

**2013 UC Compliance and Audit Symposium**  
**Health Care Compliance: Government Views**

San Francisco, January 29, 2013      Costa Mesa, February 12, 2013

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**Health Care Compliance: Government Views**

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**Agenda**

- Statistics
- Legislation and Policy Developments
- Stark Self-Disclosure Settlements
- Patient Safety
- Supreme Court Decisions
- Noteworthy Settlements
- FCA Developments
- Health Care Compliance: Enforcement and Audit Trends



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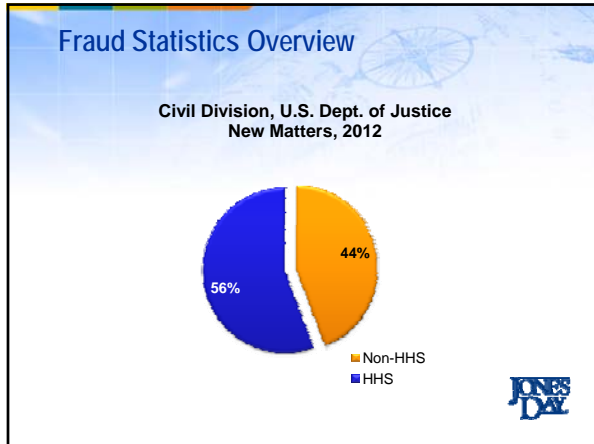
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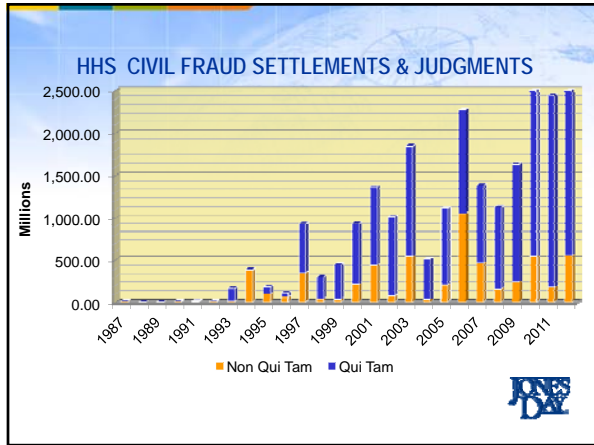
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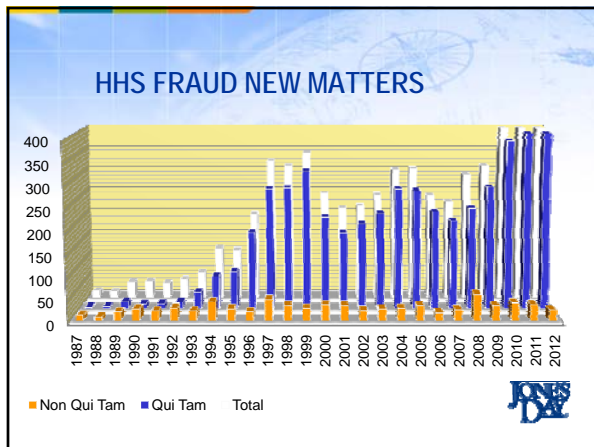
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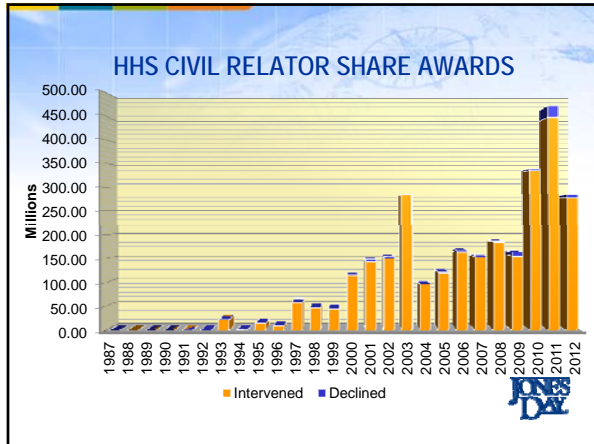
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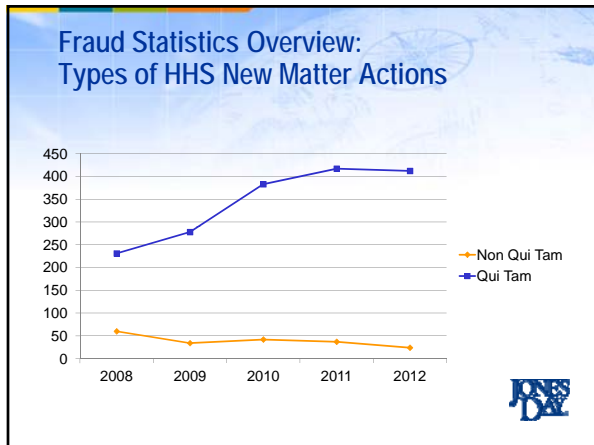
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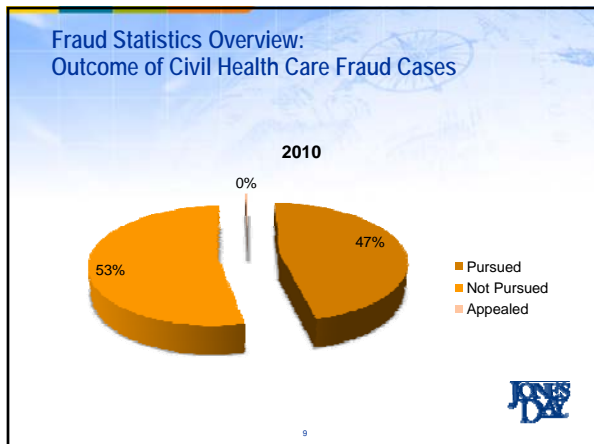
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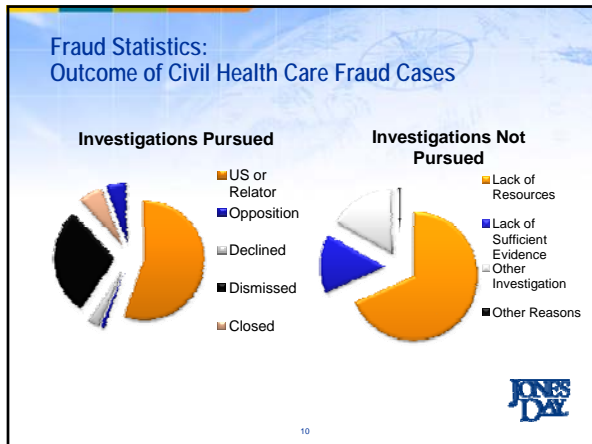
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- ### Legislative and Policy Developments
- 30-Day Readmission Penalties
  - 60-Day Rule for Overpayments Proposed Rule
  - Physician Payments Sunshine Act Proposed Rule
  - EMTALA Proposed Rule Withdrawn
  - "Without Fault" Provision for Claims Extended
  - Pending Omnibus Privacy Rule
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- ### Legislation and Policy Developments
- Effective October 1 - 30-Day Readmission Penalties
    - FY13 Penalty Capped at 1% of Medicare DRG payments
      - 2,217 hospitals will receive a readmission penalty
      - 307 will receive maximum 1% penalty
    - "Excess Readmission Ratios" are based on patients initially admitted with AMI, heart failure and pneumonia
      - Using a baseline premised on 3 years of discharges
      - Includes readmissions for **all causes**
    - CMS anticipates a recoupment of \$280 million for FY13
    - Maximum Penalty Cap to Increase
      - FY14 – 2%
      - FY15 – 3%
    - Hospital CFOs request MedPAC review readmission penalty
      - Requesting penalty be reviewed considering socioeconomic status
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### Legislative and Policy Developments

- Proposed 60-Day Repayment Rule on “overpayments”
  - Final Rule pending
  - Must report and return an “overpayment” by the later of:
    - 60 days after the overpayment was identified, or
    - the date any corresponding cost report is due, if applicable
  - A person has “identified” an overpayment when he or she:
    - has actual knowledge of the existence of the overpayment; or
    - acts in reckless disregard or deliberate ignorance of the overpayment
      - Failure to conduct a reasonable inquiry could meet this definition
  - Established a 10-year look-back period for overpayments
  - OIG or Stark self-disclosure protocols suspend 60 day period



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### Legislative and Policy Developments

- Proposed Physician Payments Sunshine Act Rule
  - Final Rule pending
    - Special Senate Roundtable Discussion
      - “Let the Sunshine In: Implementing the Physician Payments Sunshine Act”
  - Proposed Rule:
    - Payments by drug, device and medical supply manufacturers to physicians and teaching hospitals, and
    - Financial relationships between physicians, manufacturers and GPOs
  - Addresses CME and non-CME speaking engagements
  - GPO definition includes physician-owned distributorships (PODs)
  - “Teaching Hospital” defined by GME/IME payments
  - Manufacturers have duty to report
  - Data will be made available online



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### Legislative and Policy Developments

- EMTALA Proposed Rule on Transfers of Inpatients
  - Published December 23, 2010; withdrawn February 2, 2012
  - In withdrawing this proposed rule, CMS provided an additional 60 days for the public to comment on the applicability of EMTALA to specialized hospitals; no further action to date.
- “Without Fault” Time Period Extended
  - Fiscal Cliff bill extended time period from 3 years to 5 years
- Pending Omnibus Privacy Rule
  - Under review by OMB and publication expected soon
  - Rule expected to address:
    - Regulations governing use of patient information for marketing
    - Stimulus requirement prohibiting sale of patient data without patient authorization
    - “Harm standard” for breach notification
    - Relationships and terms of BAA arrangements



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## Stark Self-Disclosure Settlements

- Stark Self-Disclosure Protocol
  - 16 published settlements to date
    - 13 disclosures by hospitals
    - 2 disclosures by physician groups
    - 1 disclosure by hospice
  - Settlement Overview
    - Total settlement amount of \$1.279 million
    - Average settlement approximately \$98,000
    - Settlement ranges from \$60 to \$579,000
  - Highlights of alleged Stark exception violations
    - personal services exception
    - non-monetary compensation
    - equipment lease arrangement
    - employee exception
    - in office ancillary DME arrangement



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## Patient Safety

- Best Care at Lower Cost: The Path to Continuously Learning Health Care in America
  - New IOM report published September 2012
  - Estimates \$750 billion "wasted on unnecessary services, excessive administrative costs, fraud and other problems" in 2009
- California Health and Safety Code Fines
  - Since 2007, CDPH issues a total of 236 penalties to 135 hospitals
  - Fines range from \$25,000 to \$100,000
  - Total fines levied against hospitals is about \$8.5 million
  - Underlying violations or deficiencies based on
    - Hospital-acquired infections
    - Medication errors
    - Surgical errors (wrong side, retained foreign object)
    - Other adverse or never events



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## Supreme Court Decisions

- *National Federation of Independent Business et al. v. Sebelius*
  - PPACA insurance mandate upheld 5-4
  - Mandate survives as a tax – not via commerce clause
  - Medicaid expansion and regulations found not constitutional
- *Douglas v. Independent Living Center of Southern California*
  - Consolidated several cases brought by providers and beneficiaries against the Director of the California Department of Health Care Services
  - Plaintiffs assert enactments of rate reductions were preempted by 42 U.S.C. Section 1396a(a)(30)(A) ("Section 30(A)")
    - 9<sup>th</sup> Circuit affirmed or ordered preliminary injunctions against CDHS from implementing rate reductions
  - CDHS did not initially request HHS approval it subsequently submitted SPAs for reductions
    - HHS initially disapproved SPA for failure to comply with Section 30(A)
  - Remand to 9<sup>th</sup> Circuit by 5-4 decision
    - Require respondents to seek review of the agency determination under APA
    - Not in an action against California under the Supremacy Clause
  - Declined to address whether 9<sup>th</sup> Circuit properly recognized a Supremacy Clause action to enforce Section 30(A)



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**NOTEWORTHY SETTLEMENTS**

- **GlaxoSmithKline**
  - Largest health care fraud settlement in U.S. history - \$3 billion
  - Allegations
    - Unlawful promotion of certain pharmaceuticals
    - Failure to report patient safety data
    - False price reporting practices
  - Part of resolution is 5-year CIA
    - May not provide financial reward or discipline to sales representatives based on sales volumes
    - Requires financial recoupment program of bonuses or other long term incentives
- **Janssen Pharmaceuticals**
  - Johnson & Johnson Subsidiary
  - Texas Medicaid - \$158 million to settle claims
    - Alleged unlawful promotion of Risperdal for "off label" uses
    - Texas sought \$579 million in damages and over \$500 million in penalties
    - Settled during the trial
  - Arkansas Medicaid – civil fines of \$1.2 billion after a jury trial
    - Alleged violations of Arkansas FCA and Arkansas Deceptive Trade Practices Act
    - Theory that FDA package insert was deceptive - not an "off label" theory
    - Judge found 240,000 violations of Arkansas FCA – one for each prescription reimbursed over 3.5 years
      - Each violation carried a \$5,000 civil fine
    - Payment by the state agency for Risperdal during the relevant time period - \$8.1 million




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**NOTEWORTHY SETTLEMENTS**

- **Omnicare**
  - \$50 million to settle civil fines
  - Allegations that pharmacy facilities improperly dispensed controlled substances
    - Routinely violated Controlled Substances Act by dispensing controlled substances to long-term facility residents without a signed practitioner or from prescriptions missing essential elements
  - 2<sup>nd</sup> largest settlement under Controlled Substances Act
- **United States v. Cayuga Medical Center at Ithaca Inc.**
  - \$3.5 million settlement
    - \$3.5 million to federal government
    - \$426,305 to state government
  - Allegations by plastic surgeon that hospital recruited physicians in violation of Stark and falsely certified compliance with state and federal laws
- **Temple University**
  - \$1.1 million to resolve allegations following its voluntary disclosure
  - Disclosed conduct by Dr. Kubacki, former chair of ophthalmology department
  - Government claimed Temple billed for certain medical services performed by residents and attending physicians were not present for critical portions of the services




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**NOTEWORTHY SETTLEMENTS**

- **United States v. Rhode Island Hospital**
  - Hospital settled allegations that it billed for medically unnecessary overnight hospital stays for patients following gamma knife treatment
  - \$5.3 million settlement
    - \$2.6 million in returned reimbursement
    - \$2.7 million in double and triple damages
  - Result of investigation by US Attorney, OIG HHS, and FBI
- **United States ex rel. Guardiola v. Christus Spohn Health System (S.D. Tex.)**
  - \$5.1 million settlement
  - Allegations that 6 hospitals submitted false claims to Medicare using inpatient codes for procedures that should have been billed under outpatient codes
- **United States ex rel. Doe v. Atlantic Health System Inc. (D.N.J.)**
  - \$9 million settlement
  - Relator claims that hospitals fraudulently billed for inpatient care for patients that should have been treated as outpatients
- **United States ex rel. Curren v. Denver Health Medical Center. (D. Colo.)**
  - \$6.3 million settlement Allegations made by compliance officer that hospital miscoded or misclassified hospital outpatient observation services as inpatient services
  - "This case serves as a reminder that hospitals must scrutinize their billing practices to prevent overbilling." - U.S. Attorney John Walsh




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## FCA Developments

- **Scienter**
  - *U.S. ex rel. Williams v. Renal Care Group Inc.*, 6<sup>th</sup> Cir.
    - Overturned \$82 million SMJ against dialysis provider
    - Attempts to comply with “ambiguous” regulations not violation of FCA
    - Did not act in “reckless disregard because
      - Sought legal advice and government clarification
      - Industry publications encouraged structure
      - CMS aware of structure because of enrollment process
- **Free Speech**
  - *U.S. v. Caronia*, 2d Cir.
    - Government’s criminalization of truthful, nonmisleading speech about off-label uses of drug violates First Amendment of U.S. Constitution
- **Limits on Civil Investigative Demands**
  - *U.S. v. Kernan Hospital*
    - DOJ may not issue CIDs after its FCA qui tam lawsuit is dismissed



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## FCA DEVELOPMENTS


*United States ex rel. Jamison v. McKesson Corp.* (N.D. Miss.)

Alleged McKesson and other defendant entities formed an improper joint venture  
 Set up a “sham” DME supplier under the control of defendant SNF chain  
 One of the defendant entities was created solely to provide DME supplies and service a captive patient base of SNFs  
 Defendants violated FCA by failing to comply with 21 federal supplier standards for regulation of DME suppliers

Government failed to prove that defendant DME supplier of contract billing services violated AKS by paying in house DME supplier to acquire contract  
 Analyzing alleged AKS violations requires an understanding of key distinction that  
 AKS does not criminalize referrals for services  
 AKS criminalizes knowing and willful acceptance of remuneration in return for referrals

Government failed to prove that remuneration was below fair market value, below actual costs, or at a discount  
 Ruled government did not meet its burden  
 No evidence defendants intended to induce by offering a lower price  
 Failed to prove bidding process was noncompetitive or tainted

Bids were FMV  
 Process was arms-length and other bidders were willing to provide services for similar and lower prices




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## FCA Developments

**Rule 9(b)**

*United States ex rel. Matheny v. Medco Health Solutions Inc.*

- Relators stated with sufficient particularity that defendants knowingly concealed \$69 million of overpayments that should have been returned under terms of a CIA
- Compliance officer informed corporate executives of overpayments
- Executives developed a scheme to hide overpayments by using software program called datafix
  - Datafix transferred funds to unrelated patient accounts, fictitious patients, or eliminated data from electronic records
- Relator brought issue to compliance officer and told COO approved
- Court found the defendants devised a scheme to create false records to eliminate the overpayments



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## FCA Developments

### Rule 9(b)

- *United States ex rel. Osheroff v. Tenet Healthcare Corp.* (S.D. Fla.)
  - Court ruled the relator did not properly plead that the company provided an “indirect payment” in the form of below-market rent to physicians in exchange for patient referrals
  - Relator did not allege facts disputing fair market value or establishing remuneration
  - Relator was allowed to amend his complaint to remedy that deficiency because he was not also required to identify specific Medicare claims
    - Tenet’s public filings showing it received revenue from Medicare and Medicaid were enough to establish “reliable indicia” that claims were submitted.
- *U.S. v. Kernan Hospital*
  - Dismissed FCA action for failure to allege scheme of “systemic upcoding”
  - Alleged hospital developed scheme to fraudulently report a malnutrition condition as secondary diagnosis to increase reimbursement
  - Failed to link the scheme with any submitted claims, cost report, or how the allegedly fraudulent diagnosis was reflected on cost reports
  - FCA “does not punish a system that might allow false claims”

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## FCA Developments

### Public Disclosure/First-to-File

- *U.S. ex rel. Heineman-Guta v. Guidant Corp.* (D. Mass.)
  - Relator’s complaint must be dismissed for not being the first to be filed because of an earlier-filed complaint, though procedurally invalid, alerted the government to possible fraud.
  - Court declined to adopt an exception to the first-to-file rule that bars anyone from bringing an FCA complaint based on the same facts underlying a pending complaint when the pending complaint is legally deficient
  - Apparent split among circuit courts
    - DC Circuit (followed here) v. 6th and 9th Circuits
- *U.S. ex rel. Goldberg v. Rush University Medical Center*
  - Relator action filed by former residents reinstated
  - Amended complaint
    - Permitted supervision of multiple surgeries simultaneously
  - Alleged a kind of deceit distinct from PATH audit GAO report
  - Finding the use of “unsupervised services” as discussed in GAO report may not cover all ways supervision was missing or inadequate

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## FCA DEVELOPMENTS

### *United States ex rel. Singh v. Bradford Regional Medical Center* (W.D. Pa.)

FCA based on underlying known Stark and Anti-Kickback Statute violations

#### Highlights of facts:

2 high volume physicians decide to purchase and install technology in direct competition with hospital  
Hospital adopts Policy on Physicians with Competing Financial Interests – threaten to terminate medical staff privileges  
Hospital proposes “under arrangements JV” but negotiates sublease agreement  
Enter into sublease arrangement prior to conducting a “final FMV analysis” for lease  
Valuation performed during relationship and incorporated hospital’s expected revenues with/without sublease  
Valuation included an estimate the arrangement would generate \$402,000 in profit from referrals with sublease in place  
Final sublease also included a covenant not to compete  
Hospital executive states that sublease would not have existed if the hospital would not receive referrals  
Agreement stated technology would be located at hospital, but stayed in physician space (hospital paid rent and other expenses)  
Relationship changes to an installment buyout of equipment and includes a service agreement

Ruling: hospital and physicians were aware that arrangements implicated Stark and the Anti-Kickback Statute; but did not act knowingly for purpose of FCA

Regardless of final disposition, decision will likely influence other court’s analysis of Stark and impact the structure and valuation process for future acquisitions.

Despite declining to intervene earlier, government filed and was granted its motion to intervene

Allows government to assert common law claims for payment by mistake and unjust enrichment  
Theories that do not require a showing of the Defendants’ knowledge or other scienter



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## FCA DEVELOPMENTS

*United States ex rel. Drakeford v. Tuomey Healthcare System Inc.*

4<sup>th</sup> Circuit held trial court erred in ordering a hospital to repay government based on a jury's findings of Stark law violations

District court's decision was improper because it was based on jury findings that the district court had set aside

Arrangement at issue

Physicians obligated to provide outpatient services exclusively at Tuomey

Agreed to assign to hospital all Medicare and Medicaid payments

Permitted bonuses for physicians depending on amount of business generated at hospital

2 of 3 judges on panel went further and discussed view on what constitutes violations of Stark

Policy of Stark was to "address overutilization"

Discussed the referral was within the type barred by Stark even though personally performed

Whether an arrangement takes into account volume or value of referrals is a jury issue

Compensation arrangements in Tuomey do implicate the volume or value standard



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## FCA Developments

• *U.S. ex rel. King v. Univ. of Texas Health Science Center-Houston, D. Tex.*

• Claims of researcher who alleged her employment was terminated for reporting state university's cover-up of research misconduct must be dismissed because university is neither "person" nor "employer" amenable to suit under FCA

• *U.S. ex rel. Little v. Shell Exploration & Production Co., 5<sup>th</sup> Cir. 2012*

• 2 federal auditors who uncovered \$19 million that Royal Dutch Shell PLC owed the U.S. in offshore drilling royalties could bring a whistleblower suit even though they discovered the alleged fraud in the course of their jobs

• Both Shell and the U.S. government had argued that the FCA barred federal officials who uncover fraud as part of their official duties from bringing a qui tam lawsuit

• 3-judge appeals panel unanimous that there was no basis for that limitation in the statute's text



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## FCA Developments

### Statute of Limitations

• *United States v. BNP Paribas, S.D. Tex*

– Wartime Suspension of Limitations Act

– 2008 amendment expands definition of "at war"

– Congress enacted specific authorization for use of Armed Forces

– Applies to "any offense... involving fraud or attempted fraud"

– Court found FCA SOL suspended since 2001 and continuing

– As applied, extends SOL at least 5 years after conclusion of conflict



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Health Care Compliance

## ENFORCEMENT AND AUDIT TRENDS




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### Use of Volume or Value Data

Operational Decision:

- *U.S. v. Health Alliance of Cincinnati and Christ Hospital*
  - Offered opportunity to sit on reading panel for cardiac testing based in part in proportion to hospital utilization

Transactional Decision:

- *U.S. v. Bradford Regional Medical Center*
  - Although arrangement “carefully sought to avoid requiring referrals and attempted to make business decision based on [FMV],” the District Court found a Stark violation as a matter of law and the potential for an AKS violation where hospital’s decision to do the deal (sublease of equipment) was driven by desire to obtain referrals lost when physicians purchased their own equipment
- Bad emails about ancillary services stream



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### Use of Volume or Value Data

- Factors to Consider in Assessing Risk:
  - Reason for use
  - Availability of alternative information
  - Precise nature of the information
  - Role of persons producing or using the data
  - Nature of relationship between provider and referral source
    - Whose data is being examined
  - Temporal relationships between the production/use of the data and some transaction or operational decision involving the data



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## Medical Necessity Trends

- Medical Necessity
  - Continued area of focus by government
  - Increasing enforcement resources
  - Medicare contractors and relators:
    - Affects institution and physicians
  - Top Issues Nationally:
    - Cardiovascular Procedures
      - Patel prosecutor is educating USAOs
      - USAO Maryland
    - Inpatient (Short Stays)
    - Long Term Care
    - Skilled Nursing Facilities



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## Medical Necessity Trends

- Hospital Concerns:
  - Allegation is that the hospital *knew or should have known* medically unnecessary procedures being performed
- Is sufficient evidence of necessity for Medicare to cover procedure?
  - Cardiovascular Issues:
    - Government focused on % of stenosis
  - Medical Practice Issues:
    - Substantial judgment and differing standards applied by physicians
  - Varying Standards Issues:
    - Recognized variability in reproducing interpretations
- Even if medical necessity not supported, may not be a “false claim”



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## Medical Necessity Trends

- Lessons Learned:
  - Pay attention to rumors
  - Compliance engagement in quality processes
  - Involvement in peer review processes
  - Take appropriate steps to investigate and address concerns. Documentation should reflect process and corrective measures.
  - Evaluate medical staff bylaws and governance relationships.
  - Be in a position to demonstrate (then and now) appropriate standards and meaningful oversight in place
    - Peer review processes
    - Quality data and incident reports
    - Utilizations trends



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## Medical Necessity Trends

- Short Stays or One Day Stays:
  - Patient status determinations
    - Difficult from compliance perspective
    - Easy for third party auditors
  - CMS guidance defines inpatient as formally admitted with the expectation that will remain at least overnight and occupy a bed.
- WakeMed Settles Short Stay Allegations
  - Allegations:
    - Identified by DOJ as state's largest percentage of zero-day stays
    - Overbilled Medicare by wrongly classifying outpatient procedures as inpatient procedures
      - Relied on list of procedures distributed by hospital director instead of physician orders
  - Settlement Terms:
    - \$8M Fine; 2 year Deferred Prosecution Agreement and 3 year CIA



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## Medical Necessity Trends

- Practical Steps:
  - Identify portals of entry, standing orders, and conflicts created by EMR
  - Ensure medical staff understands criteria
  - Understand what staff is relying on for "inpatient only" determinations
  - Appropriate review processes in place, including process to address disagreements over appropriate classification
  - Review and act on PEPPER reports



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## Quality of Care Trends

- OIG Work Plan 2012, 2013
  - Increased emphasis on patient outcome audits and inspections:
    - Adverse events
    - Quality measures
    - Hospital-acquired conditions (HACs)
    - Relationship among compliance, quality and billing practices
  - Legal and Investigative Initiatives:
    - Compliance with Corporate Integrity Agreements



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## OIG Compliance Initiatives

- **Medicare Compliance Reviews:**
  - “[S]eries of OIG reviews of Medicare payments to hospitals for selected claims for inpatient and outpatient services”
- Highlight of identified risk areas for incorrect billing:
  - Inpatient HAC and POA indicator reporting
  - Inpatient short stays
  - Same-day discharges and readmissions
  - High severity level DRGs
- Data used to identify “least risky” and “most risky” hospitals
- Compare policies, procedures and compliance practices of two groups
- Interview leadership and compliance officers to gain information regarding compliance programs



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## OIG on Quality and Compliance

- Review of Quality Improvement Organizations (QIO)
  - CMS required to engage QIOs
- New work plan item for FY 2013:
  - OIG to review extent of QIO work with hospitals
  - Determine barriers faced by QIOs when engaging hospitals
- 2008 Government-Industry Roundtable on Board of Directors’ Oversight of Quality of Care
  - Co-sponsored by OIG and HCCA
  - Discussed use of scorecards and dashboards to keep leadership informed, accountable
  - Facilitate leadership involvement in quality initiatives
- OIG Adverse Event Report Audits
  - 9 reports published from 2008 through 2012
  - Reviews focused on clinical setting and state reporting
- OIG authority to terminate a provider’s participation agreement



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## OIG HHS Audit Initiatives

- FY12 and FY13 Work Plan Audit item
  - Review of provider performance under CIA
  - Separate review of provider performance for entities not under CIA identified by OIG related to a “refusal” of a CIA
- Corporate Integrity Agreement
  - Arrangement for negotiating compliance, quality, and other obligations by providers and other entities to be performed and reported to OIG
  - Usually include external and internal monitoring
- Entities that resolved fraud allegations without CIA
  - Public statements regarding “unilateral monitoring”



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### Practices to Prepare for Quality Audit Trends

- Assess and document governing board and senior management involvement and oversight of quality
- Ensure governance bylaws permit appropriate oversight of quality assurance, performance improvement, and medical staff functions and activities
- Educate clinical staff on reportable events
  - The who, what and when
  - Reiterate proper lines of communication to third parties
- Foster interdisciplinary efforts to combat and address sentinel events from the bedside to the C-suite
- Assess quality resources



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### Practices to Prepare for Quality Audit Trends

- All "incidents" need a documented resolution
  - Coordinate with appropriate departments within organization for resolution
- Ensure open lines of communication between Quality, Legal and Compliance Departments
  - Ensure process changes implemented when issues identified through peer-review and/or audit findings, including addressing, as appropriate refunds
  - Coordination with Legal on disciplinary action where warranted
  - Implement effective processes to address deficiencies, e.g., hospital readmission penalties
  - Coordination on corrective action plans
- Pay attention to VBP indicators and how data is being captured and reported



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### Clinical Research Trends

- Increased scrutiny by lawmakers, prosecutors, and relators
  - Public disclosure requirements provide opportunity for additional access and scrutiny
    - Sunshine and NIH COI rules
- Prosecutors and relators much more knowledgeable
- Evolving from solely pharma and device to capture providers
  - Physician financial relationships
- Significant risks:
  - Fines and penalties
  - Settlement costs and damages
  - Loss of funding
  - Risk to Medicare provider agreement
  - Reputational harm, both as a provider and a research partner



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## Clinical Research Trends

- More and new players entering clinical research arena creates opportunities, but also potential for additional risks
  - Some physicians/providers do not have working knowledge of governing laws and regulations
  - Misunderstanding as to what is and is not clinical research
- Focus on basic requirements
  - Processes for identifying and billing Medicare clinical trial patients
  - Ensure policies and procedures will identify trials being conducted
    - Challenges for larger systems with multiple facilities
    - Post market trials for user feedback
  - Conflict of Interest policies
    - Review and supplement to address Sunshine reporting



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