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HCCA Compliance Institute 2017 — Session 411

The Business Of Health Care Fraud Enforcement: A Pragmatic Discussion And Assessment

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Agenda

- Noteworthy settlements, cases and the resulting enforcement trends
- Insights from financial statistics and governmental data
- "What it all means" - discussion of the trends and implications

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NOTEWORTHY SETTLEMENTS, CASES AND THE RESULTING ENFORCEMENT TRENDS

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Settlement Trends

- **Pharma cases**
  - Daiichi Sanko ($39M - honoraria and meals)
  - Pfizer ($785M - alleged drug pricing)
  - Genentech ($67M - effectiveness misrepresentations)
  - Valeant ($54M free dinners and sham speaker payments)
  - Biocomparables ($36M - off label marketing)
  - Forest Laboratories ($38M - off label marketing)
  - Warner Chilcott $125M (cash payments , expensive dinners)
  - Daiichi Sanko $39M (honoraria and meals)

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Settlement Trends

- **Large AKS-based settlements (non-pharma)**
  - DaVita $389M (AKS allegations related to JVs)
  - Amedisys $150M (home health medical necessity and AKS)
  - OmniCare $124M (pharmacy and AKS w/NFs)
  - Millennium Health $256M (free specimen testing cups)
  - Health Diagnostics Lab $48.5M (free S&H, waiver of co-pay)
  - Olympus ($646M – marketing & other inducements)
  - Respironics ($35M – free call center support)
  - Tenet Health ($513M – payments to pre-natal clinics)

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Settlement Trends

- **Medical Necessity—Hospitals**
  - Premier Vein ($400K, unlicensed staff)
  - St. Joseph ($16.5M, heart surgery)
  - Health Man. Assoc. ($1M, sinus endoscopy)
  - Baptist Health ($2.5M, MS and brain disorders)
  - King's Daughter Medical ($41M, cardiac stents)

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Settlement Trends

- **Medical necessity—Long Term Care**
  - Kindred ($125M)
  - Life Care Centers ($145M)
  - No. American Health ($28.5)
  - Westlake Convalescent ($3.5M)

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Settlement Trends

- **Medical Necessity—Hospice**
  - Covenant Hospice $10.1M (also billing issues)
  - Compassionate Care Hospice Group $6M (failure to treat based on POC)
  - Good Shepherd Hospice $4M
  - Guardian Hospice of Georgia LLC $3M
  - Hospice of Citrus County $3.2M
  - Serenity Hospice and Palliative Care $2.2M (also AKS violations)

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Settlement Trends

- **Physician Employment (Stark and AKS)**
  - St. Mary ($2.3M, admin of comp terms)
  - All Children's Florida ($7M, FMV)
  - New York Heart ($1.3M, comp based on referral volume)
  - Halifax Hospital ($85M, bonus calculation)
  - Westchester Med Center $18.8M (advanced money, forgave debt)
  - Citizens Medical Center ($21.7M non-FMV)
  - Columbus Regional ($34M non-FMV)
  - Adventist Health System ($115M non-FMV and bonus calc)
  - North Broward Hospital ($69.5M non-FMV)
  - Lexington Medical Center ($17M –FMV)
  - Memorial University ($10M – FMV and practice losses)

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Settlement Trends

- **Pharmacy and prescription opioid**
  - CVS ($3.5M, 500 forged opioid prescriptions)
  - Cardinal Health ($44M, failure to report suspicious opioid orders)
  - Costco ($11.75M, inadequate opioid prescription process)
  - McKessen Corp. ($150M, failure to report suspicious opioid orders)

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Settlement Trends

- **National investigations**
  - Kyphoplasty investigation: 130 hospitals totaling approximately $105M
  - ICD investigation: 457 hospitals totaling $250M
  - Inpatient vs. Outpatient (one-day LOS)
    - CHS: $98M (7 *qui tams*)

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Court Decision Trends

- **General increase in Court of Appeals decisions**
  - 63 appellate decisions during the last year
  - Hard to see a trend in appellate rulings
  - Pleading standards and application of Rule 9(b) loomed large

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Court Decision Trends

- **Only *material* non-compliance creates FCA liability**
  - *Universal Health Services Inc. v. U.S. ex rel Escobar* (6/16/2016, unanimous Supreme Court)
  - Defendant can face FCA liability under an implied certification theory where failure to disclose *noncompliance* with statutory, regulatory, or contractual requirements *is material* to government's decision to pay the claim
  - Little guidance on what "material" mean

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Court Decision Trends

- **Allegations of fraud and noncompliance must be alleged with particularity (Rule 9(b))**
  - *U.S. ex rel. Eberhard v. Physicians Choice Lab. Servs.,* 6th Cir., dismissed claims where relator failed to include "representative examples" or plead the submission of false claims
  - *U.S. ex rel. Kelly v. Novartis Pharm*, 1st Cir., affirmed dismissal because relators did not plead particular allegations about specific fraudulent claims for payment
  - *U.S. ex rel. Chase v. LifePath Hospice,* dismissed claims because relator failed to identify which Medicare claims were fraudulent

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Court Decision Trends

- **Courts: no FCA Liability for reasonable interpretation of ambiguous regulation**
  - *U.S. ex rel. Saldivar v. Fresenius*, 11th Cir (drug overfill billing)
  - *U.S. ex rel. Olson v. Fairview Health Servs. of Minn*, 8th Cir., (definition of "children's hospital" was ambiguous)
  - *U.S. ex rel Donegan v. Anesthesia Assocs. of Kan. City*, 8th Cir., (definition of "emergence" from anesthesia was ambiguous and group's interpretation was not unreasonable)
  - *U.S. ex rel. Wall v. Vista Hospice Care* (differing opinion on hospice eligibility insufficient to create FCA liability)

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Enforcement Trends

- **Focus on individual is increasing**
  - 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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INSIGHTS FROM FINANCIAL STATISTICS AND GOVERNMENTAL DATA

No One Part of Industry is Immune

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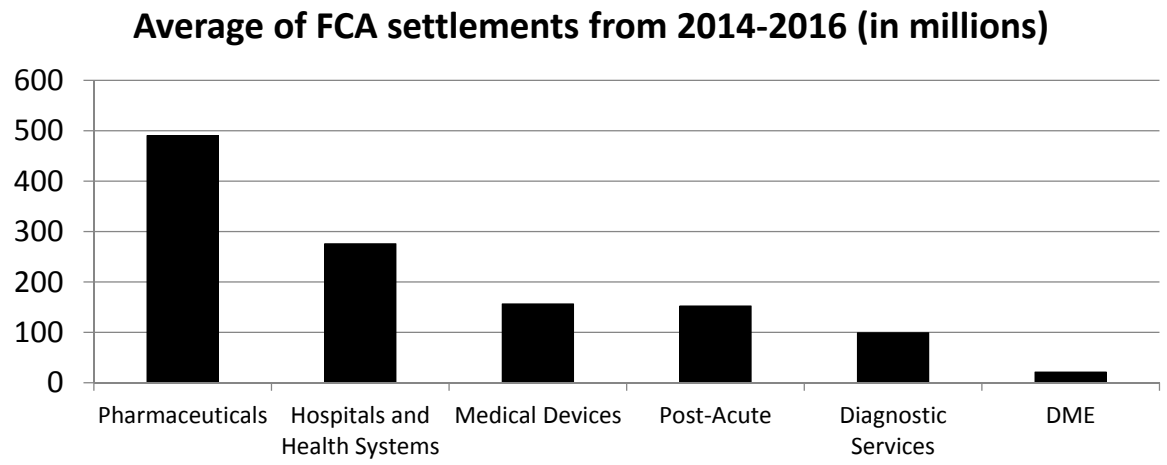
Average of FCA Settlements by Industry



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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

Pharmaceutical

Type of Behavior	2014	2015	2016
AKS	$128.2M	$460.7M	$46.5M
Beneficiary inducement	$6.3M	-	-
Billing for controlled substances w/o valid prescription	-	$31.5M	-
Failure to meet quality standards	$18M	-	-
Failure to reimburse Medicaid for drug costs	$6M	-	-
Marketing of prescription for non-FDA approved use	-	$171.9M	-
Medically unnecessary prescriptions by non-treating physicians	-	$8.4M	-
Misleading statements to market and sell medication	$63.8M	-	$62.6M
Underpayment of rebates	-	$54M	$413M
Total	**$222.3M**	**$726.5M**	**$522.1M**

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

Medical Device

Type of Behavior	2014	2015	2016
AKS	$9.98M	$2.6M	$318.8M
AKS & promotion of device for non-FDA approved use	$40.1M	$13.5M	-
Distribution of adulterated medical devices	$41.2M	-	-
Marketing and distribution of device for non-approved use	-	-	$18M
Medically unnecessary devices or supplies	-	-	-
Selling devices to government that were manufactured outside of the US	-	$12.7M	-
Unbundling	-	$10.3M	-
Upcoding	-	$1.3M	-
Total	**$91.28M**	**$40.4M**	**$336.8M**

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

Durable Medical Equipment

Type of Behavior	2014	2015	2016
AKS	-	-	$54.8M
Falsified medical documentation	-	$7.5M	-
Total	**-**	**$7.5M**	**$54.8M**

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

Diagnostic Services

Type of Behavior	2014	2015	2016
AKS & medically unnecessary services	$15.5M	$254.1M	$3.7M
Billing for services referred by non-physicians	-	$2.9M	-
Falsified medical documentation	-	$5.7M	-
Medically unnecessary services	-	$15M	-
Total	**$15.5M**	**$277.7M**	**$3.7M**

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

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"WHAT IT ALL MEANS"

DISCUSSION OF THE TRENDS AND IMPLICATIONS

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A Recent History. . .

HCFAC Data

2009 to 2016	**>$17.9 bil.**
2016	$3.3 bil
2015	$1.9 bil
2014	$2.3 bil

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A Recent History. . .

Whistleblowers Driving Enforcement

FY	NEW MATTERS 1		SETTLEMENTS AND JUDGMENTS 2				
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL	
2008	161	379	312,193,480	1,042,582,229	12,678,936	1,055,261,165	1,367,454,645
2009	132	433	469,334,681	1,959,856,256	33,776,480	1,993,632,735	2,462,967,417
2010	140	576	647,383,493	2,280,378,123	108,890,899	2,389,269,023	3,036,652,516
2011	125	635	241,365,995	2,648,195,115	173,888,703	2,822,083,818	3,063,449,813
2012	144	652	1,608,112,862	3,342,216,074	44,973,343	3,387,189,418	4,995,302,280
2013	101	755	169,126,772	2,838,439,485	127,348,056	2,965,787,541	3,134,914,313
2014	97	715	1,676,564,226	4,371,182,653	81,378,451	4,452,561,104	6,129,125,330
2015	110	639	731,342,286	1,879,431,785	1,174,568,601	3,054,000,386	3,785,342,672
2016	143	702	1,856,329,432	2,800,043,469	104,984,935	2,905,028,403	4,761,357,835
TOTAL	4,883	11,304	15,347,423,655	35,394,820,358	2,290,532,213	37,685,352,572	53,032,776,227

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What's Driving the Enforcement Environment?

- Solvency of Medicare and Medicaid Programs
- "Pay and Chase"
- High ROI to government spend
- Whistleblowers
  - Relator monetary rewards and attorney fees
  - Growth area for plaintiffs' bar

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What's Driving the Enforcement Environment?

- Dedicated enforcement resources
  - Health Care Fraud and Abuse Control Account
  - ACA included more than $350M in dedicated enforcement funding (over 10 years)
- Public and political pressure
  - Prescription opioid enforcement
  - Mylan Epi-pen ($465M Medicaid settlement)

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What's Driving the Enforcement Environment?

- Lack of other distractions (or government priorities)
- Complex regulatory environment
  - Coding systems tend to fail at the edges
  - High levels of regulatory change
- Competitive business pressures

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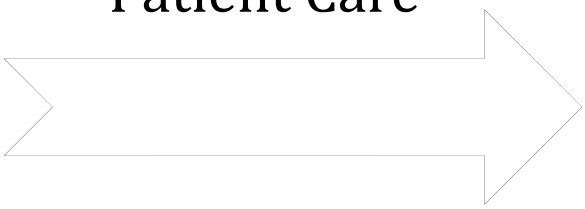
Impact on Health Care Industry

Resources for Patient Care



- Robust Compliance Program
  - Internal Audit
  - Training and Education
  - Management and Board Oversight
- Defending Investigations – even those w/out merit
  - DOJ must investigate all qui tams
  - Companies must cooperate

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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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