Healthcare Fraud and Abuse
Lessons from 2012 Settlements, Court Rulings and Advisory Opinions, and Proactive Steps for 2013

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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 <500 : 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

- Medicare 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
    - DOJ and HHS jointly conducted numerous national takedowns involving arrests of over hundreds of individuals, including doctors, nurses, health care executives and employees
    - Currently 9 USAOs host Strike Forces but will be expanding
- Health Care Fraud Prevention and Enforcement Action Teams “HEATs”
  - HEATs resemble Organized Crime Task Forces of the past
    - Search warrants, ambush interviews UC operations, informants, videotape and audio recordings, asset seizures and forfeitures
HCF Enforcement Trends: Expansion of FCA Liability

- Anti-Kickback Liability
  - Confirms AKS violations are false claims and give rise to FCA liability (in addition to AKS penalties)
  - Claims submitted in violation of the AKS automatically constitute false claims for purposes of the FCA.
  - New language of the AKS provides that “a person need not have actual knowledge … or specific intent to commit a violation” of the AKS

- Reverse False Claims
  - An overpayment means “* * * any funds that a person receives or retains under title XVIII ** * to which the person, after applicable reconciliation, is not entitled under such title.”

- Expansion of Liability for Possession of Overpayments
  - Overpayments under Medicare/aid must be reported and returned within 60 days of identification
  - Failure to timely report and return an overpayment exposes a provider to liability under the FCA
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 from 2,662 exclusions in FY 2011
    - 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
- **Whitaker v. Health Net of California Inc., E.D. Cal.**
  - No claim under HIPAA without actual damage
- **U.S. ex rel. Banignan v. Organon USA Inc., D. Mass.**
  - 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
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

• 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)
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 (released 1/17/13)
    • 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
• 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
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Healthcare Compliance Programs

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Roadmap

• Importance of effective compliance program
• Elements of an effective program
• Specific risk areas and other issues
Healthcare Enforcement Landscape

CRIMINAL

CIVIL

ADMINISTRATIVE
Corporate Criminal Liability

- Vicarious criminal liability
- Arthur Andersen prosecution
- DOJ Principles of Federal Prosecution
Principles of Federal Prosecution

1. Nature and seriousness of the offense;
2. Pervasiveness of wrongdoing within company;
3. Company’s history of similar misconduct;
4. Corporation’s timely and voluntary disclosure of conduct;
5. Existence and effectiveness of pre-existing compliance program;
6. Corporation’s remedial actions, including efforts to implement an effective compliance program or to improve existing one;
7. Collateral consequences that could result from indictment;
8. Adequacy of prosecution of individuals; and
9. Adequacy of civil or regulatory enforcement.

“Effective” Compliance Program

• DOJ – “No Formulaic Requirements”
  – Paper v. Active Program?
  – Well-designed?
  – Effective in identifying/deterring misconduct?

• U.S. Sentencing Guidelines
1. Establish Policies, Procedures and Controls
2. Exercise Effective Compliance and Ethics Oversight
3. Exercise Due Diligence to Avoid Delegation of Authority to Unethical Individuals
4. Communicate and Educate Employees on Compliance and Ethics Programs
5. Monitor and Audit Compliance and Ethics Programs for Effectiveness
6. Ensure Consistent Enforcement and Discipline of Violations
7. Respond Appropriately to Incidents and Take Steps to Prevent Future Incidents
Healthcare Enforcement Landscape

- Criminal
- Civil
- Administrative
Benefits in Non-Criminal Context

- Avoid Payment Suspensions
- Consider self-disclosure to the OIG
- Avoid triple damages for amount of potential false claims
- Avoid Corporate Integrity Agreement
- Avoid Exclusion from Federal Healthcare programs
OIG Guidance Timeline

- Hospitals/Home Health: 1998
- DME: 1999
- Physician Groups: 2000
- Ambulance: 2003
- Pharma: 2003
- Hospitals (Supplemental): 2005
- SNF: 2008
OIG Seven Elements

1. Implementing written policies, procedures and standards of conduct
2. Designation of a compliance officer and compliance committee
3. Developing open lines of communication
4. Effective training and education
5. Enforcing standards through well-publicized disciplinary guidelines
6. Internal monitoring and auditing
7. Response to detected offenses and developing corrective action
Specific Risk Areas

Hospitals

- Integrity of use of electronic health records
- Anti-kickback statute (physician’s owned hospitals)
- Free transportation

Pharma

- Switching arrangements
- Off-label marketing

Home Health

- Medical necessity, intentional failure to discharge
- Kickbacks to referring physicians
- Falsified nurse notes, missed visits
Specific Risk Areas

DME

• Billing with no CMN
• Upcoding
• Waiving co-payments

SNF/Ambulance

• Swapping arrangements

Physician Groups

• Unbundling
• Misuse of NPIs
• Payments from DMEs/Home Health
Programs should also address…

- HIPAA Privacy and Security Rules
- Exclusion and debarment screening
- Responding to Government Investigations
- Anti-identity theft education and training
HIPAA

- **Massachusetts General Hospital Settles For $1 million**

  “To avoid enforcement penalties, covered entities must ensure they are always in compliance with the HIPAA Privacy and Security Rules...A robust compliance program includes employee training, vigilant implementation of policies and procedures, regular internal audits, and a prompt action plan to respond to incidents.”

  - U.S. Dep’t of Health and Human Services, Feb. 2011

- **Massachusetts Ear and Eye Associates, Inc. Settles for $1.5 million**

  “In an age when health information is stored and transported on portable devices such as laptops, tablets, and mobile phones, special attention must be paid to safeguarding the information held on these devices...This enforcement action emphasizes that compliance...must be prioritized by management and implemented throughout an organization, from top to bottom.”

  - U.S. Dep’t of Health and Human Services, Sept. 2012