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

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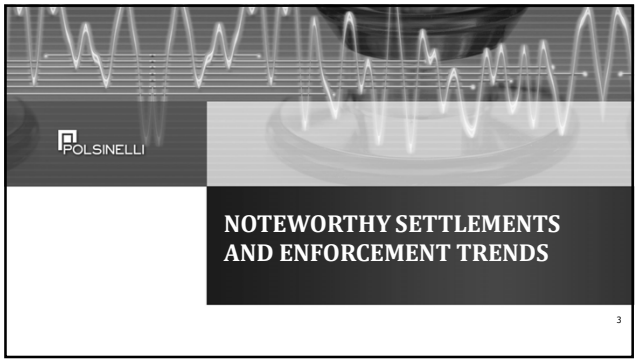

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Recent Settlements

- 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)

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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)

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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)

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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"

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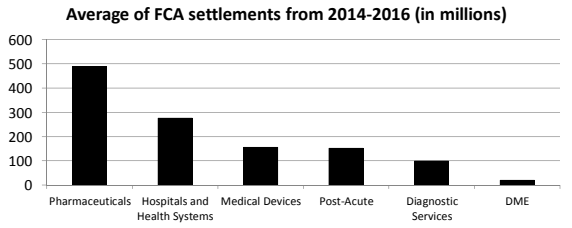
Average of FCA Settlements by Type



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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**

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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**

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

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

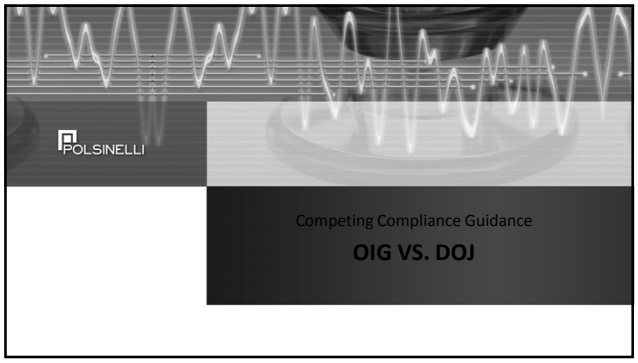
- Update to Beneficiary Inducement Provisions under the Civil Monetary Penalties Law:
- CMP prohibits offering remuneration to beneficiaries that is likely to influence selection
- ACA added an exception to permit remuneration that "poses a low risk of harm and promotes access to care

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 provided 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 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)

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Questions or Comments?

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