DEVELOPMENTS



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 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

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**

The logo for the law firm Polsinelli, featuring a stylized square icon to the left of the word "POLSINELLI" in a sans-serif font.

Competing Compliance Guidance

OIG VS. DOJ

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 the 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)

21

Questions or Comments?



Brian Bewley

Shareholder | Polsinelli PC

bbewley@polsinelli.com