

Morgan Lewis

2011 Health Law Institute:
Federal Fraud & Abuse Update

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Fraud and Abuse Remains Obama Administration Priority

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- **ACA implementation review**
- **Robust FCA enforcement and expansion**
 - FERA expansion
 - Enforcement resource commitment
 - Moving cases/investigations more quickly
- **OIG and DOJ personal responsibility initiative**
 - CEO exclusion update
- **Significant FCA/*Qui Tam* Update**
- **Aggressive approach also spreading among the states**

A Tangled Web

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- **Yesterday's Breakout Sessions covered:**
 - ACA implementation
 - Government investigations of providers
 - Managed care litigation against providers for FWA
 - Pharma/Med Device Enforcement Initiatives
 - Sunshine Act Provisions
 - ACOs
- **Although the industry is compartmentalized, fraud and abuse/program integrity becoming more holistic in approach**

Kyphoplasty Investigation

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- **Kyphon, Inc. (Medtronic) – seller of kyphoplasty kits**
 - Qui tam investigation led to \$75 million settlement
 - “Cause to submit” false claims for inpatient DRG claims
- **Kyphon II – hospital investigation of over 100 hospitals**
 - Mostly focused on medical necessity of inpatient status vs. outpatient
 - *Also* inquiries on
 - ✦ product/technique training of physicians
 - ✦ Consulting agreements/KOLs

Highly Regulated Industry: “Gotcha Game?”

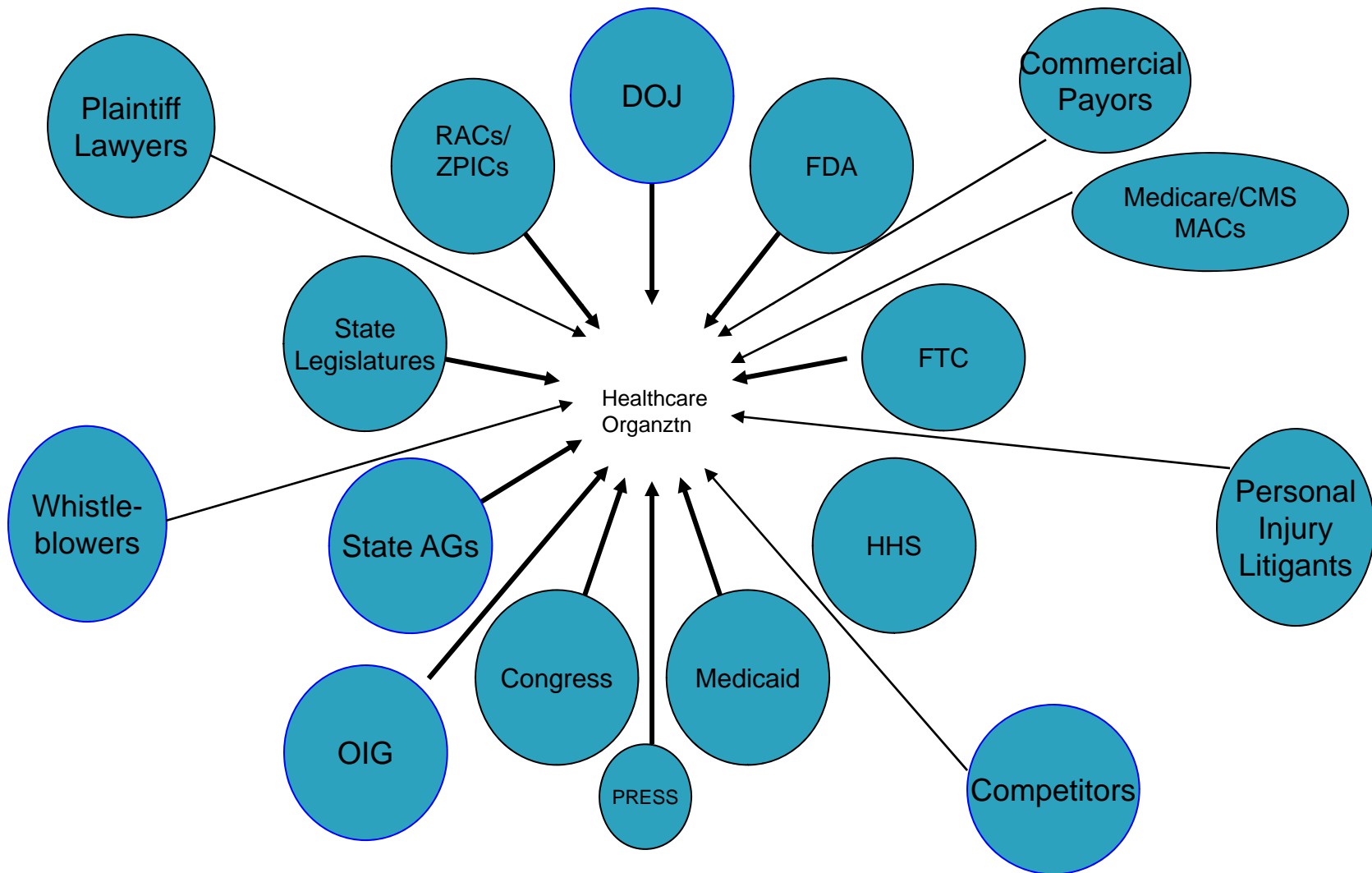
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- FDA
- Anti-Kickback Law & Stark Law
 - Federal and State
- False Claims Act
 - Federal and State
- Medicare and Medicaid reimbursement
- HIPAA/HITECH Act

- Tax Exempt/IRS
- Advertising/Consumer Protection
- EMTALA
- Antitrust
- Clinical trials regulation



Many Watchful Eyes



Affordable Care Act of 2010 (ACA)

Significant Program Integrity Provisions

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- DOJ, OIG and CMS – New Tools
- Anti-Kickback Statute (AKS)
 - Relaxes “specific intent” requirement.
 - AKS violations are now explicitly FCA violations.
 - ✦ Doctors may “cause to submit” false claims by referrals tainted by AKS violation
- Overpayments and False Claims Act
 - Medicare and Medicaid overpayments must be returned/refunded within 60 days of identification.
 - Failure to refund implicates False Claims Act, as well as expanded exclusion and CMP authority

ACA Program Integrity

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- **New Medicare/CMS Tools**
 - Revoke enrollment of a provider
 - ✦ Rules now finalized
 - Greater physician involvement
 - ✦ e.g., home health, DME and hospice face-to-face exams, certifications
 - RACs will be expanded to Medicaid, Medicare Advantage, & Medicare Part D, as well as to states.

ACA

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- **New CMS Tools (cont'd)**
 - Physicians' National Provider Identifier must be included on all claims (facilitates tracking of orders/referrals by CMS)
 - ✦ **Will help government with Stark Law enforcement**
 - Enhanced focus on correct information in provider enrollment applications and change of information forms
 - Claims submission deadline reduced from up to two years to just one year

ACA

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- **Other provisions of note**
 - Enhanced provider screening and enrollment requirements
 - ✦ mandatory compliance programs
 - ✦ moratorium for certain high risk providers
 - New Stark Law self-disclosure process
 - But under Civil Monetary Penalty – Beneficiary Inducements; new carve out for “remuneration” that promotes access to care and poses a low risk of harm to patient and the federal healthcare program

FERA Program Integrity

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- **Federal Enforcement and Recovery Act (FERA) of 2009**
 - A 2009 boost for the False Claims Act (FCA)
- **Makes clear that federal \$ spent in state Medicaid and Medicare Advantage programs actionable under FCA**
- **Legislative “override” of various FCA judicial decisions**
- **“Retention of any overpayment” constitutes a false claim under FCA (reverse False Claim)**

FERA – other changes to FCA

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- Whistleblower retaliation provisions expanded to “contractors” and “agents” in addition to employees.
- Allows the Attorney General to delegate Civil Investigative Demands (CIDs) to U.S. Attorney Offices
 - These CIDs also allow for compelling testimony in deposition under oath (over 500 issued in 2011 already)
 - Significant increase in their use since last year and expected to increase

M1

Slide 12

M1

Howard: this last part of the sentence didn't quite make sense to me.

MP072844, 5/11/2011

Mandatory Repayment of Medicare, Medicaid and SCHIP Overpayments

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- For the first time, disclosure and repayment is express legal requirement
- 60 days after “identifying” an overpayment
- Must include written explanation
- Overpayment retained after 60 days is subject to False Claims Act
- Also CMP for knowing failure to report and permissive exclusion
- Increased pressure on Compliance and Legal functions
- Will private payors (e.g., MCOs) follow suit?

Transparency Initiatives

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- **Revised Form 990 for non-profits**
 - Reporters, competitors, lawyers, government all looking ^{M2}
- **Physician Payment Sunshine Act (part of PPACA)**
 - Pharma and device must post payments to HCPs and health care institutions on website – readily searchable
 - Patients, local and national media, qui tam relators, press will be/are searching
 - Conflict of interest interplay for AMCs and hospitals – disclosure by physicians of financial relationships with “industry”
 - ✦ Many organizations are revisiting or “dusting off” COI policies

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Howard: not sure what's meant by "all looking"

MP072844, 5/11/2011

Lew Morris and Individual Responsibility

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Arising from an October 5, 2009 civil monetary penalty settlement with a hospital Compliance Officer and Executive Director for causing to submit false claims under the Stark Law, Chief Counsel Lew Morris noted in OIG press release:

"The Office of Inspector General strongly believes that, in addition to holding corporations accountable for health care fraud, **individuals who caused the fraud should also be held accountable,**" said Lewis Morris, Chief Counsel to the Inspector General. "Health care executives and compliance officers have a vital responsibility to ensure the compliance of the organizations that they serve."

OIG “Status” Exclusions of Corporate Executives/Owners

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	Name	Company Name	Description	Date
1.	Thomas Horras Former CEO and owner	Hawkeye Health Services, Inc. (home health)	7 year exclusion (false claims) and CMPs (\$711,212)	8/7/2007
2.	Paul Goldenheim, M.D. Chief Scientific Officer	Purdue Pharma	Permissively excluded following misdemeanor guilty plea for misbranding Oxycontin 15 years	4/20/2008
3.	Michael Friedman Former COO and then CEO	Purdue Pharma	Permissively excluded following misdemeanor guilty plea for misbranding Oxycontin 15 years	4/20/2008
4.	Howard Udell General Counsel	Purdue Pharma	Permissively excluded following misdemeanor guilty plea for misbranding Oxycontin 15 years	4/20/2008
5.	Marc Hermelin Chairman/Owner	KV Pharma	Misbranding	11/18/2010
6.	Rick I. Kanter CEO	Dr. Comfort footwear	Felony mail fraud; 15 year exclusion	2011
7.	Howard Solomon Chairman, CEO, President	Forest Laboratories, Inc.	Proposed exclusion after Forest plead guilty to obstructing the FDA, distributing an unapproved new drug, and distributing a misbranded drug	2011 Proposed exclusion (notified by letter from HHS-OIG 4/12/11 has 30-days to respond as to why he should not be excluded)
8.	Michael Dinkel CEO	Drew Medical Orlando, FL	b(7) false claims exclusion following DOJ FCA settlement w/ company and executive	2010 Adm. trial May 9-10, 2011

DOJ and OIG Shifting Focus to Individuals

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- High level DOJ and OIG officials have recently stressed individual responsibility and culpability in health care fraud matters to change industry
 - GSK Ass't G.C. Stevens indictment dismissed May 10, 2011 but DOJ vows to soldier on
- OIG put out guidance on use of (b)(15) permissive exclusion authority to exclude owners, directors, and managers of a sanctioned entity and has sought expansion of authority through legislation that was reintroduced in this Congress.

Strengthening Medicare Anti-Fraud Measures Act (H.R. 675)



- Expand OIG’s 1128(b)(15) permissive exclusion authority “to individuals and entities affiliated with sanctioned entities.”
- First introduced Sep. 15, 2010 by Rep. Pete Stark; passed by voice vote on Sep. 20; no further action in the Senate.
- Reintroduced by Rep. Wally Herger Feb. 18, 2011; currently has 25 cosponsors in the House.

Recent Investigations/Cases

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- **Implantable Cardioverter Defibrillator (“ICD”) investigations**
 - Hospital and physician focus, as well as Heart Rhythm Society
 - Medical device manufacturer focus
- **1/3 of qui tams – Stark/AKL allegations**
- **St. Joseph’s and Christ Hospital**
 - Enhanced CIAs
- **Pharma Off-Label**
 - Continued focus and “super CIA”
- **Part D investigations – infancy but coming**

Take Aways

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- **State/Federal hiring freezes but enforcement focus remains robust**
- **Pressure to control costs can impact internal control environments**
 - “Cut compliance budget – perhaps a reality but poses global organizational risks
- **Train your staff and Board Members**
 - A misguided email chain can “disable” an organization
 - Fraud and Abuse risk management – good for government health care programs and your organizations

QUESTIONS?

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