Fraud and Abuse: A Year in Review

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Settlement Trends—Pharma/Device

- Pharma settlements continue
  - Abbott paid $1.5B (off-label, sales conduct)
  - GlaxoSmithKine paid $3B (off label, sales conduct)
  - Boehringer paid $95M (off label)
  - Pfizer paid $55M (off label)
  - Victory Pharma paid $11.4M (sales conduct)
  - Sanofi paid $109M (sales conduct)
  - Amgen paid $762M (off label)
- Some medical device industry cases
  - Smith & Nephew paid $16.8M (sales conduct)
  - Stryker paid $15M (misbranding and sales conduct)
  - St. Jude paid $3.65M (warranty credits)
  - Orthofix paid $42M (sales conduct and medical necessity)
Settlement Trends—Hospitals

- General increase in number of settlements involving hospitals
- Inpatient/outpatient
  - Denver Health: $6M
  - Christus Spohn: $5M
  - Atlantic Health: $9M
  - Porton Plant Mease: $10.2M
  - Criminal resolution: WakeMed Health: $8M and deferred prosecution agreement
- Kyphoplasty cases: $12M from at least 14 hospitals

Settlement Trends—Hospitals

- Big systems
  - Tenet: $42.75M (inpatient rehab billing)
  - HCA: $16.5M (physician leases)
  - Mayo Clinic: $1.2M (billing issues)
- Billing and physician financial relationships
  - South Shore and Mount Vernon: $2.3M for j-code billing
  - Lenox Hill: $12M for Medicare outliers
  - Memorial: $1.3M for physician relationships
- Medical necessity and un-indicated care
  - EMH Medical Center: $3.9M and cardiology group: $550,000 for unnecessary angioplasties
Settlement Trends—HIPAA

- Increase in cases and settlement amounts
  - BCBS Tenn.: $1.5M (loss of 57 hard drives)
  - A Phoenix cardiology practice: $100,000
  - South Shore Hospital: $750,000 (lost back-up tapes)
  - Alaska Medicaid: $1.7M (stolen USB drive)
  - Accretive Health: $2.5M (laptop theft)
  - Mass. Eye and Ear: $1.5M (laptop theft)
  - Anthem BC: $150,000 (lost data)
- First security rule settlement: Hospice of No. Idaho: $50,000 for lack of computer security process

Enforcement Trends—The Numbers Tell the Story

- OIG expects recoveries of $6.9 billion from fraud-related audits and investigations in FY 2012.
  - Increase from $5.2 billion made in FY 2011
- DOJ recovered $3 billion from health care False Claims Act cases
- Congress has increased funding to combat HCF
  - Affordable Care Act has increased funding to combat HCF by $40 million dollars in FY 2013
  - Aside from ACA funds, HHS and DOJ receive millions more in funding from Health Care Fraud and Abuse Control program
Enforcement Trends—Unprecedented Collaboration

- Medicaid Fraud Strike Force
  - AUSAs and DOJ Criminal Division attorneys, together with HHS and FBI agents
  - Netted criminal filings against 305 individuals and 181 convictions in FY 2012
  - Currently 9 USAOs host Strike Forces but will be expanding

- Health Care Fraud Prevention and Enforcement Action Teams “HEATs”
  - DOJ and HHS jointly conducted numerous national takedowns
    - Involving arrests of over hundreds of individuals, including doctors, nurses, health care executives and employees
  - HEATs resemble Organized Crime Task Forces of the past
    - Search warrants, ambush interviews UC operations, informants, videotape and audio recordings, asset seizures, and forfeitures

Other Enforcement Trends

- Use of Non-HCF Criminal Statutes
  - Increase reliance on mail and wire fraud/health care fraud statute with lower evidentiary burden

- Civil exclusion authority
  - In FY 2012, OIG excluded 3,131 individuals and entities from participating in federal health care programs
    - Increase in exclusions from FY 2011 (2,662)
  - Felony criminal convictions related to health care programs result in a mandatory exclusion for a minimum of five years.
  - HHS-OIG has justified requesting longer exclusion periods, and in some cases has sought life long exclusions.

- Expansion of individual criminal liability
  - Responsible Corporate Officer Doctrine
Noteworthy Cases—Existing Law Confirmed

- **U.S. v. Krikheli**, 2nd Cir.
  - Affirming the "one-purpose test" under the AKS
  - No claim under HIPAA without actual damage
  - Standard “piercing corporate veil” law applies to FCA
- **Foglia v. Renal Ventures Management**, D.N.J.
  - State licence deficiency not a basis for FCA action
- **U.S. ex rel. Williams v. Renal Care Group Inc.**, 6th Cir.
  - FCA does not apply to conditions of participation deficiency
  - Also held that provider’s desire to maximize reimbursement was not basis for a FCA violation

Noteworthy Cases

- **U.S. v. Zhou**, 9th Cir.
  - Defendant who improperly accessed PHI guilty under HIPAA even without knowing that actions were illegal
- **Friedman v. Sebelius**, D.C. Cir.
  - Upheld exclusion for executives who pled guilty under FDA’s responsible corporate officer doctrine
- **Palomar Medical v. Sebelius**, 9th Cir.
  - RAC auditor’s decision to reopen claims not subject to judicial review, even if no good cause for reopening
- **In re Porter**, Supreme Court of Vermont
  - Supervising physician not subject to professional discipline for acts of PA
Cases That Differ From Settlements

• Average wholesale price litigation
  – *Sandoz, Inc. v. State* (Alabama)
    • Reversed $78.4M judgment and held that state Medicaid officials knew that AWP was inaccurate
  – *Sandoz, Inc. v. Commonwealth*, (Kentucky Ct. App.)
    • Reversed $30M judgment on basis that Medicaid officials knew how AWP worked
• Off-label marketing under the FDA Act
  – *U.S. v. Caronia*, 2nd Cir.
    • Truthful, off-label marketing not prohibited by FDA Act and protected by 1st Amendment

Other Developments

• OIG Civil Monetary Penalty actions
  – Four $1M+ cases (AKS cases)
  – 76% of CMP resolutions based upon self-disclosures
  – 57% of CMP resolutions based upon employment of excluded individuals
• CMS’ Stark Law self-disclosure protocol (Sept. 2010)
  – CMS reports to Congress that 148 submissions made as of March 2012
  – As of Jan 1, 2013: 15 matters settled
    • 5 settled for more than $100,000
    • 6 settled for less than $50,000
Other Developments

- OIG Alert on physician re-assignment (Feb. 2012)
  - Physicians who permit others to use their billing number are at risk if false claims submitted
- HHS/DOJ letter to AHA (Sept. 24, 2012)
  - Concern that EHRs are being used “to game the system” and that EHRs permit documentation “to be cut and pasted from a different record of the patient”
  - Concern over prompts and template information
  - No guidance, just a threat (or just politics)
- IG Levinson opined that 20-30% of all health care spending is waste and abuse (April 30, 2012 speech)

GAO Report—Types of Facilities Investigated

- Anti-fraud spending is material
  - $608M allocated to anti-fraud efforts (FFY 2011)
- 7,848 subjects in criminal investigations
  - 25% were medical facilities and 16% were DME
  - Only 13.8% were charged, of which 85% were convicted
- 2,339 subjects in OIG civil investigations
  - 20% hospitals; 18% other medical facilities
  - 47% of civil investigations pursued
    - GAO-13-213T (Nov. 28, 2012)
Schedule for 2013

• Regulations
  – Physician Payment Sunshine Act
    • Mandatory disclosure and publishing of payments between manufacturers and physicians
  – Mandatory overpayment refund rule
    • Implementing 60-day overpayment refund law
  – HITECH breach notification rule
    • Implementing duty to disclose HIPAA breaches
  – Mandatory compliance programs for providers
• Ruling in *AHA v. Sebelius*, D.D.C.
  – Calculation of overpayment in certain RAC audits
• Stark Law cases going to trial: Toumey and Halifax

The Road Ahead—Predictions for 2013

• High levels of OIG/DOJ enforcement and whistleblower activity will continue
• Continued rhetoric and attention to Medicare enrollment
• More and increasingly aggressive HIPAA enforcement
• Physician Sunshine reporting will have little widespread impact, but will be create material issues for a few
• Enforcement shifting from Pharma to hospitals and providers
  – Medical device industry may side-step acute fraud and abuse attention
• Not in 2013, but beyond: Medicaid enforcement and enforcement based upon mandatory reporting
HCCA Webinar
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Supplemental Materials
The Need for Proactive Compliance

• An effective compliance program can actually reduce the number and extent of possible FCA violations.
• Compliance program helps establish that any violation was consequence of negligence or the conduct of a rogue employee,
• An effective program can help to convince the government not to intervene
• The government’s decision to intervene or not to intervene can be decisive.
  – Over 95 percent of qui tam recoveries occur in cases in which the government decides to intervene.
  – Only a slim number of cases are successful when the government chooses not to intervene.

Compliance Program Strategies

• There is a rich history of compliance in the health care industry.
• Proactive commitment to compliance and improving compliance
• Create a culture of compliance to define compliance standards and procedures
• Health care organizations need to dedicate adequate resources to the compliance function
• Compliance program must have a procedure for ongoing risk assessments – this is the lifeblood and intelligence foundation of every compliance program.
Compliance Program Elements

- A Written Code of Conduct and Compliance Policy
- Tone at the Top Message from Senior Management and Commitment to Code of Conduct and Compliance Policies

The Chief Compliance Officer

- Authority and resources
- Clear and direct line of communication to Compliance Committee or Audit Committee
- CCO must be a Senior Manager equivalent to other C-Level offices
- CCO must be proactive and coordinate closely with internal auditors and general counsel
Training and Communication

- Training programs conducted on regular basis
- Training program must stress proper coding of services and the need to have chart documentation to support every claim.
- Continuing communications from senior management to reinforce commitment to compliance
- Annual employee certifications to reinforce compliance program
- Compliance and ethics must be part of evaluation

Internal Reporting Systems

- The most important check on fraud is encouraging employees to identify potential problems, to report them to the compliance officer and to address these complaints.
- Human resources should also be on the alert for warning signs that there may be potentially disgruntled employees or students.
- Systems should include anonymous reporting programs (Internet or hotline).
- Complaint system should be monitored and tracked
Whistleblowers: The Dangers

• Triage program for assessing complaints and launching internal investigations when appropriate.
• A team of investigators should be on call to respond to matters as they arise.
• Human Resources needs to ensure that there is no retaliation against a reporting employee, which can itself give rise to a separate legal action against the hospital.
• The reporting employee should be given feedback so the employee knows that his or her concerns and reports are being taken seriously. If ignored, the employee may become a whistleblower and file an FCA lawsuit.
• Reporting of identified issues to senior management and Board

Enforcement and Discipline for Violations

• Discipline procedures need to be established so that uniform policies and treatment of employees for violations
• Matters need to be handled quickly, efficiently and in a consistent manner.
Monitoring and Auditing Program

- Revision and improvement of compliance program through regular risk assessments
- Measuring program performance
- Monitoring and Auditing procedures and programs which are developed from a risk assessment and includes reviewing previous audits, monitors and other pertinent internal and external information and sharing information and results across the organization.

Auditing

- The most significant risk centers on billing and coding of services for reimbursement from Medicare.
- No one can review every bill or watch over every employee, but basic compliance principles can be adopted to minimize risks.
- Documentation and internal controls are key to ensure compliance and identify potential problems.
- Given the complexity of the billing and coding system, every doctor or hospital will make mistakes.
- It is important to build in practices and procedures to reduce billing errors and fix the problem once it is discovered. Corrective efforts need to be documented and measure for frequency.
- Auditing for potential fraud must be regularly conducted. A sampling of claims and charts should be identified, reviewed and, if necessary submitted for outside review.